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Myovant Sciences Ltd. NYSE:MYOV

Company Conference Presentation

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CEO & Director

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Chief Medical Officer

Lauren Merendino
Chief Commercial Officer

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Chief Financial & Business Officer

ANALYSTS

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Presentation

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Great. Hello, everybody, and welcome to the next session. I'm Roanna Ruiz, Senior Analyst at SVB Leerink focusing on infectious disease, endocrine and cardiovascular disorders. Today, I am very pleased to introduce the Myovant team, starting with Dave Marek, CEO of Myovant; Uneek Mehra, Chief Financial and Business Officer; Juan Camilo Arjona, Chief Medical Officer; and Lauren Merendino, Chief Commercial Officer. So welcome, everyone.

David C. Marek
CEO & Director
Thank you, Roanna.

Question and Answer

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Great. And so maybe just to kick it off for the audience, I'll start with a big picture question. So could you just give us a recap of the company and the therapy areas that you're focusing on?

David C. Marek
CEO & Director

Myovant was founded in 2016, we have about 550 highly talented and committed employees, and we're really focused on redefining care, redefining care for women and for men. And we do this through our science. We do this through our differentiated medicines. And importantly, for us, we do this through our advocacy efforts around education, around access to care, and working really to close health equity gaps.

We have completed multiple successful clinical development programs. And last year, we transitioned to a commercial-stage biotech company with 2 FDA-approved products. We now have ORGOVYX for advanced prostate cancer, and we have MYFEMBREE for the treatment of uterine fibroids. And we also extended last year our global impact with the European approval with RYEQO for uterine fibroids.

And as we think about really enabling further clinical development and our commercial success, we have several world-class partnerships, including Pfizer, who is our co-commercialization and co-development partner for both ORGOVYX and MYFEMBREE in the U.S. And we also have a great partnership with Gedeon Richter, who's commercializing RYEQO in the international markets.

So for us, and it's driven by our proven clinical development success and our commercial success as well as our strong financial position. We really aspire to become category-leading companies in both the area of women's health as well as in oncology.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Great. Super helpful. And so you did mention you have multiple launches going on in commercial products. So maybe could you give us a little bit of context of what are your goals across these different products and as they're moving forward?

David C. Marek
CEO & Director

Well, we really have 3 areas of focus when it comes to commercialization for the coming year. If we start with ORGOVYX, we need to continue to increase the breadth of prescribing that we have. We already have over 1,800 treatment centers that have utilized ORGOVYX, but we're also going to focus really on increasing the depth of prescribing. And we do that first with a focus on our clinical profile. ORGOVYX is really differentiated in that we can achieve vast testosterone suppression without testosterone spike. So that's a key clinical benefit that we have. We can have profound testosterone reduction and quick recovery. And we can do that as the first and only oral ADT therapy for advanced prostate cancer. So we'll pull through that clinical messaging, but also, we can do that on a foundation of really outstanding commercial and Medicare Part D coverage. We have 81% of commercial lives covered and 99% of Part D lives covered.

And then we're going to kick off more of our patient activation efforts for ORGOVYX in the coming year. We saw success at the beginning or through parts of last year, that will continue. So ORGOVYX is really well positioned for growth into 2022.

From MYFEMBREE and uterine fibroids, we'll also focus on really driving the breadth of prescribing. We also have significant payer coverage with 83% of commercial lives covered. So we'll pull that through

in terms of the outstanding coverage that we have. And we'll also initiate some very targeted consumer efforts for consumers with women with uterine fibroids.

And then the third key area of commercialization for us is the potential approval or the pending approval MYFEMBREE for uterine -- or excuse me, for endometriosis. And assuming we get approval from the FDA, we're very excited about the potential. You're looking at over 1 million women with endometriosis that are failed by their first-line therapy. We think that we have a particular advantage in this case -- in this therapeutic area that we will have the same brand that we have with uterine fibroids, the same 1 pill, once a day dosing. So the familiarity that gynecologists would have with MYFEMBREE and uterine fibroids over to endometriosis. And we have an outstanding clinical profile there.

So those are the 3 pillars that we have for this year. It's an exciting year of growth for Myovant and we're really looking forward to it.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Awesome. That's great. And so I think I'll just walk through each program as you talked about it. So starting with ORGOVYX in prostate cancer, can you just remind us how big do you think the opportunity is there for ORGOVYX? And how has awareness and appreciation for the ORGOVYX profile sort of changed as you've sort of gotten to the 1-year mark of your launch?

David C. Marek
CEO & Director

Certainly, Lauren, do you want to take that?

Lauren Merendino
Chief Commercial Officer

Absolutely. Thanks, Dave. So with approximately 300,000 men with advanced prostate cancer, starting or being treated with an ADT each year. About 100,000 of them are starting for the first time on an ADT. So there's a huge market We're proud of the 11,000 cumulative patients that have been treated with ORGOVYX in the first year of launch. But obviously, there's significant room for many more men to benefit from ORGOVYX, and we're motivated to help these patients and to maximize the commercial potential.

In the first year of launch, we were successful in driving awareness and building a base of prescribers. As Dave mentioned, we have over 1,800 treatment centers utilizing ORGOVYX today. And we've also established great payer coverage.

So for 2022, we're looking to leverage those wins in order to further broaden and deepen our utilization and drive further belief in our clinical profile. And as Dave mentioned, we'll be dialing up our patient engagement as well. So as we look over the longer term, we do think that there's additional opportunity to unlock some commercial potential with some incremental clinical data. And so we'll be able to share additional information on our life cycle plans in the coming months.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Got it. Super helpful. And this is a common question we've got from investors. Just curious how do you -- the potential cardiovascular benefits for ORGOVYX compared to those of Firmagon or degarelix in clinical practice?

David C. Marek
CEO & Director

Juan Camilo, would you take that?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes. Thanks, Dave, and thanks, Roanna. Of course, we don't have a head-to-head study versus the Firmagon particularly at all, but particularly in the assessment of the cardiovascular outcomes. What I can tell is both our antagonist, GnRH receptor antagonist. And the cumulative data that's been accrued over time for Firmagon. There's a big net analysis that was conducted the small Phase II study and the data from our own HERO study was the first prospective assessment of cardiovascular safety between entities and agonists have all shown a benefit for antagonists compared to agonist like leuprolide.

As you will recall from our HERO study, we demonstrated a pretty substantial difference with lower incidence of major adverse cardiovascular events versus leuprolide. and that was even more important in patients that had already had a prior event of mate. So we feel very proud of that data, and it's been very well received by the clinicians.

I think that to get to a definitive answer to the question of the difference between antagonists and agonists for the data will be required.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Yes. That's fair. And digging in a little bit more, I was curious, thinking about the prescriber segments for ORGOVYX, urologists versus oncologists. What's your sense of which one of them might be the more durable revenue stream in terms of patients staying on ORGOVYX for the long run?

David C. Marek
CEO & Director

Lauren, do you want to take that?

Lauren Merendino
Chief Commercial Officer

Yes. So hands down, the answer here is urologists. So urologists generally see a higher volume of advanced prostate cancer patients. They're the ones who usually are making the initial ADT treatment decision, and then they manage those patients for a longer period of time. And so the urologists really are a bigger business focus for us.

On the oncology side, by the time a patient sees on oncologists, they're generally in a more advanced stage of their disease. And so these patients are generally on an ADT at that point. And oncologists are looking to treat them with additional therapies, and that's really where their focus is. So they rarely focus on the choice of the ADT because the patient is already on one.

With that being said, there are, of course, some de novo patients who are diagnosed later in disease where oncologists do make that to make that choice. So this is consistent with what we're seeing with over 60% of our commercial volume for ORGOVYX coming from urologists and the remaining coming from oncologists.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Interesting. Got it. And thinking about the use of ORGOVYX sort of a tougher question, but I'm curious what you think what are the possible sticking points that might be preventing some physicians from prescribing more ORGOVYX now, either in the urologist or the oncologist side and how might you overcome those?

Lauren Merendino
Chief Commercial Officer

Yes. So the main challenge that we're facing here is habit. So they've been using injectable leuprolide for nearly 40 years. So for most of them, the entire time they've been in practice, right? So their practices, their operations, the financials of their practice have been set up for the injectable leuprolide utilization. And so we believe that ORGOVYX offers prescribers greater control over testosterone with the no

testosterone spike, the profound reduction in testosterone. And if a patient does discontinue therapy at some point, a faster recovery of testosterone.

All of that in addition to the fact that it's an oral formulation, which is preferred over injection by the majority of patients. And so we do believe we have a unique value proposition here. But we need to change the prescribing behavior and the practice economics, which takes time. And we've seen some large urology and oncology practices make that shift, and broadly adopt ORGOVYX, and we expect to continue to see this in other practices over the -- in the years ahead.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Got it. Got it. And I know you've talked about this a few times in the recent months, but I am curious to check in. So on gross to net for ORGOVYX. How should investors think about these dynamics looking ahead to 2022, and -- what -- can you just remind us what's driving the gross to net factors here?

David C. Marek
CEO & Director

Yes, Uneek, why don't you take this one?

Uneek Mehra
Chief Financial & Business Officer

Sure. Thanks, Roanna, for the question. We -- as you mentioned, we said recently that on our fiscal Q3 gross to net was in the low 40%. And we expect the gross to net to remain in the low to mid-40% for the foreseeable quarters. No, we believe that these discounts that we are paying, they are helping us do exactly what we intend to, which is to remove any potential access or practice economic disincentives to prescribe ORGOVYX because when physicians simply evaluate their options based on the clinical characteristics against what they believe is best for their patients, we think it favors ORGOVYX and is 1 of our factors that we've so far seen in our early success.

Looking forward, we are not expecting gross to net to increase significantly in the coming quarters as we saw over the course of calendar year 2021, has more rebates associated with broadening insurance coverages were paid.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Got it. That's helpful. And I think you mentioned briefly the contracts and GPOs have been in place since ORGOVYX launched, I believe, so how might physician awareness of these benefits from these contracts increase in the future? And how do you plan to help build awareness there?

David C. Marek
CEO & Director

Yes. We really -- we understood the value of the GPO contracts. And so you're correct. We did have those established from the beginning. Lauren, do you want to address how we're going to pull those through?

Lauren Merendino
Chief Commercial Officer

Absolutely. So we've been able to educate around our contracts since launch, and there is a broad awareness of our contracts and a broad utilization, especially amongst urologists.

On the oncology side, there are a number of contracts because they dispense a larger swath of products. And so that may be an area where we need to continue to build awareness. But the GPOs also educate their members on the contracts that are available and can also help that assist them in the operationalizing of dispensing orals in their practice, which is really important because that's something we're not able to do.

But we believe that the messaging and the conversations we've had so far have been well received. And we've not heard that practice economics are a reason for why a practice is not utilizing ORGOVYX. So we think we've been successful in this respect.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Makes sense. Great. And flipping gears a little bit to your free sample program, which I believe launched in November. What do you expect to achieve here? And what should investors know about how this impacts possibly net sales or prescribing dynamics?

David C. Marek
CEO & Director

Lauren?

Lauren Merendino
Chief Commercial Officer

Yes. So you're absolutely right. So we launched a starter program in November, but it's important to note that this program was replacing a prior program. So since launch, we have had a free trial program, which provided up to 2 months of free product to a new patient. And that program was implemented through our hub. So it requires physicians to fill out paperwork in order to get the product shipped to the patient.

And the feedback that we heard from customers was we really like to have that product here in office. So when I make that decision to start a patient on ORGOVYX, I can hand them the bottle and get them started today. And so our shift to a starter program was really based on our customers' feedback. And the response has been really positive since rolling out the program.

And so the starter program provides 1 month of product to get that patient started. And we believe that this is really important as physicians are making that treatment decision to have the ability to get the patients started right there, and we've heard from physicians that this is meaningful to them.

So we believe that, although it's still early days, this will be a very successful program for us as a brand.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Got it. Very helpful. And last question on ORGOVYX before I do want to make time for MYFEMBREE. So as you work towards improving payer coverage of ORGOVYX, what are the most significant questions or comments that you're hearing from payers?

Lauren Merendino
Chief Commercial Officer

Yes. So we've been really proud of the progress we've made with our coverage. As Dave mentioned, we have now 81% of commercial lives covered and 99% of Part D lives. So essentially, we have excellent coverage. And more importantly is the quality of this coverage, which is very good. So the prior authorizations are not onerous and there are no step edits required for the vast majority of patients whose insurance covers ORGOVYX.

So as far as the payer feedback, payers continue to -- those payer discussions continue to go very well. However, we're really proud with where we are today, and we'll continue to have conversations with payers who've not yet made decisions, but overall, we're really pleased with where we are.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Great. Sounds good. So flipping gears to MYFEMBREE, and I'll start with the uterine fibroids piece. So big picture, what feedback have you received so far from physicians and maybe also patients on MYFEMBREE's clinical profile?

Lauren Merendino
Chief Commercial Officer

Yes. So overall, the feedback from our customers around our clinical profile continues to be very positive, and they see the benefits of MYFEMBREE applying to a broad set of uterine fibroid patients, which is really important and consistent with our label.

When we look at our market research, we do see that there are some messages that our customers are finding really motivating. And that is -- those are messages around our efficacy. So the 84% reduction in the menstrual blood loss, as well as the improvement in the hemoglobin response in patients with anemia. Those are 2 really important factors that physicians are considering.

And then, of course, our convenient, our convenience 1 -- the convenience of 1 pill once a day is really important in this market as well. So those tend to be the messages that we're hearing are most meaningful to our customers.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Great. Sounds good. And probably still for you, Lauren, what is the general split of types of patients that are currently being prescribed MYFEMBREE? And what are you seeing early on in the launch?

Lauren Merendino
Chief Commercial Officer

Yes. So the great news is we're seeing a broad set of patients being prescribed MYFEMBREE. So when we talk to physicians, they often think of those symptomatic patients whose life is being impacted by their heavy menstrual bleeding, which can be a pretty broad set of patients in and of itself. They also think of using MYFEMBREE for those patients who are thinking about a bridge to get that patient to menopause or to surgery at some point.

And so the large majority of these patients have been previously treated with an oral contraceptive, which is not surprising to us. OCs have been the standard initial treatment for these patients for years. And recently, there was a change in the ACOG guidelines that we may see this change over time because those guidelines now reflect that a GnRH antagonist should be considered frontline. And so those guidelines are still relatively new, but we are encouraged to see that the thinking is evolving.

And then the majority of the patients who are receiving MYFEMBREE are naive to GnRH antagonist therapy. So this is important because what we're seeing is, as physicians are making a treatment choice for a new patient that MYFEMBREE is now being chosen about half of the time when compared with other GnRH antagonist. So this is evidenced by our 49% NBRx share. And so some of these patients may have previously been considered for ORIAHNN, but many of these patients would not have received a GnRH therapy. So MYFEMBREE is also helping to expand the market for this class of drug.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Got it. And so you did touch upon ORIAHNN, which is AbbVie's product. So I was curious maybe you could lay out for the audience that's newer to the story, what differentiates MYFEMBREE from ORIAHNN and other GnRH antagonist?

Lauren Merendino
Chief Commercial Officer

Sure. So -- so when a physician is thinking about therapy, the first place that they think about is efficacy. And with our ability to reduce heavy menstrual bleeding by 84% is really impressive, and it's helping them to achieve what they want for their patients which is a dramatic and meaningful reduction in what bothers patients most.

Next, they look at the side effect profile. And while no physician group likes to have patient callbacks, we find that gynecologists in particular, really try to avoid having patients calling their office. And so 1 of the side effects that drives callbacks is hot flush. And our data looks really good here with only 11% experiencing hot flush, which is not that much different than the 7% seen in the placebo group. .

So MYFEMBREE is delivering that great clinical profile, clinical and safety profile with just 1 pill once a day. And that's a meaningful differentiator for clinicians but even more so for patients. So the increased awareness of the MYFEMBREE profile prescribers are quickly recognizing the differentiation. And when given a choice, they're increasingly choosing MYFEMBREE. So that's evidenced, as I mentioned, by the NBRx share of about 49% of patients at this point receiving MYFEMBREE as their GnRH antagonist.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Got it. Very helpful. And I did want to switch a little bit with MYFEMBREE in endometriosis. So maybe zooming out a little bit, could we talk a little bit about how the endometriosis population is different from the uterine fibroid population and how we should think about that space?

Lauren Merendino
Chief Commercial Officer

Sure. So we're excited about the opportunity for MYFEMBREE in endometriosis, obviously, it's still pending FDA approval, and our PDUFA date is in May. So we're eager to hear the FDA's response. Unlike in uterine fibroids, endometriosis is a disease that's not always resolvable with surgery such as a hysterectomy. So it's better suited for medical management, and we see much better acceptance of medical treatment by physicians for endometriosis. .

And as we look at our prelaunch market research, we see that 45% of OBGYN surveyed expressed greater urgency to treat endometriosis versus uterine fibroids. And that's really driven by the fact that these patients are oftentimes experiencing pain. And so that's a great motivator for the physician to treat that patient.

So it's important to note that there is significant unmet need here with over 1 million women diagnosed with endometriosis but having failed their initial therapy. And so we believe that MYFEMBREE can address their treatment needs, of course, pending FDA approval later this year.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Got it. And you briefly touched upon this, but I did want to dig in a little bit. So where would MYFEMBREE for endometriosis actually fit in the current treatment paradigm? I know you mentioned surgery briefly. So could you just elaborate on that a bit more?

Lauren Merendino
Chief Commercial Officer

Sure. So obviously, we're under review, and we don't have an approved FDA label. So it's a little hard to be specific here. But in general, we do believe that with the unmet need that I mentioned here that there are many women that can be helped by MYFEMBREE, that we have strong clinical data here to support these women and that we -- that with the experience that GYNs have had in uterine fibroids, that there will be a positive halo in the treatment choice as we launch in endometriosis, hopefully, knock on wood.

But in our SPIRIT clinical trial program, which is what supported our SNDA. We were evaluated in a wide range of women from age 18 to 50. And so we believe that MYFEMBREE, we hope that, that will be reflected in our label and that MYFEMBREE would be able to support this broad range of women.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Makes sense. And so as you mentioned, the PDUFA date is coming up for MYFEMBREE in endometriosis. So if we zoom forward and assume that it's approved, what sort of strategies would you plan to use for endometriosis specifically? And knowing that AbbVie has also walked into this indication as well with their GnRH antagonist, how could you learn from them and imply even better strategies going forward?

Lauren Merendino
Chief Commercial Officer

Yes. So obviously, without having our approved label, it's a little bit difficult to share our strategies but we believe our key differences will, of course, start with our clinical and safety profile, but also there's this element of simplicity that we believe MYFEMBREE brings to this marketplace. So should we be approved, we will have 1 brand across both indications, 1 dose, 1 pill, once a day. And so it's very simple and easy for clinicians and also, of course, simple for women to utilize.

With our competitors, clinicians need to remember multiple brands with 3 dosing options across 2 different indications. And so we've heard feedback from our customers that this can be a bit confusing. And so I hesitate to comment further regarding our launch strategy until we've had an opportunity to have a finalized label, but that gives you a sense as to some of the differentiation we see.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Fair point. So I also want to ask somewhat more practical question. I know investors sometimes like to think about this. So could you speak to your current cash runway, plans for being efficient around future spend and investing appropriately with your ongoing commercial launches as well?

David C. Marek
CEO & Director

Uneek, you want to take that?

Uneek Mehra
Chief Financial & Business Officer

Yes, sure. Thanks, Roanna. So first and foremost, I'd like to point out that we're in a strong financial position today, and we do not see any need for any near-term external financing. As of December 31, 2021, we had cash and committed funding of $569 million, which includes the remaining $41 million of the DSP loan commitment. We believe this capital provides us to appropriately resource our product launches, expand our pipeline as well as pursue value-creating business development opportunities as they come about.

We're going to be very pragmatic and selective about those because our first priority is to ensure funding the product launches, especially now that endometriosis is also potentially around the corner. We expect revenues for both ORGOVYX and MYFEMBREE to continue to increase. And I'd note that we split 50-50 with Pfizer, certain relugolix-associated U.S. development and commercialization expenses both of which help mitigate our future cash burn.

Finally, there are also potential other future milestones, including $100 million should we receive FDA approval for MYFEMBREE in endometriosis that will further strengthen our financial position.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Great. Very helpful. And I think in our last minute, I did want to briefly chuck in as well on your ongoing search for an ex U.S. partner for ORGOVYX and switching back to ORGOVYX and oncology or relugolix. So what -- where are you there? Any updates you can share with us since the last time we talked?

David C. Marek
CEO & Director

Yes. We've made great progress. Uneek, do you want to take that one as well?

Uneek Mehra
Chief Financial & Business Officer

Yes. No, sure. As we mentioned, we alas time, we continue to assess partnership opportunities. Europe or ex U.S. opportunity from a size perspective is as big as the U.S. with almost 300,000 men with ADT on therapy every year. So we remain on track given multiple parties who are interested to partner with us to reach an agreement with a partner by the anticipated European Commission approval of relugolix in the middle of this year.

So it's pretty encouraging. In the meantime, I'll also point out we continue to work with the EMA through the ongoing review process and other prelaunch activities related to pricing, reimbursement so that we choose the right partner and position the partner to execute shortly once we -- on the launch once we get the regulatory approval.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Sounds good. A lot of things in the works. So I think we're up on time now. So I want to thank the Myovant team for walking us through the story and what's going on, and we look forward to more updates in the future.

Uneek Mehra
Chief Financial & Business Officer

Thank you so much, Roanna.

Lauren Merendino
Chief Commercial Officer

Thank You.

David C. Marek
CEO & Director

Thank you, Roanna. Have a great day.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division
Thanks.