EDITED TRANSCRIPT

MYOV – Q3 2020 Myovant Sciences, Inc. Earnings Call

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OVERVIEW:
Co. reported third fiscal quarter 2020 financial results and provided a general business update.

CORPORATE PARTICIPANTS

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

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

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

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

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

CONFERENCE CALL PARTICIPANTS

Jason Nicholas Butler, JMP Securities LLC, Research Division - MD, Director of Healthcare Research & Equity Research Analyst

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

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

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

Mohit Bansal, Citigroup Inc. Exchange Research - Research Analyst

Ami Fadia, SVB Leerink LLC, Research Division - MD of Biopharma & Generics and Senior Analyst

PRESENTATION

Operator

Good day, everyone, and welcome to Myovant Sciences Third Quarter of Fiscal Year 2020 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 for a general business update and to review the financial results of Myovant's third quarter of fiscal year 2020. Joining me for today's call are Dave Marek, Myovant's Chief Executive Officer, Frank Karbe, President and Chief Financial Officer; Adele Gulfo, Interim Chief Commercial Officer; and Dr. Juan Camilo Arjona, Chief Medical Officer.

In addition to the press release issued earlier this morning, the slides that will be presented during today's webcast are available on our Investor Relations website, investors.myovant.com.

During the course of this conference call, we'll 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 an obligation to update any forward-looking statements made during this call.

With that, 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. Since our last earnings report in November, I'm pleased to report that Myovant has achieved 4 landmark milestones: an FDA approval, a collaboration agreement with Pfizer, positive data from a Phase III extension study and a product launch. These are huge milestones that have helped transform us into a commercial-stage company with compelling near-term opportunities in oncology and women's health.

Before we review these milestones in more detail, let me first comment on the ORGOVYX launch. It's still early days, but I'm encouraged by the initial feedback we've heard from the field and the ordering trends we've seen after just 5 weeks. Through the end of last week, approximately 1,800 bottles of ORGOVYX have been shipped into our distribution channels, which include our specialty distributors, specialty pharmacies and our free-trial program. We will learn more about this inventory and how it's being dispensed to patients as we receive more patient and provider-level detail and data in the coming weeks. From a customer standpoint, I'm pleased that 10 of our top 20 highest priority accounts have placed at least one order for ORGOVYX. And overall, of customers that have placed an order through the end of last week, 30% have already placed reorders. So in summary, great progress in the early days of the launch, but we're just getting started.

In December last year, the FDA approved ORGOVYX, our oral relugolix monotherapy, 120-milligram tablet for the treatment of adult patients with advanced prostate cancer. As the first and only approved oral gonadotropin-releasing hormone receptor antagonist, we believe ORGOVYX is poised to become the new androgen deprivation standard of care, and this is based on its differentiated clinical profile, coupled with its patient-preferred oral formulation.

And prostate cancer represents a substantial opportunity to improve or redefine care. It is the second most common type of cancer in men in the United States with approximately 3 million men living with this disease. And of those, approximately 300,000 patients are projected to receive androgen deprivation therapy, or ADT, this year alone. And of those patients, approximately 100,000 patients will initiate ADT this year and about 200,000 continuing ADT as part of their prostate cancer treatment journey. And due to advances in prostate cancer care and an aging population, the number of men with advanced prostate cancer in the U.S. is expected to grow by mid-single digits annually in the coming years. Also, 2 out of 3 men with prostate cancer have cardiovascular risk factors, and an estimated 30% of prostate cancer patients have diagnosed cardiovascular disease. So in fact, more men with prostate cancer die of cardiovascular disease than from prostate cancer itself. And it's well recognized that injectable LHRH agonist, such as leuprolide, the current ADT standard of care, as well as certain other prostate cancer medicines may increase the risk of cardiovascular events.

The approval of ORGOVYX now offers men with advanced prostate cancer rapid, profound and sustained testosterone suppression, and this is without an initial surge in testosterone levels that can exacerbate clinical symptoms known as hormonal flare. And for men who receive time-limited treatment courses and who would benefit from a faster return-to-normal testosterone levels, ORGOVYX offers testosterone recovery within 90 days of treatment discontinuation for the majority of men. One of the clinical attributes providers have told us they find most compelling is that men treated with ORGOVYX in the Phase III HERO study had a lower incidence of major adverse cardiovascular events, including heart attacks, strokes and death from any cause, compared to those receiving LHRH agonist injections.

And finally, as a one-pill, once-a-day therapy, ORGOVYX provides a convenient alternative for patients compared to the injectable options which require travel to the clinic or hospital for administration. So as you can imagine, this is particularly important for this population of patients with advanced prostate cancer during the ongoing COVID-19 pandemic.

Now let's briefly review the Myovant-Pfizer collaboration that was announced shortly after the ORGOVYX FDA approval.

In December, Myovant and Pfizer entered a broad collaboration agreement to jointly develop and commercialize ORGOVYX and relugolix combination tablet in the U.S. and in Canada. Together, we believe we will maximize the benefit relugolix can bring to patients across therapeutic areas and across markets. We'll evenly split relugolix-associated profits and certain development and commercialization expenses in the U.S. and Canada. In exchange for these co-development and co-commercialization rights, Myovant is eligible to receive up to $4.2 billion of net payments from Pfizer. Additionally, Pfizer obtained an exclusive option to develop and commercialize relugolix in oncology outside the U.S. and Canada, excluding certain Asian countries.

So let me highlight more specifically the deal economics. We entered into this transaction because we believe it's good for patients, and it creates significant incremental value for Myovant. Adding Pfizer's capabilities to our own has the potential to significantly increase the value of the relugolix franchise by accelerating product uptake and increasing overall peak revenue. The partnership will also allow us to maximize the clinical potential for relugolix while reducing Myovant's cash burn through the sharing of certain expenses. The substantial deal economics dramatically strengthen our current financial condition and significantly improve Myovant's financial outlook, and this will now enable us to invest in our pipeline beyond relugolix sooner than we previously planned.

In addition to the $650 million upfront payment, Myovant could also receive additional payments of up to $250 million within the next 18 months. This could be composed of up to $200 million of regulatory milestones for FDA approvals in women's health as well as a $50 million payment that would be triggered should Pfizer exercise its option to develop and commercialize rights to relugolix in oncology outside the U.S. and Canada. And this is a decision we anticipate Pfizer will make during the first half of this year.

Myovant is also eligible to receive up to $3.5 billion of tiered sales milestones equally split between ORGOVYX in oncology and relugolix combination tablet in women's health based on annual net revenues for each product in the U.S. and Canada. Myovant and Pfizer will also split 50-50 certain relugolix-associated development and commercialization expenses. This will enable us to reduce our anticipated cash burn compared to developing and commercializing relugolix by ourselves.

So in summary, the significantly increased value of the relugolix franchise that we anticipate from the collaboration, coupled with the rich deal economics, is expected to more than offset the 50-50 profit split, resulting in greater overall value for Myovant.

I'll now turn the call over to Juan Camilo to discuss the recent SPIRIT extension results and to share some exciting details on a near-term life cycle opportunity [for] relugolix combination tablet. Juan Camilo?

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

Thank you, Dave.

Last month, we reported the 52-week results for the SPIRIT extension study in women with endometriosis. These results built on the positive 24-week data from the SPIRIT 1 and SPIRIT 2 Phase III trials we presented last year. SPIRIT 1 and SPIRIT 2 had identical designs and enrolled women with moderate to severe pain associated with endometriosis surgically diagnosed in the last 10 years. Approximately 1,250 women were enrolled across both studies and were randomized 1:1:1 into 3

groups to receive placebo for 24 weeks, relugolix combination therapy once daily for 24 weeks or relugolix monotherapy for 12 weeks, followed by 12 weeks of relugolix combination therapy. This last group allowed us to compare the safety of relugolix combination therapy with that of relugolix alone over the first 12 weeks of treatment.

The two co-primary endpoints, defined as the proportion of women with a clinically meaningful reduction in dysmenorrhea or menstrual pain and a clinically meaningful reduction in non-menstrual pelvic pain, both assessed by a numerical rating scale, were analyzed after 24 weeks of treatment and compared the relugolix combination and placebo groups.

Following the 24-week treatment period, patients were given the option to enroll in an extension study for up to 80 additional weeks with an initial analysis of efficacy and safety at week 52. Another analysis will be conducted at week 104 in about one year from now. A total of 802 women enrolled in the extension study, all of whom received relugolix combination therapy, regardless of their treatment assignments in SPIRIT 1 and SPIRIT 2.

Let's first review the 24-week results of the SPIRIT studies. As you can see from the data in the orange columns over 24 weeks, relugolix combination therapy demonstrated significant and very consistent efficacy results in both SPIRIT studies with a responder rate for dysmenorrhea of about 75%; responder rate for non-menstrual pelvic pain of over 60%; an improvement in dyspareunia, or painful intercourse, a key secondary endpoint. Women receiving relugolix combination therapy had minimal, non-clinically meaningful bone mineral density loss and a low incidence of hot flashes.

To put these results in context, we present on the right side of the table the results from the elagolix monotherapy pivotal studies called Elaris 1 and Elaris 2. While these studies have all similar designs, let me remind you that comparing data from different studies must always be done with caution. As you can see, after 24 weeks, relugolix combination therapy has an efficacy profile comparable to that of the high dose of elagolix with a safety and tolerability profile more like that of the low dose of elagolix.

Let's now review the 52-week results of the SPIRIT long-term extension study for those women who received relugolix combination therapy for 1 year. The 52-week results for this group are consistent with the efficacy and safety profile initially observed through 24 weeks. 85% and 73% of women, respectively, reported clinically meaningful reductions in dysmenorrhea and non-menstrual pelvic pain at 1 year. Importantly, bone mineral density loss, which was minimal and not clinically meaningful after 24 weeks, stabilized from week 24 to week 52. The proportion of patients reporting hot flashes after 1 year was also consistent with the initial 24-week treatment period despite an observation period that was twice as long.

Now let's consider these results in comparison to the results from the 52-week extension study for elagolix monotherapy, which are displayed on the right side of the table. Once again, comparing data from different studies must always be done with caution. Results after 1 year of treatment suggest that relugolix combination therapy has the efficacy profile comparable to or slightly better than that of the high dose of elagolix with a safety and tolerability profile that is comparable to or slightly better than that of the low dose of elagolix. Given the SPIRIT extension data generated after 1 year, we believe relugolix combination tablet, a one-pill, once-a-day treatment, has the potential to be a best-in-class option for women within endometriosis.

I'd like to use this opportunity to share with you a new clinical study we plan to initiate in coming weeks that we believe will provide valuable information to women and their health care providers and could further differentiate relugolix combination tablet from other GnRH antagonist treatment options for uterine fibroids and endometriosis.

We learned from market research that contraception is important to women with uterine fibroids or endometriosis. Approximately 65% of current uterine fibroid patients taking oral contraceptives for treatment believe that contraception is an important factor in considering a uterine fibroid treatment. Similarly, approximately 78% of women taking elagolix as a treatment for endometriosis believe that contraception is an important treatment consideration.

Currently available GnRH antagonist therapies for uterine fibroids and endometriosis require concomitant use of barrier or nonhormonal contraceptives and their use with hormonal contraceptives may be associated with decreased efficacy and increased risk of adverse events.

Relugolix combination therapy has already demonstrated 100% ovulation inhibition in a Phase I, open-label, single-arm study in 67 healthy women over an 84-day treatment period. Based on these results, we are planning to start the SERENE study, a Phase III study to assess the contraceptive efficacy of relugolix combination tablet. The SERENE study will enroll sexually-active, healthy women ages 18 to 35 years with presumed normal fertility. All women will receive once-daily relugolix combination tablet for 13 28-day cycles. The primary efficacy endpoint will be the Pearl index, defined as the number of on-treatment pregnancies per 100 women-years of treatment. Positive data from the SERENE study could further differentiate relugolix combination tablet by potentially adding the benefit of prevention of pregnancy for women being treated for uterine fibroids or endometriosis, if approved for these indications.

We believe that relugolix combination tablet, which combines 40 milligrams of relugolix with 1 milligram of estradiol and 0.5 milligram of the progestin norethindrone acetate, could have a meaningful impact in the field of women's health. We have heard from prescribers, primarily OB/GYNs, that they are still looking for better medical treatment options for endometriosis and uterine fibroids as an alternative to surgery. Their top priorities for treatment are very clear and consistent: stop the symptoms, minimize the side effects and make it easy for them and their patients.

We believe that relugolix combination tablet has the potential to meet those treatment requirements based on the results from our Phase III LIBERTY and SPIRIT clinical studies. Symptom relief was significant in these studies with a 90% average reduction in menstrual blood loss in women with uterine fibroids and an 83% average reduction in menstrual pain for women with endometriosis both after 1 year. Relugolix was generally well tolerated with stable bone mineral density at 1 year after an initial minimal loss following treatment initiation and rates of adverse events, such as hot flashes, were low and not meaningfully different from placebo.

Finally, dosing for relugolix combination tablet is convenient, one pill, once a day with combination therapy from the start, and is the same for uterine fibroids and endometriosis. We believe we may have found the right balance with relugolix combination tablet, reducing estrogen levels to a range that improved symptoms while minimizing the side effect of low estrogen. And we look forward to potential of bringing this product to women with uterine fibroids later this year, pending the FDA's decision, which we expect by June 1.

I will now turn the call over to Adele to discuss the launch of ORGOVYX. Adele?

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

Thank you, Juan Camilo. It has certainly been an exciting first month of our promotional efforts. After our launch meeting just 5 weeks ago, we are already receiving tremendous prescriber interest and feedback which lead us to believe that ORGOVYX has the potential to be everything we hoped.

Our long-term goal is to establish ORGOVYX as a standard-of-care androgen deprivation therapy for men with advanced prostate cancer. Executing on our launch priorities represents the first steps towards achieving this goal. Educating physicians, so they have confidence prescribing ORGOVYX, establishing broad access by enabling seamless treatment starts and engaging patients to drive awareness are all foundational to our commercialization strategy. We've made significant progress across each of these priorities, which I'll now review in more detail.

Due to the large percentage of in-office dispensing and specialty pharmacy distribution, we believe that achieving broad ORGOVYX adoption goes beyond clinical education to encompass office economics and operational considerations, including e-prescribing. I'm happy to say we are making significant strides across all 3 areas. The clinical component is being driven by our sales force who are initially targeting key prescribers and are equipped with materials and technology to perform this function virtually as well as in person. The economic component primarily impacts those practices with in-office dispensing capabilities. The vast majority of these practices now have access to our ORGOVYX contract, which was designed to ensure they are not economically disadvantaged when prescribing ORGOVYX. For those customers without dispensing capabilities, ORGOVYX is available through a specialty pharmacy network.

And finally, we need to ensure that prescribing ORGOVYX is seamless. This includes supporting office e-prescribing systems, ensuring that practices and patients take advantage of reimbursement and financial support offered through the ORGOVYX support program and where necessary that ORGOVYX is appropriately added to the clinical pathways to support prescribing.

We are very pleased with our early efforts to reach prescribers. We have had over 10,000 total touch points with health care providers since launch, a high concentration of our meaningful interactions to date have been with Tier 1 or Tier 2 accounts, including academic centers and large urology and oncology group practices that drive a significant share of ADT scripts. We were able to accomplish this in just 5 weeks and almost exclusively with Myovant's 100-person sales force. We are proud to have hired a highly experienced sales team in urology and oncology, averaging 8 years, and many with local established relationships.

Anecdotally, our representatives are seeing customer engagements reaching over 30 minutes with tremendous enthusiasm for the clinical profile, particularly the compelling efficacy; the cardiovascular profile; and given the ongoing pandemic, ORGOVYX's oral formulation. We are pleased to report that the Pfizer sales team is now fully trained and joined us in the field last week which should bolster the early momentum that we were able to generate.

As mentioned previously, the vast majority of in-office dispensing practices have access to our contract pricing, and these early efforts are translating into ORGOVYX orders. In fact, 10 out of our top 20 highest priority accounts have already placed orders and, an in another encouraging sign, 30% of all accounts that have placed ORGOVYX orders have already re-ordered. In addition, half of our highest priority accounts have ORGOVYX in their e-prescribing system which is great progress.

We have also made notable progress in establishing broad patient access to ORGOVYX. Our distribution channel was fully stocked within 72 hours of launch. And our patient support program, including the free-trial program and co- pay support for commercial patients, went live during the first week of launch.

Regarding payer coverage, approximately 30% of commercial patients currently have access to reimbursement today via pre-review coverage, and more may have access through the formulary exceptions process. Part D patients may also have access today via their formulary exceptions process. Our patient support services include support for prior authorization, and we have seen a good success rate with these requests so far.

Engagement with payers continues with initial commercial coverage decisions expected in the first half of 2021 which should support coverage for most commercial patients beginning in the second half of 2021. The path to broad Medicare Part D coverage starts with submitting our bids for the 2022 plan year, and we expect decisions by the May or June time frame. Following these decisions, we do expect some Medicare Part D plans to offer access to ORGOVYX in 2021 with broad coverage anticipated no later than January 2022.

Our strategy for engaging patients has 3 phases, 2 of which have already launched. The goal for our initial campaign is to drive early brand awareness with highly engaged patients, let them know ORGOVYX is approved and available and drive them to talk to their doctor. In the second half of this year, after prescriber education milestones are met, we will look to broaden our awareness efforts with the goal of increasing patient activation through targeted direct-to-consumer campaigns.

Our efforts to drive patient adherence utilize a 3-pronged approach. When a patient initiates ORGOVYX, nurse services are offered to each patient to coach them through the early days on therapy. A welcome kit with information on what a patient should expect after starting ORGOVYX, as well as a treatment planner to help the patient remain on track, is also provided. As treatment continues, patients are sent monthly mailers that provide helpful information on ORGOVYX and other content to maintain engagement and adherence.

We are off to a great start regarding patient engagement. In the few weeks since launch, we had over 37,000 total visits to our ORGOVYX patient website, 83% of which were unique visitors with nearly 1 in 5 visitors downloading material. This is 4x higher than our benchmarking data for other recent oncology product launches and likely reflects just how engaged men with prostate cancer and their caretakers are in making decisions regarding their health.

We are very pleased with the early progress we have made on all 3 of our launch priorities and look forward to keeping you updated in the future.

I will now turn the call over to Frank to review our fiscal third quarter financial results. Frank?

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

Thank you, Adele, and good morning, everyone.

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. Please remember that Myovant's fiscal year starts on April 1, so the financial results for the quarter ended December 31, 2020, represent our third fiscal quarter of 2020.

I will begin with revenue. We recorded $1.4 million of collaboration revenue, which represents about 1 week's amortization of the upfront payment received from Pfizer. Given the signing of the deal occurred in late December, the amortization period in fiscal Q3 was very short. Collaboration revenue related to the upfront payment will increase to $21 million in fiscal Q4 and is expected to remain constant each quarter thereafter over the next 6 years.

R&D expenses in the quarter were $30.5 million compared to $48.9 million for the comparable prior year period. The decrease in R&D expenses primarily reflects the completion and continued wind down of Myovant's Phase III programs, partially offset primarily by increased expenses associated with the build-out of Myovant's medical affairs organization in preparation for the U.S. launch of ORGOVYX and the potential commercial launches of relugolix combination tablet for women's health. Our R&D

expenses in the quarter also reflects a cost-sharing reimbursement from Pfizer of $7.6 million for expenses associated with prelaunch commercial inventory.

SG&A expenses in the quarter were $49.2 million compared to $29.1 million for the comparable prior year period. The increase was primarily due to increased spending on commercial readiness activities to support the U.S. launch of ORGOVYX; personnel-related costs, including the hiring of our oncology sales force; and other general overhead expenses, as we continue to prepare for the potential commercial launches of relugolix combination tablet in the women's health indications.

Total operating expenses for the quarter were $79.7 million, of which approximately $7 million was stock-based compensation. We also incurred a $5.8 million gain on foreign currency during the quarter that was recorded in our other income line.

Myovant generated a net loss of $73.8 million in the third quarter of 2020 compared to $85.6 million for the comparable prior year period. On a per-share basis, our net loss was $0.82 in third quarter 2020 and $0.96 in the prior year period.

Now looking ahead, we expect R&D expenses over the next several quarters to be at roughly similar levels to our fiscal Q3 2020 R&D expense, excluding the $7.6 million of expense reimbursement from Pfizer. Declining spend on clinical programs that are winding down, as well as our sharing of certain expenses with Pfizer, are expected to be offset by incremental spend on relugolix life cycle management activities, such as the planned Phase III SERENE study. In upcoming quarters, where regulatory filing expenses are incurred, there could be modest deviations from this trend.

SG&A expenses, overall, are expected to continue to increase from fiscal Q3 2020 levels as we continue to build out our commercial capabilities and support our commercialization activities. This increase is primarily driven by the hiring of our women's health sales force, which we now expect will be comprised of approximately 120 sales professionals and is expected to occur in fiscal Q1 2021 as we approach the FDA's uterine fibroid target action date of June 1, 2021. Additionally, our fiscal third quarter 2020 reflected only partial expenses of our prostate cancer sales force because the hiring occurred gradually over the course of the quarter. Finally, please note that in fiscal Q4 2020, we expect to record incremental non-cash stock-based compensation expense of approximately $28 million due to the accelerated vesting and modification of our former CEO's equity awards upon her separation from the company.

Let me wrap up by commenting on our cash position. We ended the quarter with $746 million of cash, cash equivalents and marketable securities on our balance sheet. This was bolstered by the $650 million upfront payment that was received from Pfizer in late December 2020. As of the end of fiscal Q3, there was approximately $86 million of capacity remaining under the low-cost loan facility that Sumitomo Dainippon Pharma, our majority shareholder, extended to us. An additional $200 million loan commitment that was extended to us by DSP in August 2020 also remains available to us until March 2021.

Let me also remind you that there are several potential milestone payments anticipated in coming months that will further enhance our strong liquidity position. As Dave mentioned in his opening remarks, Myovant could receive additional payments of up to $250 million under the Pfizer collaboration alone within the next 18 months. This could be composed of up to $200 million of regulatory milestones for FDA approvals in women's health, as well as a $50 million payment that would be triggered should Pfizer exercise its option to obtain development and commercialization rights to relugolix in oncology outside the U.S. and Canada. This is a decision we anticipate Pfizer will make during the first half of this year.

So overall, Myovant is well capitalized to advance our commercial launches and potentially expand our pipeline. Now with that, I'll turn it back to Dave for some closing remarks.

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

Thank you, Frank, Adele and Juan Camilo. In summary, this is an exciting time for Myovant with the ongoing launch of ORGOVYX and the potential upcoming launch of relugolix combination tablet in the uterine fibroids indication around mid-year. Our focus is squarely on successfully executing these launches and working with Pfizer to ensure we are efficiently bringing these important therapeutic options to patients in the U.S.

And as Frank highlighted, we are approaching commercialization from a position of financial strength, which we expect to continue to build as we achieve additional upcoming milestones. The 1-year SPIRIT results position relugolix combination tablet as a potential best-in-class therapy for women with endometriosis and will support upcoming regulatory filings in the U.S. and EU.

I am extremely proud of all of the work done by the Myovant team to get us to this point, and I look forward to what's ahead.

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

And our first question, coming from the line of Jason Butler with JPM Securities (sic) [JMP Securities].

Jason Nicholas Butler, JMP Securities LLC, Research Division - MD, Director of Healthcare Research & Equity Research Analyst

I guess just the first one on the commercial side. Can you speak to the types of patients that are being initiated on therapy first, newly diagnosed versus having been through prior therapies, severity of disease, et cetera?

And then just on the contraception program, can you just speak to -- I guess just review for us the data you have from your Phase III trials -- the completed Phase III trials and extension studies in terms of pregnancy frequency and just any regulatory dialogue or precedence that you think is relevant here.

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

Sure. Thanks for joining us this morning, Jason. Really appreciate the questions. I'll cover the types of patients, and I'll ask Adele to weigh in, and then I'll turn it over to Juan Camilo for the contraception study.

But just as a reminder, when we look at the types of patients, I just want to recall -- I know many of you know this regarding our distribution channel. So while we are a retail product, we don't receive the same data that would be typical as an oral agent in the retail setting. Recall, we're in the specialty pharmacy distribution. And therefore, the visibility we have as the product goes into our specialty distributors and then ultimately to in-office dispensing, the visibility we have on patient-level data is limited. So I just put that as a reminder, and I'll turn it over to Adele to add color on what we would expect to see in terms of the patient profile. Adele?

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

Yes. Thanks for that, and thanks for the question. What I will say, it is a bit early. We will still continue to gather information on our patients and have a bit more insights into that. But what I can tell you today is that our medical affairs team is actually engaging our providers on how we would go about transitioning patients who are on other therapies as well as initiating. So what that tells us is we are hearing what we would expect to hear is that doctors are interested in starting patients on ORGOVYX who are either new to therapy or who are experienced. So what I can tell you is that's what we're seeing to date.

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

And then Juan Camilo, would you take the contraception question?

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

Yes, yes. Dave, thank you. So Jason, with the -- we're excited, very excited about the contraception study. And I heard 2 questions in your question. One is any regulatory precedent and comment on the pregnancy in prior studies.

I'll start with the second one. As we've mentioned in our prior presentations, we have seen a few pregnancies in our prior studies, mostly on the placebo patients, but a couple in patients receiving relugolix combination therapy. In these studies, we were not set up for assessing prevention of pregnancy nor patients were instructed to take this drug as their means for prevention of pregnancy. Every patient in these studies was required to use nonhormonal methods of contraception, so these studies are not really set out for assessing the contraceptive efficacy of relugolix combination therapy.

We have shown before our ovulation inhibition study that demonstrated 100% ovulation inhibition, and this is a study specifically designed to assess the effect of relugolix combination on ovulation. So we're very, very confident on that. And therefore, we decided to take the next step, which is to conduct a study that is a pretty standard design study. This is the way the studies look like when you're assessing contraception. So we have decided to run that study to provide that information to patients and physicians. I hope I answered your question.

Operator

Our next question, coming from the line of Phil Nadeau with Cowen.

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

Congrats on the progress. First one on the commercialization efforts with Pfizer. Can you discuss how the resources you're getting from Pfizer and their sales force is coordinating with your own plans in the U.S.? Who takes what? And how is that decided?

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

Sure. I'll kick off. And once again, I'll turn it over to Adele. I think, again, we view Pfizer as really the ideal partner, not only for women's health eventually, but right out of the gate here with prostate cancer. And one of the areas that we really value from Pfizer is the long-standing relationships they have with customers and their knowledge of the -- of prostate cancer itself but also the speed in which they've moved to really activate around this launch and that they were fully trained and in the field as early as just last week. So we're really heartened by the speed in which they've been able to be trained and get up to speed on the therapy and then really start to contribute.

So I'll turn it over to Adele to add her perspective as well.

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

I would ask you, Dave, to come online in the last week, and what we're hearing and actively monitoring is the very active collaboration at the ground level. So the reps are coordinating in terms of the calls that they're making on the prescribers. And also, we're actively ensuring that they're working collaboratively as it relates to our most important accounts because in addition to the sales representatives that we have from Pfizer, we also will have the opportunity to tap into their key account managers and the teams that they have that are covering these large group practices and those other accounts that are primarily the ones with the in-office dispensing that we talked about.

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

Great. That's very helpful. On the economics deal, how does it work pre and post profitability? Is there a true-up every quarter on your expense lines on SG&A and R&D? Or will there be a separate reimbursement line where you'll record some of the reimbursements as revenue pre-profitability? And then post profitability, will there be a collaboration profit share in your expense lines?

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

Yes. So I will -- there was a little feedback on the beginning of that. But I think, Frank, if you caught that question, I'll turn it over to you to clarify.

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

Yes. I think I caught it. Thank you, Phil. Let me maybe speak more broadly about how the Pfizer collaboration will be reflected in our financial statements, and there's maybe 4 points to make here.

The first one is remember that Myovant will record 100% of the net product revenue. So under our revenue section in the P&L, going forward, there will be several captions. One of them will be net product revenue that will show 100% of the net product revenue. There will also be a line that will be titled something along of collaboration revenue, which will be comprised of the amortization payments from the upfront payment and any potential milestone payments.

And then under our cost of goods portion of the P&L, we will have a line item called collaboration expense, and that will reflect the gross profit share with Pfizer, will essentially be comprised of the net product revenue, minus cost of goods, and half of that is attributable to Pfizer. So you'll see that on a separate line item called collaboration expense.

And then thirdly, with regards to expense sharing, the allowable expenses that are subject to expense sharing will flow through the respective line items in R&D and in SG&A. And the way this will appear on our P&L is basically as a reduction in our expenses. So R&D and SG&A expenses will appear lower, going forward, than they would have been without the Pfizer collaboration.

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

That is very helpful. And then one last question from us. Just on the -- it's a follow-up to the question on the pregnancy study. In terms of the Pearl index, what needs to be achieved in order to support licensure? Is there any regulatory precedence for what you have to show?

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

Juan Camilo?

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

Yes. Thank you, Phil. As I mentioned before, this is a pretty traditional design, like any other contraception study. And it's based on regulatory guidance documents from the FDA and how the study should be designed. And the Pearl index, it's a pretty simple calculation. It's just the number of pregnancies that occur over a 100-patient years of exposure. So we enroll patients that are otherwise believed to be fertile, and they agree to use relugolix combination therapy as their only method for prevention of pregnancy. And then we collect the number of pregnancies and divide it by the number of months that women were taking this the medication, and that gives you the Pearl index.

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

Right. But is there a specific hurdle that you have to reach? Like if the Pearl Index is over x, you can't get the label, but if it's below x, it might -- could be approved.

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

Yes. We're not going to comment on that at this moment. I think that you just want to demonstrate the ability to prevent pregnancy, and we're pretty confident, based on our ovulation inhibition data, that we will get a Pearl index that is pretty reassuring to physicians and patients.

Operator

Our next question, coming from the line of Eric Joseph with J.P. Morgan.

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

Was just wondering if you could elaborate on how long the free-trial period is being offered to patients with ORGOVYX, particularly among government-insured patients. I guess will physicians have sort of enough flexibility to write to Medicare patients until there's a formal Part D coverage decision and then I have a follow-up on the contraception study.

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

Yes. Well good morning, Eric, regarding the free trial program, the free trial program is available to all patients. As I'm sure you know, that has an extension of up to 2 months. And then beyond that, we have a bridge program that's open to commercial patients in which that enables patients to stay on therapy while commercial coverage is being determined. So 2 months for the free trial and then an extension for commercial patients on bridge.

Regarding progress on what we're seeing in terms of Medicare coverage, I'll turn it over to Adele.

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

The point that Dave made is the right one, is that the free-trial program is offered to both commercial and Medicare patients. And what I can say about the Medicare patients is that they do have access to the formulary exception process, and we're seeing this actually happen. So we have the formulary exception process for those Medicare patients -- who were Medicare Part D patients. And I'll comment that we continue to have very good discussions with the Medicare Part D plans. And I'll remind you that by May, June time frame of this year, we should have our decisions. And we do expect some plans will come on online, even in 2021. Of course, the majority of coverage starts in January of '22, but we will expect to see some plans come online this year.

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

Okay. Got it. And I guess just trying to better understand the rationale -- the strategic rationale behind the contraception study with the combination tablet. Is it correct to read this as a desire to directly compete with OCTs and potentially forego the need to step through oral contraceptive use in the endometriosis segment? And then if that's the case, have thoughts around sort of pricing of the combination tablet change as a means of maximizing the value proposition there?

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

Yes. Well, regarding pricing, I think we're not in a position to talk yet about pricing, but I'll ask Juan Camilo to talk about the strategic rationale.

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

Yes. Thank you, Dave, and thank you, Eric. So let me just clarify one thing. We are not going to compete with combined hormonal contraceptive in the overall population. What we've heard loud and clear from patients and from their physicians is that we're talking about a premenopausal population for both indications: endometriosis and uterine fibroids. And in addition to wanting treatment for these conditions, they want to manage their lives, and contraception is a component of that.

So as I mentioned in my remarks that what's available today in terms of GnRH antagonist treatment does not provide -- well, requires the use of barrier methods of contraception that, quite honestly, are not usually desirable by patients nor consistently used. So we believe that -- having seen the data from our ovulation inhibition study. With 100% of ovulation inhibition, we have an opportunity to provide a full prevention of pregnancy, in addition to the treatment of symptoms of uterine fibroids or endometriosis, if approved, for these patients that desire it. And we believe that would be highly differentiating from other drugs in the class.

Operator

And our next question, coming from the line of Paul Choi with Goldman Sachs.

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

First, just on the Part D discussions. I was wondering if you could just clarify and elaborate a little bit. First, is there a possibility of temporary codes for 2021 versus the exception process? And then also, just to confirm. You're seeking a permanent J-code or something comparable to that for '22.

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

So Adele, I'll let you address the -- our expectations around Part D coverage.

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

Yes. And we can double check this. But in terms of codes, we're not pursuing any of that. We're going with the standard process, so I'm not quite sure that's relevant for us. We have been having very good discussions with the payers, as I've said, both on the commercial and on the Medicare side. And we started this process end of last year, and we're continuing it with coverage decisions midyear and plans coming online thereafter.

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

Okay. Then last, just with regard to Europe, can you maybe tell us where you are with regard to your own commercial infrastructure build? Specifically, I know you're considering and still waiting on the potential Pfizer opt-in but just where you are with respect to your commercial infrastructure development in Europe.

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

Sure, Paul. I think when you look at women's health in Europe, we've already established a collaboration with Gedeon Richter. So we're very enthusiastic as we approach the potential commercial approval in uterine fibroids that we would hope would come around midyear. And so Gedeon Richter will be the lead commercial or will lead the commercial efforts in women's health.

Regarding prostate cancer, as we've mentioned, Pfizer has the first option or right of first refusal, so to speak, of the prostate cancer. We expect that they will make that decision in the first half of this year. In our negotiations and the collaboration, they were very enthusiastic about that opportunity, so we will await their decision as we get closer. Should they choose not to take that option, we did have and still do have other partners who are very interested in the prostate cancer opportunity in Europe. And so we will have plenty of time to determine another partner that could potentially launch prostate cancer in Europe. We are not currently building out our European infrastructure to support those launches directly. We will do that through partnerships.

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

Okay. Great. And then just lastly, in terms of your physician checks and just sort of where the European practitioners broadly see relugolix fitting in, in terms of the ADT landscape for prostate cancer, can you maybe just comment on what your early market research is suggesting where it could potentially fit in?

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

Thank you, Paul. I will ask Adele to comment on the -- on your question.

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

Yes. In terms of Europe, we haven't done an extensive amount, but how physicians prescribe and maybe Juan Camilo could just add, but we see patients with advanced prostate cancer and the incorporation of ADT in a similar manner. And just as we would expect in the U.S., we have our goal of ORGOVYX becoming the new standard of care for ADT. We would hope to see that in Europe. But I'll ask Juan if you -- Juan Camilo if he wants to comment on prescribing because it's pretty parallel.

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

Yes. Thank you, Adele. I think you're right. It's pretty parallel to the U.S. Agonists are the primary form of ADT use there. With the physicians that we've spoken in Europe, there is a high enthusiasm for the

antagonists being now available in a way that is -- well, not available, but could potentially be available for an oral route, and they look forward to seeing it. So I don't think it's very different than what we see in the U.S.

Operator

And our next question, coming from the line of Mohit Bansal with Citi.

Mohit Bansal, Citigroup Inc. Exchange Research - Research Analyst

Great, thanks for taking my question and congrats on all the progress. Maybe a couple of questions. So one question on the cadence of revenue uptake going forward, it sounds like you are saying that, I mean you're creating the awareness and obviously there is probably more towards the back half of the year as you get into some of those Medicare plans and maybe more to come in 2022. Am I reading it right? And to that end, I mean consensus seems to be assuming about $50 million in 2021 calendar year, does this seem reasonable to you considering all that?

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

Well, I, I'm not sure I heard the entire question, there was a little breakup there. But let me just speak to, we're not in a position to provide revenue guidance at this point, we need a few more quarters, I think to get a sense of the trajectory that we are seeing. What we can say is that we are very pleased that we already have 30% of commercial plans that are providing coverage prior to their formulary decisions. And so we feel very comfortable that, that's a great statement in terms of how payers are viewing the therapeutic area and the role ORGOVYX can play. We anticipate that we will have more commercial decisions not only this quarter but leading into second quarter. So our ability to monetize the demand trajectory that we're seeing looks very promising. And then as you mentioned in terms of Part D plans, I think Adele mentioned that we expect that some of those decisions will begin happening we anticipate this year. But much of that coverage will actually take place at the beginning of next year. So, that's when we would see more monetization of that patient volume will be more substantial as we get into the beginning of 2022. So I hope that provides clarity on what you're looking for there, Mohit.

Mohit Bansal, Citigroup Inc. Exchange Research - Research Analyst

No, this is very, very helpful. And maybe one big-picture question. Now that cash is not an issue for you, plus, I mean, the Pfizer option, you could have more cash coming in. How are you thinking about growing beyond relugolix? And would that be something internal in terms of building your pipeline? I'm quite intrigued by the R&D comment that R&D would probably be stable for a few quarters. So just thinking about the future, 4 to 5 years down the line, how you are thinking about using this cash, utilizing this cash to build a company for the future.

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

Yes. Well, I'll make some intro comments, and then I'll turn it over to Frank here. But I think from a big-picture perspective, we have 2 large corporate priorities this year. The first is execution. We will

execute on our launches. We will work diligently to make sure that we get our therapies in the hands of patients. And part of that execution is also our regulatory filings and seeing those through.

But you've touched on the second large pillar of our strategy this year, which is really building a sustainable growth for many years to come, and that has to do with really building out our pipeline. I think our organization has demonstrated that we are an outstanding clinical development organization, and we want to leverage those strengths to really make sure that we are building our pipeline. So when we talk about the cash, the areas of focus will be, first of all, partnering with Pfizer on building out the relugolix franchise because we see additional opportunities there in women's health and in cancer and oncology. And so that will be one of the key areas of priority, and we've already made significant progress with Pfizer in the discussions around the prioritization there.

Second, in terms of building our pipeline, of course, we have MVT-602. And we are assessing what the different applications of that therapy could be and will come back at a future date with kind of prioritization of how we see any potential development there.

And then third is really the business development efforts. As you can imagine, we would stay closer to home in terms of our focus being women's health as well as oncology. Those would be the areas of prioritization in building out our pipeline. So those would be kind of the strategic direction.

And I'll turn it over to Frank, if you want to add any further color on how we might allocate that and making sure that we -- as we look at business development, we're really looking towards the right valuations.

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

Maybe just to highlight again the comment I made about sort of the directional guidance where we expect R&D expenses to grow. As you said, Mohit, we expect it to be constant over the next few quarters. Keep in mind, I mean, R&D expense overall has come down quite substantially, about $20 million from the same quarter a year ago. But we expect it now to be about constant because, as Dave said, we have this proven development engine, and we want to keep that engine humming. And in the first instance, we are not doing this with some life cycle management opportunities. You heard the first example of that with the SERENE study that we plan to initiate, and there are likely others to follow. And then beyond that, of course, we are now evaluating other opportunities to bring in assets that extend the Myovant pipeline beyond the relugolix franchise.

Operator

And our next question, coming from the line of Ami Fadia with Leerink.

Ami Fadia, SVB Leerink LLC, Research Division - MD of Biopharma & Generics and Senior Analyst

Firstly, just on the commercial front. Maybe a question for Adele. Can you talk about how your and the Pfizer sales force is sort of coordinating on sort of splitting up the various territories, et cetera? And you kind of talked about 10 -- sorry, 20 key accounts. Can you help us understand how much the 20 -- top 20 accounts that you're focusing on accounts for the total addressable market here?

And then secondly, I had a question on just sort of commercial coverage. What is your anticipation with regards to any type of prior authorization that may be required, even on the commercial side or Medicare side, in order to get relugolix?

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

Adele?

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

We're -- just on the commercial coverage with prior authorizations, we are not seeing any issues in that when they're -- when the -- if the plan requires a prior auth, it usually just to ensure the patient is actually according to label. So it's been very administrative to date. It's early days on that, but I just want to signal that we're not seeing any challenges as it relates to the offices who need any support with prior authorizations. We're in there. We're helping with them, and that's going extremely smoothly.

As it relates to Pfizer, as I mentioned, there's great coordination. So the way to think about it is that our field representatives, our 100 field reps, as well as their 100-plus reps are working together. They're collaborating on the highest priority positions. These are the physicians that are our top deciles. They're working most closely across those doctors. And as I said, we've had very good, meaningful interactions with the top accounts. These are the high- priority accounts. They could be academic centers or mostly the large urology group practices, oncology practices, multi-specialty disciplines, these are the ones that are generating a large share of the prescriptions. Mostly they have in- office dispensing, and those are the accounts that we're really focused on. Some of them are volume, and some of them are about influence, especially those large academic centers. I could rattle off to you, but those are the ones that you would know the big brand new ones that we're really focused on.

Ami Fadia, SVB Leerink LLC, Research Division - MD of Biopharma & Generics and Senior Analyst

I guess my question is -- sorry, I'm hearing some feedback here. But the -- is it that highly concentrated in terms of the market that the top 20 are extremely influential or carry a fair amount of prescription volume?

Adele M. Gulfo, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

They are a combination of very influential as well as they're the ones that are having a lot of volume flow through them.

Operator

And that's all the time we have for questions today. I would now like to turn the call back over to our speakers for closing remarks.

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

Thank you, Olivia. Our journey to commercialization is just beginning, and it's built on a strong foundation from the efforts of last year. In addition, we now have more resources than ever to look towards product development and pipeline expansion. So 2021 is certain to be a very exciting year for Myovant, and I'm confident in our ability to deliver on our purpose of redefining care for patients.

So thank you for joining us today, and I look forward to keeping you updated on our progress.

Operator

Ladies and gentlemen, this concludes Myovant Sciences Third Quarter of Fiscal Year 2020 Earnings Conference Call. Thank you for your participation. You may now disconnect.

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