EDITED TRANSCRIPT

MYOV – Q2 2020 Myovant Sciences, Inc. Earnings Call

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

CORPORATE PARTICIPANTS

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Lynn Seely; Myovant Sciences; CEO

Adele Gulfo; Myovant Sciences; Interim Chief Commercial Officer

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Jason Butler; JMP Securities LLC; Analyst

Ami Fadia; SVB Leerink; Analyst

James Shin; Citigroup Inc.; Analyst

Eric Joseph; JPMorgan Chase & Co.; Analyst

Brian Skorney; Robert W. Baird & Co.; Analyst

Phil Nadeau; Cowen and Company, LLC; Analyst

Paul Choi; Goldman Sachs Group Inc.; Analyst

PRESENTATION

Operator

Good day, everyone and welcome to Myovant Sciences Second Fiscal Quarter 2020 Earnings Conference Call. Today's call is being recorded.

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

Ryan Crowe – *Myovant Sciences, Inc. – VP of IR*

Thank you, Operator. Good morning and thanks for joining us today for a general business update and to review Myovant's second fiscal quarter 2020 financial results. Joining me for today's call are Dr. Lynn Seely, 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 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 latest 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 Dr. Lynn Seely, Myovant's Chief Executive Officer. Lynn?

Lynn Seely – *Myovant Sciences, Inc. – CEO*

Thank you, Ryan, and good morning everyone.

Today we'll review Myovant's progress to-date and more importantly, where we are headed as we approach our first commercial launches. At Myovant, we aspire to redefine care for women and for men through purpose-driven science, empowering medicine, and transformative advocacy. Our lead investigational drug candidate is relugolix, a small molecule oral GnRH receptor antagonist which is being evaluated as a one pill once a day treatment option for women with uterine fibroids or endometriosis and for men with advanced prostate cancer.

We have developed two distinct formulations for relugolix which will be branded separately if approved. First, we have a relugolix combination tablet for our women's health indication. We expect to have a single dose and one brand name for both uterine fibroids and for endometriosis. For men with advanced prostate cancer, we have a once-daily monotherapy tablet containing a higher dose of relugolix.

Since our founding in 2016, we have conducted five large multinational Phase 3 clinical trials, each of which has been robustly positive, forming the basis for three new drug applications. For relugolix combination therapy, we have conducted the LIBERTY and SPIRIT programs. The LIBERTY program in women with uterine fibroids consists of two positive Phase 3 six months studies, a completed long-term extension study, and a one-year randomized withdrawal study which is ongoing. The SPIRIT endometriosis program consists of two positive Phase 3 studies and a long-term extension study which is ongoing. We have also conducted a one-year prospective observational bone density study in untreated women with uterine fibroids and endometriosis.

For men, with advanced prostate cancer, we're developing relugolix monotherapy, we have successfully completed our Phase 3 HERO study designed for global regulatory filings. We have also a second therapeutic candidate underdevelopment for women with infertility. MVT-602 is a novel oligopeptide kisspeptin-1 receptor agonist that is completed Phase 2a clinical study.

2020 has been a pivotal year for Myovant. In uterine fibroids, our NDA was accepted for review and given an FDA target action date of June 1, 2021. We also submitted our marketing authorization application to the European Medicines Agency in March 2020. Efficacy and safety data from our long-term extension study evaluating women with heavy menstrual bleeding and uterine fibroids were presented during a prizewinning oral presentation at the American Society for Reproductive Medicine Meeting in October. In the study, 88% of women on relugolix combination therapy achieved the responder criteria for reduction in menstrual blood loss at one year, and on average women experienced a 90% reduction in menstrual blood loss from baseline.

Data from the LIBERTY program depicted in orange demonstrated preservation of bone density in women treated with relugolix combination therapy over one year. Data from a Natural History Observational study, consisting of 262 women with uterine fibroids is shown in green. Women in the Natural History study were age matched and enrolled concurrently at the same site as women enrolled in our LIBERTY studies, but did not receive GnRH treatment.

This is the first longitudinal dataset evaluating bone mineral density in premenopausal women with uterine fibroids. As you can see, changes in density over one year in women with uterine fibroids treated with relugolix combination therapy are consistent with those of untreated women. We believe

that relugolix combination tablet, if approved, has the potential to be a best-in-class medical therapy for the millions of symptomatic women with uterine fibroids.

We also have presented the efficacy and safety data from our two positive Phase 3 SPIRIT clinical studies in women with moderate to severe pain associated with endometriosis in October. This oral presentation was selected as the best clinical paper in endometriosis at the ASRM 2020 Annual Meeting. Data from the replicate Phase 3 SPIRIT studies evaluating women with moderate to severe endometriosis are presented in the orange columns at this slide. Approximately 75% of women responded to relugolix combinations with a clinically meaningful reduction in dysmenorrhea, or pain during their period. And also a significant reduction in dyspareunia or painful intercourse, a particularly important finding is dyspareunia is a very common and concerning symptom in women with endometriosis.

These benefits were achieved with minimal tolerability issues, hot flashes, and bone density loss. Comparing data for different studies must always be done with caution, but especially in this case in different assessment measures for used. However, as you can see from the data in this slide, we believe 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.

We believe relugolix combination tablet, a one pill once-daily treatment for endometriosis, if approved, is poised to have a differentiated profile from other approved endometriosis treatments.

Our NDA for advanced prostate cancer was granted priority review and has an FDA target action date of December 20, 2020. The Phase 3 data from the Global HERO study in men with advanced prostate cancer were presented at the American Society of Clinical Oncology Meeting and simultaneously published in the New England Journal of Medicine earlier this year.

On the business development side, we have also been quite active in 2020. In March, we entered into a license agreement with Gedeon Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in certain international markets including Europe and Latin America.

In August, we entered into a commercial collaboration agreement with Sunovion Pharmaceuticals, a subsidiary of Sumitomo Dainippon Pharma, a majority shareholder, to support the planned U.S. commercialization of relugolix including logistics, trade and retail distribution support, as well as contracting and other market access services. We also obtained an additional $200 million, low interest five-year term loan commitment from Sumitomo Dainippon Pharma. With this latest commitment, Sumitomo Dainippon's total financing support for Myovant has reached $600 million, providing us with the financial flexibility to appropriately resource our potential upcoming launches, but without right to relugolix itself.

In short, we have been busy in 2020. And the fact that we were able to achieve all of these milestones despite the challenges posed by the COVID-19 pandemic is truly a testament to the dedication of all of the Myovant employees and our partners around the world.

The progress we've made so far in 2020 has positioned the next 12 months to be a truly transformational period for Myovant as we prepare for the potential launches of two products, ultimately expected in three indications. For our uterine fibroids program, we look forward to the FDA target action date of our NDA on June 1, 2021. We also anticipate a decision next year from the European Commission for a Marketing Authorization Application. Finally, we expect to report top-line results from our randomized withdrawal study in Q1 2021.

For endometriosis, we plan to announce one year results from our SPIRIT long-term extension study in the first quarter of 2021. The results of this study, in addition to the positive Phase 3 SPIRIT 1 and 2 studies are expected to form the basis of regulatory filings in the U.S. and EU next year.

Finally, we look forward to the FDA decision next month for relugolix in advanced prostate cancer and if approved launching in the U.S. in early 2021. We also expect to submit our MAA for advanced prostate cancer to European Medicines Agency in the first half of 2021.

As I think about the next 12 months, strong commercial execution is clearly Myovant's highest priority. And I couldn't be more pleased with the progress our commercial team has made towards this goal. Commercial execution starts with our potential launch of the prostate cancer indications in early 2021 an opportunity Adele will now discuss. Adele?

Adele Gulfo – ***Myovant Sciences – Interim Chief Commercial Officer***

Thank you, Lynn.

Our long-term goal for relugolix is to establish it as the frontline medical therapy for men with advanced prostate cancer. We believe relugolix could become the foundational Androgen Deprivation Therapy for use alone and in combination with other prostate cancer medicines. The commercial team has been working hard developing a comprehensive launch strategy that, following approval, will enable us to rapidly and efficiently deliver relugolix to urologists, medical oncologists, and their patients.

There are 3 million men with prostate cancer in the U.S. Of those approximately 300,000 patients are projected to receive Androgen Deprivation Therapy or ADT in 2021 with the majority remaining on therapy for several years. Prostate cancer is the second most common cancer in men in the U.S. Notably, more men with prostate cancer will die of cardiovascular disease rather than a prostate cancer itself. This is particularly important when we consider today's treatment options for advanced prostate cancer.

Now a few words on the current ADT market landscape. Testosterone suppression is the first line medical therapy used to treat advanced prostate cancer and injectable depot agonists such as leuprolide are the current standard of care. However, agonist injections must be given in the clinic and have limitations based on their mechanism of action. Agonist results in an initial surge in testosterone that can exacerbate clinical symptoms of prostate cancer. In addition, it can take PSA weeks to decline. Finally, testosterone can take months to recover after agonist injections are discontinued due to their long-acting depot formulations. If approved, relugolix would be the first and only GnRH antagonist for advanced prostate cancer.

In addition to the convenience of being a once-daily tablet, the HERO study demonstrated that 97% of men had sustained testosterone suppression to the target range and that relugolix suppressed testosterone faster than leuprolide and did so without the testosterone surge and clinical flare.

Additionally, a higher proportion of men in the relugolix group achieved a PSA response by day 15 compared with those in the leuprolide group. Discontinuation of relugolix treatment also reversed testosterone suppression faster than after leuprolide discontinuation. In the HERO study, 90 days following treatment discontinuation over half of men in the relugolix group achieved normal testosterone levels, compared to 3% of men in the leuprolide group.

Finally, in a Safety Analysis from the HERO study, men in the relugolix group had a lower incidence of major adverse cardiovascular events compared to men in the leuprolide group.

Given the extensive market research conducted to-date with hundreds of patients, physicians and payers, I'm confident that relugolix, if approved, will have a significant role in the treatment of prostate cancer.

From a patient standpoint, our market research indicates that men want a pill, not an injection. In a survey of more than 500 men with prostate cancer, 62% were dissatisfied with the injection of leuprolide; men rated “once-daily oral” as the most attractive attribute of relugolix. Approximately 30% of men with prostate cancer have diagnosed cardiovascular disease and cardiovascular risk factors are extremely common in men with prostate cancer.

In fact, nine out of 10 men enrolled in the HERO study had at least one risk factor for cardiovascular disease, whether it be age, hyperlipidemia, hypertension, diabetes, smoking or obesity, to name a few.

From a physician standpoint, we have heard very consistent feedback in our market research and from ad boards. For example, in a recent survey of 407 urologists and medical oncologists, 60% indicated they're “very likely” or “extremely likely” to prescribe relugolix based on its clinical profile.

We've also found that physicians understand most of their patients are already at increased risk for cardiovascular disease. Finally, payer research and ad boards suggests that payers readily understand the clinical benefits of relugolix both in terms of efficacy, and safety. They are particularly impressed by an economic analysis presented at the AMCP Nexus 2020 Meeting, indicating that the number needed to treat with relugolix to prevent one major adverse cardiovascular event was 31 versus patients receiving leuprolide injections.

Our first launch priority following approval will be to leverage our very experienced 100 person salesforce to educate urologists and medical oncologists and other prescribers on the safety and efficacy profile of relugolix according to the approved label. We believe that based on this profile established by the Phase 3 HERO study, relugolix has the potential to become the new standard of care for men with advanced prostate cancer.

Initially, our detailing efforts will focus on high volume prescribers. There were approximately 10,000 physicians in the U.S. that write most of the ADT prescriptions with a majority belonging to either multi-specialty practices, or large urology group practices, also known as LUGPAs. Approximately 60% of multi-specialty clinics and LUGPAs have in-office dispensing capability and that proportion continues to grow year-over-year.

It is essential that we establish broad patient access, our second priority. Here we're taking a very deliberate approach focusing on pricing and contracting, distribution and fulfillment, payer coverage and patient support. Based on our pre-approval information exchange meetings, payer ad boards, and payer research, we're confident in our ability to gain coverage for commercial and Part D patients with key commercial PBM coverage decisions starting as early as the first quarter of 2021 and continuing to increase throughout the year.

Our third launch priority is to raise awareness among patients regarding their prostate cancer treatment options. We have identified through research a patient segment that is very engaged in their disease and actively seeking education. The clinical profile and oral administration, particularly in the time of COVID-19 is very attractive to these patients.

In summary, we're approaching this launch from a position of strength and look forward to delivering relugolix to patients early in the New Year.

With that, I will now turn the call over to Frank to discuss our second quarter financial results. Frank?

Frank Karbe – *Myovant Sciences, Inc. – President & CFO*

Thank you, Adele and good morning everyone.

I'll 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 September 30 of this year represent our second fiscal quarter of 2020.

R&D expenses in the quarter were $40.5 million compared to $50.8 million for the comparable prior-year period. The decrease in R&D expenses reflects the completion and continued wind down of Myovant's Phase 3 programs, partially offset primarily by increased expenses associated with a build-out of Myovant's Medical Affairs Organization in preparation for our upcoming potential commercial launches of relugolix.

G&A expenses in the quarter were $31.3 million compared to $16.6 million for the comparable prior-year period. The increase was primarily due to increased spending on commercial readiness activities, personnel-related costs, and other general overhead expenses as we continue to prepare for the potential commercial launches.

Total operating expenses for the quarter was $71.8 million, of which approximately $7 million were stock-based compensation.

We also incurred a $7 million gain on foreign currency during the quarter that was recorded in our other income line.

Myovant generated a net loss of $67.1 million in the second quarter of 2020 compared to $70.6 million for the comparable prior-year period. On a per share basis, our net loss was $0.75 in second quarter 2020 and $0.79 in second quarter 2019.

Looking ahead, we expect R&D expenses over the next several quarters to be at similar levels to our second quarter 2020 R&D expense, as declining spend on clinical programs that are winding down is expected to be offset by incremental spend on certain lifecycle management activities and potential new investments in our pipeline. In upcoming quarters, where regulatory filing expenses are incurred, there could be modest deviations from this trend.

G&A expenses are expected to increase as we continue to build-out our commercial capabilities, particularly driven by the hiring of our oncology and women's health sales forces. The hiring of our prostate cancer sales force is well underway and expected to be completed in December of this year. The majority of the hiring of our women's health sales force is expected to occur in calendar second quarter of next year, as close as possible to the FDA's uterine fibroid target action date of June 1, 2021.

Let me wrap-up by commenting on our cash position. We ended the quarter with $111 million of cash, cash equivalents, and marketable securities on our balance sheet. Note that we currently fund our operations through a low cost loan facility that Sumitomo Dainippon Pharma, our majority shareholder extended to us. In totality, the loan commitments, including the $200 million committed in August 2020 amount to $600 million, of which a portion has already been used. In order to minimize our interest expense we draw from this facility on a quarterly basis to fund our near-term operations. The remaining borrowing capacity as of September 30, including the new $200 million commitment amounts to approximately $350 million. Therefore, in total between our cash and committed financing from

Sumitomo Dainippon Pharma, we had approximately $460 million available to deploy as of September 30.

Lastly, with our first drug launch anticipated in early 2021, and the second one potentially by the middle of next year, both of which are targeting significant commercial opportunities, we expect our future cash burn to be partially offset as revenue increases.

Now I'll turn it back to Lynn for some closing remarks.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thank you, Frank and Adele.

In summary, this is an exciting time for Myovant as we approach potential U.S. launches of relugolix in the prostate cancer indication in early 2021, and the relugolix combination tablet in the uterine fibroids indication in mid-2021.

Our focus is squarely on successfully executing these launches, and bringing these important therapeutic options to patients. We have multiple upcoming clinical data and regulatory milestones in the next 12 months, and we're in a strong financial position with approximately $460 million of cash and committed financing to appropriately resource potential upcoming product launches.

Finally, we have full U.S. rights for the relugolix franchise, providing us with maximum optionality for business development opportunity. I'm extremely proud of all the work done by the Myovant team to get to this point, and I look forward to what is ahead for Myovant. Thank you for your attention.

I'll now turn it over to Ryan to begin the Q&A session.

Ryan Crowe – Myovant Sciences, Inc. – VP of IR

Thank you, Lynn.

One note before we open it up for questions, given our ongoing discussions with regulatory authorities, we will not be responding to any questions regarding our regulatory interactions. With that said, operator, can we now please poll for questions?

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions)

Our first question comes from Jason Butler with JMP Securities. Your line is now open.

Jason Butler; JMP Securities LLC; Analyst

Hi, thanks for taking the questions and congrats on the progress. Just a couple on the prostate cancer launch. First, you mentioned the 10,000 high volume prescribers, can you give us any more details about what proportion of those docs you'll be initially focused on and on what the split might be

between those multi-spec centers versus other docs and then can you just give us a breakdown of the market in terms of reimbursement between commercial and Part D coverage? Thanks.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thanks, Jason. Adele, why don't you take those questions?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Sure, if I heard you correctly. The first question was with regard to the 10,000 high volume prescribers, we expect that a very substantial piece of our business will come from those multi-specialty clinics, whether they be urology clinics, medical oncology, or the LUGPAs as I mentioned in the call, because that's who is doing the large majority of prescribing the ADTs today. And what was your second question?

Jason Butler; JMP Securities LLC; Analyst

Just how the market breaks out between commercial and Part D coverage?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

It's approximately, I would say 50:50, right, 50% of our business, we expect to be commercial patients, they'll be commercially insured. The other half, patients out there are let's assume they're Medicare. They're on Medicare plans. From that proportion of Medicare patients, it's important to note that about half of those will have plans that enable them to have a more affordable copay. They may either be on low income subsidies; they may have employer waiver group plans. So we feel there's a nice chunk or 25% of that other piece of Medicare that will have a plan that will enable them to have affordable access.

Jason Butler; JMP Securities LLC; Analyst

Okay, great. Thanks for taking the questions.

Lynn Seely – Myovant Sciences, Inc. – CEO

Jimmy, next question, please.

Operator

Thank you. Our next question comes from Ami Fadia with SVB Leerink. Your line is now open.

Ami Fadia; SVB Leerink; Analyst

Hi, good morning. Thanks for the question. I have a couple. Firstly, just with regards to your regulatory review for prostate cancer. Can you talk about any progress with regards to a pre-approval inspection

with the FDA and if you've begun any sort of discussions around labeling at this point. Secondly, can you try to narrow down kind of your pricing philosophy for us, both in prostate cancer as well as in women's health? In prostate cancer on one hand, we have Lupron, if you can give us some color on where the net price of Lupron stands. And then of course, Xtandi in tens and thousands of dollars, so where would you think about pricing relugolix there. And then I have one more question, but let me pause here.

Lynn Seely – Myovant Sciences, Inc. – CEO

Well, sure Ami thanks for the questions. Let me begin with your question about regulatory approval. I think we stated very clearly during this conference call that we're on track for the FDA approval action date, the PDUFA date, December 20, 2020. So we're pleased with the progress that we've made. But obviously, we're not going to comment further on ongoing regulatory interactions.

I think with respect to price, I appreciate the question. We believe pricing of new medicine should be based on the value that they bring to patients. In our case with relugolix based upon the efficacy and safety profile that has been presented in our Phase 3 study, published in the New England Journal. And I think, based on the value that relugolix brings to patients, and particularly the lower incidence of cardiovascular events, compared with leuprolide, we expect to price relugolix at a premium to the wholesale acquisition cost of Lupron.

Ami Fadia; SVB Leerink; Analyst

Got it, okay. That's helpful. Can you, at this point quantify how much of a premium or is it too early to give that level of color?

Lynn Seely – Myovant Sciences, Inc. – CEO

Yes, I think we'll be talking more about price around the time of approval. Thank you.

Ami Fadia; SVB Leerink; Analyst

Okay. If I could just ask a question to Adele, just with regards to the launch ramp. Where do you see relugolix getting the initial adoption, whether and in terms of which practices might adopt it first, and also patients with what stage of disease might be the first to get treated with relugolix and then also put in context for us the initial launch ramp as we think about the time it takes to get coverage from payers and then get the product sort of prescribed and then, patient getting on the product? Thanks.

Lynn Seely – Myovant Sciences, Inc. – CEO

Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes, thanks. Thanks for the question, Ami. A lot, a lot packed into that. So first, I would say that, I want to reiterate physicians are very excited about the product profile. As I said, there is -- in our most recent

survey over 60%, were extremely likely or very likely to prescribe relugolix based on the clinical profile. So we have that parameter that we're excited.

There's also very high awareness among physicians, early at this stage pre-launche is a little bit atypical, and it could be because of our New England Journal publication. So those two things from the physician. We also know that patients in a time that patients men truly prefer a once-daily oral versus an injection. So we think there will be interest from the patient community as well.

And then as I mentioned, our 100 person salesforce, we're hiring very experienced rep, reps who have not only knowledge of the urology marketplace, and medical oncology, but who are very adept at selling in this virtual environment. So we've screened and done a very rigorous job in getting sales representatives who have the therapeutic area expertise as well as the technology expertise as well. So when we factor all those together, we feel that we will have a -- we're on track for a very comfortable ramp-up with the physician community as well as the patients coming together. I'll leave it at that.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thanks, Adele. And I might just add to that that we all know that coverage takes time. And so we expect that the revenue ramp will reflect that time that it's going to take to get coverage. And yes, there is a COVID pandemic going on which we have been preparing to launch within. So that's no surprise but is important to consider. I will say that that's offset by the fact that we're going to be offering an oral option for men, where the current standard of care requires them to go into the clinic for an injection. So again, we're as prepared to launch into this COVID pandemic as we can be.

Ami Fadia; SVB Leerink; Analyst

Thank you.

Lynn Seely – Myovant Sciences, Inc. – CEO

Operator, next question?

Operator

Thank you. Our next question comes from Mohit Bansal with Citi. Your line is now open.

James Shin; Citigroup Inc.; Analyst

Hey, good morning. This is James on for Mohit. I had a question for Adele, PDUFA for prostate cancer is right around the corner and given more so in the pandemic, like you guys mentioned, can you tell us what you're seeing on the ground from the private urology offices?

Lynn Seely – Myovant Sciences, Inc. – CEO

Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

From the private urology offices, can you just be a little bit more clear on that, what we're seeing?

James Shin; Citigroup Inc.; Analyst

Well, I guess like, are they open to patients right now? Are they still operating at full capacity, and they actually it doesn't even have to be private urology offices. Let's just make it broader urology offices are these centers widely open, are these sort of at 75% capacity? What are you seeing there so far?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

They're growing. I would say it's growing from where it was a couple of months ago. Now, the oncologists have been pretty stable. And now the urology community is also picking back up. So there's the access to sales representatives is not the same in terms of in-person, but there is access from a virtual perspective.

And what we're seeing is that doctors are very interested in the product profile of relugolix. And whenever you have a product like this that we feel as we said could actually represent a new standard of care. They want to hear about it. So we're having, we've had no trouble securing physicians to attend ad boards, to go to meetings, to answer questions that we have as we're doing our diligence. So we're pretty confident that the urology practices and the oncology practices will be open to hearing from our representatives because we represent a really important product for them.

James Shin; Citigroup Inc.; Analyst

Got it. And then if I may, one more on, I know you guys aren't going to give too much status updates from the filing itself. But could you share if the bone mineral density for uterine fibroids was submitted to the FDA, at least?

Lynn Seely – Myovant Sciences, Inc. – CEO

Juan Camilo?

Juan Camilo Arjona; Myovant Sciences; Chief Medical Officer

Yes, thank you. I can confirm that in our initial NDA, we included the one-year data for uterine fibroids, so bone mineral density as well as the data from our Natural History study one-year for patients with uterine fibroids.

James Shin; Citigroup Inc.; Analyst

Got it, appreciate it. That's it from my end.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thank you. Next question, Jimmy?

Operator

Thank you. Our next question comes from Eric Joseph with JP Morgan. Your line is now open.

Eric Joseph; JPMorgan Chase & Co.; Analyst

Hi, good morning. Thanks for taking the questions. I guess, first is thinking about product, initial product uptake in prostate cancer. Is there a meaningful switch opportunity here and then currently on ADT, either with Lupron or other Depot therapy? And then secondly, thanks for highlighting the split between -- the coverage split between Part D and commercial. Is there -- should we anticipate a differing rate in adoption for coverage adoption in those different segments? Thanks.

Lynn Seely – Myovant Sciences, Inc. – CEO

Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes, so I'll start with the rate of coverage adoption. Yes, because of the Medicare bid cycle, we would expect to have information regarding our formulary coverage for Medicare by about June of next year, realizing that there are also medical exception processes for patients that are on Medicare. So that will come, that's on the Medicare front. On the commercial front, as I said, during the prepared remarks, we would expect to start seeing coverage as early as the first quarter of next year.

Lynn Seely – Myovant Sciences, Inc. – CEO

And then I think in terms of your second question about the opportunity for patients with relugolix again, we believe relugolix is appropriate for a broad spectrum of men with advanced prostate cancer and that will include both treatment naive patients as well as patients who are currently on therapy.

Eric Joseph; JPMorgan Chase & Co.; Analyst

Okay, great. Thanks for taking the question. Just one follow-up if I could actually. Maybe I can get you to speculate on sort of the importance of detailing to consumers and directing treatment decisions. I guess, to what extent longer-term is DTC part of the launch strategy for relugolix in prostate cancer, thanks.

Lynn Seely – Myovant Sciences, Inc. – CEO

Sure. Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes, thanks again for the question. What I would say is, most importantly, we have to ensure that our physicians are very well educated on the product profile and they understand it. So the last thing we want to do is drive patients into an office where the physician is not adequately prepared. With that said, we do appreciate from our market research that there is a very clear and identifiable pretty large segment of men who're very actively engaged in their disease and are constantly seeking awareness and education and wanting to know more about their treatment options.

So at the appropriate time, we'll ensure that we do the adequate programs to reach these patients and their caregivers, because we know a lot of these men have daughters who are their caregivers and who also are very actively seeking information.

However, when you say DTC that conjures up a lot of things, there's big broadcast TV, television. That's not what we think is needed for this patient population. There are very efficient ways in which we can reach this segment. And those are the plans that we have in place right now.

Eric Joseph; JPMorgan Chase & Co.; Analyst

Okay, got it. That's helpful. Thanks for taking the questions.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thanks, Eric. Next question, please.

Operator

Thank you. Our next question comes from Brian Skorney with Baird. Your line is now open.

Brian Skorney; Robert W. Baird & Co.; Analyst

Hey, good morning. Thank you for taking the questions. Just a couple on the impending prostate cancer launch, I guess when I look at Lupron, it's kind of difficult to track true new starts. And I was wondering if you guys had any better data in terms of annual new starts to castration therapy in the prostate cancer segment? And, if you have any sort of indication in terms of how much that dipped through the pandemic, and should we be expecting sort of a rebound or even a warehouse effect maybe once we get through the next couple of months? And then just in terms of durability, what is your sort of expectations are in terms of how long patients will be on drug on average? Thank you.

Lynn Seely – Myovant Sciences, Inc. – CEO

Sure. Adele?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Yes. So let me just the first question around data. What I would say is, from the research, and as well as the big secondary data polls that we have indicated about 100,000 patients, new starts coming on ADT. As I said in prepared remarks, there's approximately 300,000 that we're estimating will be on

therapy in 2021 with approximately 100,000 new starts coming on year-over-year. That's what we have. And that's what we've been forecasting our patients around those numbers.

With regard to I'm sorry, I forgot. I was making sure I had the -- your information on the data question. What was your second question?

Brian Skorney; Robert W. Baird & Co.; Analyst

Sure. It was just in terms of any kind of data in terms of any dips and delays on starts due to the pandemic? Would you expect a substantial decline given the increase in patients? And would we maybe even expect some sort of warehouse effect, following like late 1Q, 2Q to new starts? And then separate question, what are you expecting in durability?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

For durability, we always think about this as a backbone therapy. So men will be on this for years, not months as they -- even as they continue to get other therapies. So, that's -- that's the piece on durability.

With regard to data, we haven't, here's what I would say is -- the market -- we've actually seen this market continue to grow about 5% annually. We haven't seen dips. So what I would say is that, it's a large market a 300,000 with about 5% growth year-over-year for the ADT prescriptions. And that's, I would say that's the best we can comment relative to the data that's available today.

Brian Skorney; Robert W. Baird & Co.; Analyst

Okay, thank you.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thanks, Brian. Next question, please.

Operator

Thank you. Our next question comes from Phil Nadeau with Cowen and Company. Your line is now open.

Phil Nadeau; Cowen and Company, LLC; Analyst

Good morning. Congrats on the progress. Couple of questions on prostate cancer then one on the actual rest of the pipeline. First on prostate cancer, one place physicians have thought relugolix would fit in perfectly is for those men, either on intermittent therapy or who want to be on intermittent therapy. Do you have any figures for currently the number of men who are on intermittent therapy and any idea in the trends -- of the trends in the adoption of that paradigm?

Lynn Seely – Myovant Sciences, Inc. – CEO

Sure, thanks Phil. So as we said earlier, we believe relugolix is appropriate for the broad spectrum of men with advanced prostate cancer. But it is absolutely true that the profile of relugolix which with the recovery after discontinuation of therapy is particularly attractive to many men who have an opportunity to discontinue therapy.

And you may recall that three months after stopping relugolix, 54% of men had testosterone within the normal range versus 3% of men on leuprolide, 90 days after their last injection. And so this can be particularly attractive to men who may have the opportunity for intermittent therapy, which is basically drug holidays after their PSA has been controlled. And we estimate today about 30% to 35% of men are receiving intermittent therapy and that is something that could grow over time.

Phil Nadeau; Cowen and Company, LLC; Analyst

Perfect, that's very helpful. Then second on the CV safety benefit, do you have any plans to follow-up on the signal that you saw in the study in particular, maybe do a specific CV safety study similar to the one that's completing for degarelix now?

Lynn Seely – Myovant Sciences, Inc. – CEO

Yes, it's a great question. And that's absolutely something we're considering and looking at the feasibility, but we've not made any decisions about that at this time.

Phil Nadeau; Cowen and Company, LLC; Analyst

Great. And then last question is actually just on MVT-602. What are your most recent plans for advancing that? Do you have any plans in 2021 to start a next study?

Lynn Seely – Myovant Sciences, Inc. – CEO

Yes. We're very excited about MVT-602 as you know; it's a novel kisspeptin agonist that we have been developing for female infertility. At this point in time, we're clearly and squarely focused on our launches. But we expect that you'll be hearing more about MVT-602 in 2021.

Phil Nadeau; Cowen and Company, LLC; Analyst

Great. Thanks for taking my questions.

Lynn Seely – Myovant Sciences, Inc. – CEO

Operator, next question?

Operator

Thank you. And our next question comes from Paul Choi with Goldman Sachs. Your line is now open.

Paul Choi; Goldman Sachs Group Inc.; Analyst

Thank you. Good morning and congrats on all the progress. Either for Lynn or for Adele, can you maybe just talk about what is the current frequency of utilization of GnRH products between medical oncologists and the urologists in LUGPAs and how do you think about maybe threading the needle, so you don't isolate one population there in terms of promoting your prostate cancer launch?

Lynn Seely – Myovant Sciences, Inc. – CEO

Sure, thanks, Paul. Adele do you want to start?

Adele Gulfo – Myovant Sciences – Interim Chief Commercial Officer

Sure. We believe that there's perhaps a slightly higher rate of our high volumes -- high volume prescribers that are coming from the urology office. But the medical oncologists are also a very important target audience for us. And they're also high prescribers for this disease. We see our plans are to adequately educate both of those populations and our sales reps are going to be in there targeting both. And I don't see that we'd be distancing one from the other. They're both very important prescribers for men with advanced prostate cancer.

Paul Choi; Goldman Sachs Group Inc.; Analyst

Thanks, Adele. And then maybe as a follow-up just on the -- with regard to the HERO survival data, you referenced earlier, your prior market research suggesting that, 60% would be willing -- physicians would be willing to prescribe it, can you maybe just provide any updated feedback that you may have received from physicians post the survival data, and just how they're thinking of about utilization, and any changes there? Thank you very much for taking our questions.

Lynn Seely – Myovant Sciences, Inc. – CEO

Thank you. I can just comment on the castration resistance free survival data that was presented recently and demonstrated outcomes similarly between relugolix and leuprolide. While we didn't show superiority over leuprolide, the data were comparable. And I think what we found is that the physicians are actually reassured that they can get the benefits of relugolix treatment, including the lower incidence of cardiovascular events with comparable outcomes. And so we really haven't seen any differences in our research about utilization or interest. So, operator, I believe that's the last question.

Operator

I'm showing no further questions in the queue at this time.

Lynn Seely – Myovant Sciences, Inc. – CEO

Okay, thank you.

As you've just heard, let me make some closing remarks. As you've just heard, the next 12 to 18 months are expected to be truly transformational for Myovant as we look to launch two products and three indications. We remain confident in our strategy and are highly motivated by the opportunities before us in prostate cancer and in women's health. I look forward to updating you on our progress in future calls.

Thank you all for joining us today and for your continued engagement with Myovant. Stay safe and healthy.

Operator

Ladies and gentlemen, this concludes Myovant Sciences second fiscal quarter 2020 earnings call. Thank you for your participation. You may now disconnect.