EDITED TRANSCRIPT

MYOV – Q3 2021 Myovant Sciences, Inc. Earnings Call

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

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PRESENTATION

Operator

Good day, everyone, and welcome to Myovant Sciences' Third 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

Good morning and thanks for joining us today to review the financial results of Myovant's third 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; Uneek Mehra, Chief Financial and Business 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 third fiscal quarter, representing the three months ended December 31st 2021, as our third quarter or Q3 throughout this presentation.

During 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 continued to make significant progress with our U.S. launches of ORGOVYX and MYFEMBREE during our third fiscal quarter of 2021.

Myovant recorded $54.4 million of total revenue, including $29.3 million of net product revenue. ORGOVYX achieved net revenues of $24.4 million in its fourth quarter on the U.S. market, reflecting 40% sequential volume growth compared to fiscal Q2, partially offset by a lower net selling price. MYFEMBREE generated net revenue of $2.4 million, reflecting steadily increasing growth over each month of fiscal third quarter. By December, MYFEMBREE had captured 45% of new-to-brand prescription share among GnRH antagonists approved for uterine fibroids, more than double the 20% share that MYFEMBREE held only three months prior. RYEQO revenues from Gedeon Richter, our international commercial partner for women's health, were $2.4 million, primarily reflecting revenues for product supply to Richter to support their European launches.

Turning to business development and financial updates. We're currently engaged in a formal process to assess partnership opportunities for international rights to relugolix in oncology, focusing on potential partners with an established European commercial presence in urology or oncology. We remain on track towards our goal of reaching an agreement with a partner by the anticipated European Commission approval of relugolix for prostate cancer, expected in the middle of this year. In the meantime, we continue to work with the EMA through the ongoing review process and on other pre-launch activities related to pricing and reimbursement so our chosen partner will be in a position to execute a launch shortly after regulatory approval.

Finally, we remain in a strong financial position to support ORGOVYX and MYFEMBREE commercialization activities while seeking to expand our pipeline. As of December 31st, Myovant had cash and committed financing of nearly $570 million.

With the start of the new calendar year, I would like to briefly discuss our goals and objectives for 2022. Building on the strong momentum we generated last year, we expect to drive ORGOVYX growth by increasing the depth and breadth of prescribing while increasing patient engagement. For MYFEMBREE, we expect to accelerate uptake in uterine fibroids and, pending FDA approval, to launch MYFEMBREE for endometriosis pain, where there is also high unmet need for large patient population searching for an effective treatment option. Significant prescriber overlap will enable us to execute an efficient launch for this new indication, if approved, by leveraging the same brand, the same dose, the same one-pill once-a-day that is approved to treat uterine fibroids.

In addition to executing commercially, we also need to build for tomorrow through pipeline expansion. We plan to advance relugolix lifecycle opportunities, to advance MVT-602 clinical development, and to announce an international partnership for relugolix in oncology. Finally, we will also continue to look externally for opportunities -- primarily in urology, oncology, and women's health -- to add fuel to our clinical development engine and to complement our commercial capabilities.

We are excited about the commercial momentum for ORGOVYX and the early launch progress for MYFEMBREE. Together with our upcoming clinical and regulatory milestones, Myovant remains well-positioned for strong commercial execution and sustainable, long-term growth.

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

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

ORGOVYX momentum continues to build as we and Pfizer drive incremental adoption and ultimately work toward establishing ORGOVYX as an androgen deprivation standard of care. In our first year on the U.S. market, we recorded $57 million of net revenue and estimate that 11,000 men were treated with ORGOVYX.

As Dave mentioned, ORGOVYX generated $24.4 million of net revenue in fiscal Q3, reflecting 40% sequential volume growth, driven by growing patient and clinician demand for ORGOVYX and improving payer coverage.

Estimated cumulative patients on therapy has continued to steadily increase month over month. Since the end of September, we estimate that at least 3,000 additional men were treated with ORGOVYX, bringing the total to 11,000 patients through December, including patients on free and commercial drug but excluding patients utilizing product samples. During November, we began distributing ORGOVYX samples while enrollment in the free trial program was discontinued at the end of the month. Therefore, unlike prior months, the estimated number of incremental patients treated in December did not include any new patients from the free trial program. In terms of patients taking ORGOVYX, market research continues to suggest that it is being utilized across the spectrum of advanced prostate cancer settings.

We initiated the sample program to provide patients and physicians the opportunity to gain experience with ORGOVYX and to facilitate new patient starts at the point-of-care, immediately upon treatment decision. Since November, we have distributed over 2,200 monthly samples to nearly 1,000 providers with high-prescribing potential. We have received positive feedback from many providers regarding the additional convenience of having ORGOVYX at the ready for appropriate patients to trial. And for practices that do not allow samples, we have provided vouchers that enable patients to receive an initial month of ORGOVYX for free.

Breadth of prescribing has steadily increased since launch. Approximately 1,800 treatment centers have dispensed or prescribed ORGOVYX through December, an increase of approximately 300 from the end of September, and nearly doubling since May. The re-order rate remains high, at approximately 90%, which we believe demonstrates very high satisfaction with the overall ORGOVYX treatment and prescribing experience.

The mix of specialties prescribing ORGOVYX since launch remains at approximately 60% urologist, 40% oncologist. Approximately 75% of total commercial volume has been dispensed via the specialty distributor channel, which serves practices with in-office dispensing capabilities, including large group practices, hospitals, academic centers, and integrated delivery networks. We expect this channel to remain our primary source of business going forward. The remaining 25% of ORGOVYX volume was distributed via the specialty pharmacy channel, which generally serves practices that do not have in-office pharmacies.

Coverage for ORGOVYX continues to improve, with 190 million lives covered across commercial and Medicare Part D as of January 2022. Since October, we obtained coverage for an additional 17 million lives, bringing commercial coverage to 81% and Part D coverage to 99% of lives.

Out-of-pocket costs for commercial patients, which we estimate are approximately 50% of ORGOYVX patients treated to date, can be reduced to as little as $10 per month with use of a co-pay card. Nearly all of the remaining ORGOVYX patients to date are on Medicare Part D plans, with approximately half of these men eligible for either the low-income subsidy or an employer group waiver plan, both of which significantly reduce patient out-of-pocket costs compared to a standard Part D beneficiary. For the remaining Part D patients not eligible for LIS or an employer plan, independent third-party patient support foundations may be able to provide financial assistance to offset their out-of-pocket costs.

In closing for ORGOVYX, I'd like to highlight our tremendous opportunity to redefine care for so many more men with advanced prostate cancer. This year, of the 3 million men living with this deadly disease, approximately 300 thousand are projected to receive androgen deprivation therapy with approximately 100 thousand initiating ADT for the first time. We are excited about the momentum we were able to generate in our first year of launch and the opportunity for substantial future growth that lies ahead.

Now turning to MYFEMBREE. We are very pleased with the continued progress that we've made on the uterine fibroids launch. Since its May FDA approval and mid-June launch in the U.S., MYFEMBREE has generated $4.1 million of net revenue, more than half of which we recorded in our most recent quarter. Approximately 1,400 women were treated with MYFEMBREE through November, including patients on free or commercial drug, but excluding patients utilizing samples. This is more than double the number of patients treated through the end of September and reflects the rapidly expanding pool of prescribers, which reached 800 through December. Also encouraging was the 45% new-to-brand prescription share that MYFEMBREE captured in December among GnRH antagonist therapies FDA-approved for uterine fibroids, up from 20% in September.

Provider education has been a hallmark of our launch and continues to have a significant impact on awareness. Since launch, the Myovant and Pfizer sales teams have conducted 134 thousand calls, reaching 85% of our high and medium priority target prescribers. This activity has continued to drive awareness. Among potential prescribers, aided awareness has grown from approximately 30% pre-launch to nearly 90% as of December. Unaided awareness has also improved remarkably, with 2 in 5 target providers now able to identify the MYFEMBREE brand.

Increasing awareness has clearly had a favorable impact on the MYFEMBREE launch trajectory, its prescriber base, and overall class growth. New-to-brand prescription share is a key leading indicator for future adoption and we are proud that in the first 6 months of launch, MYFEMBREE had already captured a 45% share of this class. We believe this rapid shift in share reflects the simplicity, convenience, and desirable clinical profile of MYFEMBREE as well as the effectiveness of our sales and marketing efforts.

The full potential of MYFEMBREE can only be unlocked by growing the overall uterine fibroids market and the GnRH antagonist prescriber base. Providers are recognizing MYFEMBREE's clinical profile, reflected by the rapidly increasing number of prescribers in every month since launch. Through December, approximately 800 providers had prescribed MYFEMBREE at least once. The pool of prescribers has also expanded, as nearly 60% are first-time GnRH antagonist prescribers for uterine fibroids.

We have also seen class growth since the MYFEMBREE launch. The four-week moving average of total GnRH antagonist prescriptions for uterine fibroids increased 81% from late-June through December, demonstrating that this market can be expanded with the right treatment option.

Obtaining high-quality commercial payer coverage for MYFEMBREE has been a critical launch priority given approximately 85% of women who are candidates for MYFEMBREE treatment are commercially insured. We have made extraordinary progress in the six months since our launch, achieving coverage for 148 million, or 83% of commercial lives, an improvement of nearly 40 million lives since October. Negotiations continue with other commercial payers that have yet to make a coverage determination and we expect coverage to continue to expand in coming months.

Just as important as having broad coverage is having high-quality coverage that supports prescriber choice, while minimizing out-of-pocket costs for patients and other barriers to access. Of the commercial covered lives to date, 77% have prior authorization criteria that is at parity with ORIAHNN. And out-of-pocket costs for commercial patients can be reduced to as little as $5 per month with the use of our co-pay card.

Pending FDA approval by its May 6th PDUFDA date, we expect to launch MYFEMBREE in endometriosis in May. Endometriosis impacts approximately 8 million women in the U.S., of which 6 million experience often-debilitating symptoms like pelvic pain, pain during intercourse, and infertility, which can significantly impact quality of life. Approximately one million women with symptomatic endometriosis are failed by initial therapy, underscoring the high unmet need for this disease.

We have a very clear and direct strategy for our endometriosis launch. Pending FDA approval, we intend to highlight the clinical profile and leverage the same one dose, one pill, once-a-day approach currently approved for uterine fibroids. Additionally, given the significant prescriber overlap between uterine fibroids and endometriosis, we plan to utilize the existing women's health sales forces and leverage prescribers' familiarity with MYFEMBREE.

Incumbent GnRH antagonists offer a confounding array of two brands, three doses, and multiple dosing intervals across uterine fibroids and endometriosis. MYFEMBREE on the other hand, resembles the once-daily dosing for oral contraceptives, with which many women are already experienced, and is often the initial therapy prescribed by gynecologists to treat these diseases. We believe that these factors combined with accelerated payer coverage should help to support initial uptake in endometriosis if MYFEMBREE is approved by the FDA for this indication.

There are approximately 5 million women in the U.S. with symptomatic uterine fibroids who are seeking treatment and 6 million women with symptomatic endometriosis. Of these women, approximately 4 million are failed by initial treatment for their disease. While we realize that changing entrenched prescriber behavior takes time, even capturing a small share of this four-million patient market would result in a significant commercial opportunity for MYFEMBREE. We are off to a great start with a differentiated product that, with time, has the potential to change the treatment paradigm in uterine fibroids as well as in endometriosis, pending FDA approval.

I'll now turn the call over to Uneek to review our financial results.

Uneek Mehra, Myovant Sciences Ltd. - Chief Financial and Business Officer

My comments today will focus on the highlights of our financial performance in the third fiscal quarter ending December 31st 2021. Please refer to our press release and Form 10-Q issued earlier today for additional information.

Let's begin with revenue: Consistent with the preliminary revenue ranges we provided earlier this month, Myovant recorded $54.4 million of total revenue for the quarter. Q3 net product revenue was $29.3 million. ORGOVYX net revenue was $24.4 million, reflecting 40% sequential volume growth, partially offset by a decrease in net price due to a higher gross-to-net discount compared to Q2. The gross-to-net discount for ORGOVYX in fiscal third quarter was in the low-40%'s, and we expect it to remain in the low-to-mid 40%'s, for the foreseeable future. For fiscal Q4 2021 specifically, we anticipate the impact of gross-to-net discounts for ORGOVYX to be in-line with the impact from fiscal Q3.

MYFEMBREE net revenue was $2.4 million, reflecting steadily increasing demand for the differentiated clinical profile of MYFEMBREE along with class growth. We recorded $2.4 million of net product revenue from Gedeon Richter, primarily reflecting revenues for product supply to support their European launches of RYEQO and, to a lesser extent, royalties.

We also recorded $25.2 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 $4.2 million related to the partial recognition of a $100 million regulatory milestone payment triggered upon FDA approval of MYFEMBREE for uterine fibroids. In future quarters, we will continue to amortize these milestones at these same amounts through the end of calendar year 2026, when the amortization period is scheduled to end.

Moving on to other highlights of our Income Statement: Cost of product revenue for the quarter was $4.2 million and largely comprised of expenses related to the cost of goods sold as well as the royalty on net sales of relugolix, payable to Takeda.

Collaboration Expense was $12.1 million, reflecting Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S. during Q3.

R&D expenses in the third quarter were $25.7 million compared to $30.5 million for the comparable prior year period. The decrease in R&D expenses was mainly driven by a reduction in clinical study costs as well as higher cost sharing with Pfizer for certain R&D expenses.

SG&A expenses in the third quarter were $72.1 million compared to $49.2 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, including 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 $63.4 million, or 68-cents per share, in the third quarter of 2021 compared to a net loss of $73.8 million, or 82-cents per share in the prior year quarter.

Looking ahead, R&D expenses for fourth fiscal quarter 2021 are projected to be in line with Q3 actual spend. Subsequently, we expect fiscal year 2022 R&D expenses to increase as compared to projected fiscal year 2021, driven by spending on relugolix lifecycle opportunities, such as the Phase 3 SERENE study, as well as on post-marketing requirements as agreed upon with the FDA.

SG&A expenses for fourth fiscal quarter 2021 are expected to decline modestly from Q3 actual spending, which included expenses for certain sales and marketing activities that were originally expected to be incurred in fiscal Q4. Subsequently, we expect SG&A expenses to be higher in fiscal year 2022 compared to projected fiscal year 2021 due to increased marketing and promotional expenses to support the ongoing commercialization of ORGOVYX and MYFEMBREE in the U.S.

We ended fiscal Q3 with total cash, marketable securities, and committed financing of $569.1 million, comprised of $527.8 million of cash 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.

Our cash position and potential future milestone payments coupled with the sharing of certain relugolix-related development and commercial expenses with Pfizer as well as the anticipated increase in ORGOVYX and MYFEMBREE revenues puts Myovant in an excellent position to execute our commercial strategies while, at the same time, expanding our pipeline.

I'll now turn it back over to Dave for some closing remarks. Dave?

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

Thank you, Uneek and Lauren. In closing, we believe ORGOVYX adoption will continue to build as breadth and depth of prescribing increases and as we step up patient-activation efforts. After our first year on the market, we continue to believe that ORGOVYX is poised to become an ADT standard of care in advanced prostate cancer, representing a significant commercial opportunity over time.

MYFEMBREE has the potential to impact the lives of millions of women by transforming the treatment paradigm for uterine fibroids and, if approved by the FDA, for pain associated with endometriosis. Our recent launch progress in uterine fibroids has been encouraging as we've been able to rapidly gain new-to-brand prescription share while simultaneously growing the class and the prescriber base.
We have plans to expand our pipeline this year by executing on relugolix lifecycle opportunities, by advancing MVT-602, and by pursuing business development, which can all be supported by our strong financial position.

In addition to executing commercially, in the coming months, we expect to complete multiple regulatory filings, receive multiple regulatory decisions, read-out important clinical data, and potentially initiate additional clinical studies, all of which will better position us for sustainable long-term growth.
I am confident in our ability to deliver on our mission of redefining care for those who depend on us for our differentiated medicines... and I look forward to this translating to long-term value creation for shareholders.

Thank you for your attention and I'll turn it 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)

Our first question comes from the line of Roanna Ruiz with SVB Leerink. Your line is now open.

Roanna Ruiz, SVB Leerink – Senior Research Analyst

Great. Thanks and morning everybody. I have a question for ORGOVYX, perhaps could you update us on the status of your efforts negotiating with large group purchase organizations and removing disincentives for in office dispensing and do you expect these efforts to taper off anytime soon, or are you going to continue it through the year?

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

Yes. Thank you, Roanna. Lauren, would you like to take that?

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

Yes, sure. So, from a GPO perspective, we have contracts in place with key GPOs that enable the practices to purchase our product, purchase ORGOVYX through our specialty distribution channel. And so those contracts exist and are in place and are being utilized by our accounts today.

Roanna Ruiz, SVB Leerink – Senior Research Analyst

Okay. Great. And so are there any other smaller accounts that might tag on, or is this relatively stable?

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

It's relatively stable at this point.

Roanna Ruiz, SVB Leerink – Senior Research Analyst

Great. Thanks.

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

Thank you.

Operator

Our next question comes from the line of Eric Joseph from JP Morgan. Your line is open.

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

Hi. Good morning. Thanks for taking the questions. First is on your -- potentially European launch and partnering considerations. You talked a little bit about having started some initial pricing and reimbursement work in Germany. I'm curious to know whether Myovant launch or led a launch in Europe is one of their specific alternatives you -- that might happen here and whether the relationship with Sunovion is an opportunity to leverage and [inaudible] in the European market.

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

Good morning, Eric. I'll let Uneek address that I believe you're referring to the European opportunity for ORGOVYX. So Uneek, could you take it?

Uneek Mehra, Myovant Sciences Ltd. - Chief Financial and Business Officer

Yes. Hey. Good morning, Eric. At this point in time, we're not contemplating Myovant led launches in Europe. As we stated before, we are -- a formal process is underway right now to evaluate potential partners for ORGOVYX in ex-U.S. markets and we have considerable interest in the opportunity as mentioned before, we are also seeking partners, who have established commercial infrastructure in Europe preferably in urology and oncology, and consistent with our previous remarks, we hope to have a partner in place ahead of the EU approval decision, which is expected sometime in the middle of this year.

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

And thanks for that. And just on the U.S. lodge, you -- at least at the conference, you highlighted the expectation of stabilized gross to net. Can you just talk a little bit about how far out your current contracts reach, any guidance as to how we'd be speaking about (inaudible) ORGOVYX in the outer years going forward from here?

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

Yes. Certainly, Uneek, can you address the gross to net outlook?

Uneek Mehra, Myovant Sciences Ltd. - Chief Financial and Business Officer

Yeah, sure. Eric. So we expect in the foreseeable future, which should be at least till the end of calendar year 2022 gross to net to be in this sort of low-to-mid 40%. Most of our contracts typically will go until that point in time and then beyond the calendar year-end 2022 there will be some sort of renegotiations that may likely happen. But our guidance right now is at least until the end of 2022, we

expect to be in that range.

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

Okay. Great. Thanks for taking the questions.

Operator

Our next question comes from the line of Phil Nadeau from Cowen. You may begin.

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

Good morning. Congrats on the progress and thanks for taking our questions, a few from us. So, I guess first on the ORGOVYX launch in the U.S. You discussed a bit about the physicians, who are prescribing the drug. What about the patients who are being the first to put on it, any unifying characteristics among those patients? For example, do they have cardiovascular risk or anything else notable?

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

Lauren?

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

Yes. When we do an analysis of our claims data, so keep in mind due to our distribution model, we have limited data to access. But with the data that we have, we're able to analyze the types of patients that are receiving ORGOVYX today.

And we look at them grouped into three groups. So, the localized -- those with localized disease, those who have locally advanced disease and those with metastatic disease. And what we see is that about half of ORGOVYX patients have localized disease. And so this means there are earlier in their disease course and about 35% of patients are metastatic to have more advanced disease. But this is a very similar patient distribution to Lupron and also generally, reflective of the size of these patient groups.

So that's generally how we look at the patient subsets. We don't have access to data that allows us to assess cardiovascular risk; however, we do hear anecdotally from the field that that is a consideration for physicians as they make treatment decisions.

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

Perfect. That's very helpful. The second question on ORGOVYX in the EMA, have you received the Day 120 questions from the EMA and any notable issues raised if you have?

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

Juan Camilo, I'll let you address that. I know we typically don't discuss kind of the regulatory discussions. But maybe, you could provide some context in terms of our feeling on the progress there.

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

Yes. Yes, thank you, Dave and hi, Phil. Yes. As Dave pointed out, we usually don't provide that granularity; however, I'll tell you, we are -- we remain on track for a May 2022 decision. And if you do the math and knowing that the process is (inaudible) regulated in Europe, we are definitely past the Day 120, and we are excited to see the next steps towards the final decision.

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

Perfect. And then one last regulatory question from us and if you're kind of willing to answer. In terms of the two-year BMD data that will be filed, any recent thoughts on the ability of that data to remove the limitation and duration of use from the U.S. label of MYFEMBREE.

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

Yes, Juan Camilo.

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

Yes. Similarly, as we stated before, we are very excited about data we saw from the randomized withdrawal study. We are pretty confident on our -- or we believe that data together with the rest of the data from the LIBERTY program have shown that the limited effect of MYFEMBREE on BMD.

So, we are putting together our submission, that should go as planned in the next few weeks into the FDA. However, we cannot predict how FDA will interpret the data. And then what is the likelihood of that having an impact on the duration of treatment. So, we'll -- we are putting our best case forward and with our assessment of data and we'll wait for their review.

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

Perfect. Thanks for taking our questions and congrats again, on the progress.

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

Yes. Thanks, Phil. And just to add on to the last responsible, just remember the label is one area that physicians will look for those data. We also certainly expect that it will be available through publications and other means as well. Next question, please.

Operator

Our next question comes from the line of Brian Skorney from Baird. Your line is open.

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

Hey. Good morning. Thank you for taking the question. I was hoping maybe, you could discuss the intended submission of the LIBERTY randomized withdrawal study, and how you think getting this added to the label could wind up impacting uptake and the ability to detail relative to ORIAHNN.

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

Yes. Juan Camilo maybe again, let's just kind of touch on that regarding, how you believe prescribers will? How important this data is to prescribers, regardless of where it ends up in the label or in the public. And then Lauren, maybe just talk about what we hear from physicians in our promotional efforts. So Juan Camilo, why don't we start with you?

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

Yes. Thanks, Dave. Yes. As Dave pointed out, we will disseminate the data in multiple ways, right? The first one is we're providing, submitting, to the FDA and we expect the data -- at least some of the data to be reflected in the label. As I mentioned before, if it affects the duration of treatment, will be an FDA decision.

In parallel with that, we are proceeding with presentation of the data and multiple scientific conferences, and we will move forward to also a publication of the data we consider very robust and in that way, physicians will have all the information that we believe would be useful to them, to make their treatment decisions. And as a reminder, we are the only -- MYFEMBREE is the only GnRH antagonist that has run two-year trials that are now publicly available. And I think that adds another layer of confidence of high prescribers on the profile of MYFEMBREE. And Lauren?

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

Lauren, you’re on mute.

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

Sorry. From a physician perspective, we continue to hear that physicians are focused on UF, uterine fibroids as a long-term disease. And so they're looking for therapies that match their patients' needs, which we believe MYFEMBREE offers a unique clinical profile for those patients.

And so as more data becomes available and once we have approval to use it promotionally we'll of course, do that and payers will also have access to the data as soon as it's available and published.

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

And Brian, one other addition, when we think about the SPIRIT data of the longer-term data, many times, we focused on the BMD results. I know their clinicians are very focused on that. But the other part that gets a little less air time is what happens when you discontinue MYFEMBREE and what we see is the symptomatology returns back very quickly for these women. And so I think that's a consideration as physicians look to make treatment decisions down the road and why the BMD data is important. But also, the -- what happens when you withdraw and then reinitiate MYFEMBREE of course, the efficacy returns, fairly rapidly. So, that's another key part of that dataset.

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

Great. Thanks. That's very helpful.

Operator

Next question will come from the line of Madhu Kumar from Goldman Sachs. You may begin.

Madhu Kumar, Goldman Sachs Group, Inc., Research Division - Equity Analyst

Okay. Hey. Thanks for taking our questions. So, kind of following up on that last comment about the withdrawal studies. In kind of commercial practice, what kind of feedback are you getting on the idea of kind of this two-year period of use limitation to uptake and that people don't want to have to go on to a therapy and then come off of it, and have like their disease rebound, like how much of that is a barrier to that end, kind of following up on both Phil and Brian's questions, how much would it kind of removal to limitation of use resolve that issue?

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

Juan Camilo, as a physician, I know you have faced these types of decisions. I'll let you talk about your perceptions of how physicians would view again, the long-term considerations for uterine fibroids.

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

Yes. Thanks, Dave. And hi, Madhu. I think that there are multiple things that are considered by physicians that treat women with uterine fibroids. I think that, one thing that has been very clear, now that the ACOG guidelines have been updated is that what is very important is that for women to have multiple options for treatment. Until recently the options were limited, some of the medical treatment options had limited efficacy, like contraceptives or NSAIDs. And therefore, the addition of GnRH antagonist adds another layer of effective -- now effective treatments that provide options for women. What we've heard from our market research is that women in general would rather not have major surgery in the cornerstone of treatment of uterine fibroids with myomectomies and hysterectomies.

So, from a treating physician perspective, I think that, that is the value that is the MYFEMBREE brings the table is another option that provides predictable efficacy and safety, and allows women to delay or

prevent the need for surgery.

Madhu Kumar, Goldman Sachs Group, Inc., Research Division - Equity Analyst

Okay, great. And one follow-up question for Uneek. How should we think about -- you're having a good color on fiscal '22 R&D and SG&A spend, how should we think about the growth of those relative to the growth from fiscal '20 to fiscal '21?

Uneek Mehra, Myovant Sciences Ltd. - Chief Financial and Business Officer

Yes. Thanks, Madhu for the question. We'll be providing more color on the dimensionalization of that growth in our fiscal Q4 call in May, as we sort of work through the end of this year, as well as close out the activities for this year, in our alliance with Pfizer. At that point, we will be in a better position to give you the dimensionalization of that increase.

Madhu Kumar, Goldman Sachs Group, Inc., Research Division - Equity Analyst

Okay, thank you.

Operator

And our last question will come from line of Gavin Clark-Gartner from Evercore ISI. Your line is open.

Gavin Clark-Gartner, Evercore ISI – Research Analyst

Hey. Thanks for taking the questions. Just had a couple. First -- some (inaudible) recently issued guidance, that states pairs and discover FDA-approved contraceptives with no out-of-pocket costs. Once the SERENE indication is on the label, but this guidance likely applied to all MYFEMBREE patients.

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

Juan Camilo?

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

Yes, Gavin. Good morning. So first, let me just say that we are very excited about our SERENE study. We believe that having a product that provides the treatment for uterine fibroids and hopefully endometriosis, if approved, that also provides contraception would be very meaningful for prescribers and for patients. This is -- contraception is something that is a consideration that is top of mind for women in this reproductive age that suffer for uterine fibroids endometriosis. And therefore, we believe that successful SERENE study would be a critical differentiator for MYFEMBREE. As you pointed out, the regulations or the rules require prior that all at least one contraceptive of a specific class is covered at no cost for the patient and that certainly has been a consideration, but we will wait until we have the

data and there, we will go through the process of assessing that to determine the full implication of that if applicable for MYFEMBREE. But we remain very excited about the SERENE study and how the value that it will bring for prescribers and for patients.

Gavin Clark-Gartner, Evercore ISI – Research Analyst

Yes. Got it. And there are also 3.5 billion in potential tiered sales milestones from Pfizer under the partnership. Can you share any more details on what the Tier A or B sales thresholds are, what the milestone payments are? When it's possible that any of these milestones could be reached?

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

Yes. And Uneek, would you like to discuss the -- I know we are providing specific numbers on the tier. But maybe, you can add some color there.

Uneek Mehra, Myovant Sciences Ltd. - Chief Financial and Business Officer

Yes. Thanks. It's -- we have not provided any details in terms of the tiers on these milestones. I think when you look at the 3.6 and typically billion and then spread it across generally available four or five tiers. You can probably estimate where those tiers are and in regards to your second part of follow-up as to when we would likely expect to achieve those tiers, I think, still too early. Given that our launches are just gaining traction on both MYFEMBREE and ORGOVYX. But at this point, it's a little early to sort of indicate when we would have that achievement of those tiers.

Gavin Clark-Gartner, Evercore ISI – Research Analyst

Yes. Got it. Thanks. And maybe, one last one on ORGOVYX. Are you around bigger urology and oncology practices adopting formal preferences for ORGOVYX vs. other GnRH agents? So, it could be kind of listing it as a preferred agent in their EMR or ePrescribe system, or alternatively are they just including in their system with parity access to the other agents and leaving the decision up to the prescribers. Thanks.

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

Yes. Thank you, Gavin. Lauren?

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

So, we don't have complete transparency into the EMR systems. We more receive feedbacks from our customers about their preferences and how they're utilizing ORGOVYX, and it seems that for certain patient types, they do have a preference to start with ORGOVYX. But it is an individualized treatment decision with each patient.

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

Okay. Operator, are there further questions?

Operator

Thank you. And I'm not showing any further questions at this time. I'll turn the call over to Dave for any closing remarks.

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

Thank you. As you can hear today, we are very encouraged by the progress we have made on the ORGOVYX and MYFEMBREE launches. We are energized by the tremendous remaining commercial opportunity for both brands. We are well positioned to deliver strong commercial execution while building sustainable long-term value through pipeline expansion. So, thank you and I look forward to keeping you updated on our progress. Have a good day.

Operator

Ladies and gentlemen, this concludes Myovant Sciences' third fiscal quarter 2021 earnings conference call. Thank you for your participation. You may now disconnect. Everyone have a great day.

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