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Myovant Sciences Ltd. NYSE:MYOV

Company Conference Presentation

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Table of Contents

Call Participants

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Madhu Sudhan Kumar
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Presentation

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division
All right. Thanks, everyone, for joining us at the Goldman Sachs Global Healthcare comp. It's really excited to have the team from Myovant here to walk us through where things are with the company and where they're moving forward to.

Question and Answer

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So let's just dive in and start with the discussion of MYFEMBREE in endometriosis, question really at the top of mind to most investors and the name. Could you give us an update on the extension of the PDUFA date to August 6? And how to think about the FDA's request for more bone mineral density data?

David C. Marek
CEO & Director

Yes, certainly, first of all, thank you for inviting us today. Really excited to be here. The FDA asked for additional bone mineral density analysis on data we had already provided fairly late in the cycle as you're aware. And they said they needed additional time to be able to review those analyses, which puts us out to an August 6 PDUFA date.

And so look, we are continuing doing our dialogue with FDA. We look forward to continuing those discussions and the date on August 6. And we feel very confident in the clinical profile that came out of the SPIRIT program for efficacy and safety in endometriosis, and we look forward to their ongoing review and discussions that we'll have on August.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Sure. And so in light of this bone mineral density analysis that you mentioned, how should you think about the question we get a lot about the potential for a 24-month limitation of use for MYFEMBREE and endometriosis and what is the kind of puts and takes there?

David C. Marek
CEO & Director

Yes. Well, certainly, look, we know BMD is an important topic for FDA and for women with uterine fibroids and endometriosis. We followed the same approach that we used in uterine fibroids. So in uterine fibroids, our LIBERTY data reported out with the 1-year data, and that was used as our submission that ultimately led an approval for uterine fibroids with a 24-month duration of use.

Subsequently, in uterine fibroids, we reported out our longer-term data. And now we've submitted that as an sNDA after the approval. We're following the same process with endometriosis. We submitted the data. That was part of the SPIRIT pivotal trials. That is through 1 year, and we have since announced the safety and efficacy of the SPIRIT long-term extension trial through 2 years, and we would look if we get approval to submit that after the potential approval.

So we're following the same path that we used in uterine fibroids. But the data looks very strong. The 2-year data, particularly for BMD looks very strong in both LIBERTY and SPIRIT.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Fair enough. So if approved in Indonesia which is on August 6, how much do you believe that endometriosis market opportunity could expand the commercial TAM for MYFEMBREE relative to what you can see now uterine fibroids?

David C. Marek
CEO & Director

Yes. Well, it would be significant. And it's significant for 2 reasons. First of all, if you look at the patient population, for uterine fibroid, you have about 6 million women who are seeking treatment for uterine fibroids. About 3 million of those women have already been failed by their first-line therapy.

So it's a pretty substantial population. If you translate that over to uterine -- or to endometriosis, you're looking at about 5 million women who are seeking treatment and about 1 million of those have already failed their first line or have been failed by their first-line therapy. So it's almost doubling the size of the patient population.

And then when you look at our ability to compete in that marketplace, we feel very good about -- if we're approved for endometriosis, we feel very good about the clinical profile that we have and our ability to differentiate MYFEMBREE in the endometriosis space and really serve the women that need a better option.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. I guess kind of another like at practical level, how do you know the margin implications of having endometriosis in terms of like a higher-margin opportunity relative to uterine fibroids is kind of like [indiscernible] approval indication for MYFEMBREE.

David C. Marek
CEO & Director

Yes, I'll let Uneek...

Uneek Mehra
Chief Financial & Business Officer

Thanks, Madhu. I do think we will have a significant improvement in margins once centimeters get approved. As Dave said, I think, there is a close to 90% overlap with the physician targets that we envisage for endometriosis. Uterine fibroids now with almost 60% NBRx share, we believe that those same physicians are well aware of MYFEMBREE as a product.

So as endometriosis as and when that gets approved, we expect that we would -- it would be the same physicians and hence, quite a large amount of synergies in terms of commercial promotion and thereby on margin implications.

And just to finish on that, I think, endometriosis is just also our second indication. We potentially are looking at other potential indications for MYFEMBREE, which would also be calling on the same physician. So there is quite a systematic plan in our mind that the margin improvement would be sort of continuous.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

I mean a follow up on that. How do we -- what should we be thinking about in terms of other indications beyond uterine fibroids and endometriosis where MYFEMBREE get the hell of an opportunity?

David C. Marek
CEO & Director

Yes. I think first, when we look at uterine fibroids and endometriosis, one of the tremendous areas that we think is a value proposition is the same brand and the same dose across both of those. When you talk about synergies, we would be the only therapy, GnRH antagonist therapy that would be the same brand, the same dose, same dosing regimen, one pill once a day. Now for OB/GYNs, that makes things very straightforward.

And remember, as Uneek said, we've got tremendous momentum already in uterine fibroids. So those same physicians that are gaining experience and now the lead market share in terms of new patients that treatment experience can carry over and their confidence in MYFEMBREE can carry over to endometriosis.

So -- and then when we look at ways that we can further develop MYFEMBREE, it first starts with enhancing the labels we already have. So we've already talked about the 2-year data that we've submitted on uterine fibroids. We would plan to do the same on endometriosis that could have implications on the label.

We've also announced the SERENE study where we're very -- we believe that has significant potential to unlock value. SERENE is designed to help demonstrate the effectiveness as a contraceptive. So for women who are already treating their uterine fibroids or their endometriosis, one of the challenges with GnRH antagonist is that the requirement to use barrier method contraception.

Well, we know that's a limitation for some women. If MYFEMBREE had the potential to not only treat the uterine fibroids or endometriosis, but could simultaneously act as their hormonal contraceptive, we think that really unlocks value in the marketplace and better serves the women's needs out there.

So that's part of it is just enhancing the label and then we look at other potential indications. We're in discussions with Pfizer as our co-collaboration partner, our co-development partner. And we think there are multiple potential areas of utilization for MYFEMBREE, and we hope to talk about those very soon.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So on the point around the 2-year withdrawal data potentially rule of the 2-year limitation of use. To what extent kind of in the field is that a limitation for patients who would -- or prescribers to get people onto the MYFEMBREE that they would want to do it, but it's only for 2 years, and it's like you want to have a drug that work layover 2 years and you've got to stop and go back to where you were.

David C. Marek
CEO & Director

Well, we haven't heard that in the field as a limitation of use right now for physicians. What they're looking at, and of course, we haven't been out for 2 years. So we haven't heard that as an objection. But just in terms of choosing the patients and the criteria by which they're looking at treatment.

What we're seeing is more emphasis on medical options. So we know that hysterectomies are -- there's 0.25 million hysterectomies a year for uterine fibroids. And even ACOG has come out and said that they really hope that physicians are laying out all the treatment options for patients so they can make the right decision for them.

And I think as they're looking at uterine fibroid treatment, we're not hearing that the 2-year limitation is what's holding them back in terms of prescribing. And as a matter of fact, we've seen the market growth since we've been out by 137%. So that shows that we're drawing in additional prescribers, and we're expanding the marketplace.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Is there any sense that expansion of the market, the expansion of nonsurgical options for uterine fibroids, how much of that is tied to kind of surgical constraints in hospital limitations? And how persistent kind of that seems to be like obviously with COVID, there was a sharp decline in procedures. That's come back, but it seems like it's not come back to the same extent that it was pre-COVID. So like how are you hearing about that in terms of like surgical procedures like hysterectomies that might have been used heavily or not so much which kind of opens a window for a nonsurgical option like MYFEMBREE?

David C. Marek
CEO & Director

It certainly helps. So I think the larger factor is just the dialogue that physicians are having with patients now that they have a therapy that they believe can address the efficacy while being -- having the safety profile and the tolerability profile of MYFEMBREE.

So low incidence of hot flush, which we know gets in the way of patient persistency and compliance. And as a bother even for the physicians when they get called back. So I think the rates that we see in hot flush and the confidence that they see in the BMD data that we talked earlier are really the drivers for why physicians are trying MYFEMBREE. And then when they try it, there is a tremendous satisfaction.

Our recent data for our target physician showed that 87% of physicians that we surveyed have an intent to prescribe MYFEMBREE in the next 90 days. So that says that physicians are even more excited about the -- what MYFEMBREE is bringing to the treatment landscape.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So to that last point. When do you think that effectively translates into kind of substantial further growth in NBRx and then kind of subscription start forms, so we can follow on a more like active basis?

David C. Marek
CEO & Director

Yes. I mean I think if we look at the prescription growth that we're seeing, it has been pretty substantial. We already have between 3,000 and 4,000 patients that have already started or tried MYFEMBREE, and we're seeing continued growth with that, and we're seeing continued adoption.

We now have 1,700 prescribers of MYFEMBREE, and we're not even at the 1-year mark. So we think that we've already have tremendous momentum, not only in patient starts, but in physician adoption. And that's really leading to what looks like a good growth trajectory moving forward.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

And on that point, to what extent is the kind of effort from MYFEMBREE about like finding new prescribers versus tracking like low-volume prescribers and making the my-volume prescribers. Like how do you think about those 2? I know the overlapping strategies, but how do you think about those strategies for MYFEMBREE?

David C. Marek
CEO & Director

Yes. It's really exciting for us to have the partnership that we have with Pfizer. And when you think about what that partnership gleans in terms of value, there are a lot of benefits. And one of those benefits is we have dual field forces.

So we have roughly 100 account managers that are in oncology and roughly 100 in women's health. And so that allows us to deploy Pfizer's 100 and R 100 in oncology to overlap those that make the most sense and to go broader where necessary. And then women's health, we're doing the same thing.

So we actually -- because of the flexibility we have with 2 field forces. It allows us to double up on those physicians who are already interested in uterine fibroids, already prescribing and making sure they get the message and for those physicians who are just now kind of showing up to this -- to the treatment landscape with uterine fibroids and with GnRH antagonist, we still have the ability to kind of prospect with those because of the reach that we have across 2 field forces.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

I want to circle back on SERENE and on the contraceptive implications for MYFEMBREE. Can you remind us what fraction of patients with endometriosis and uterine fibroids would specifically want to prevent pregnancy? Like [indiscernible] there's a market survey work, like what [indiscernible] on a hormonal contraceptive option as part of that therapy?

David C. Marek
CEO & Director

Yes. I mean we start by thinking about this patient population. So women of child-bearing age, premenopausal women, family planning is a big part of their frame of reference when they're thinking of any therapies that they have. And women with uterine fibroids and endometriosis are no different than the rest of the women in terms of family planning being a key area of concern.

And so the need to move from a hormonal contraceptive to a barrier method contraceptive can be a hurdle. We know that there's less satisfaction with barrier methods and less reliability with barrier method.

So when you think about our ability to step into that and provide one pill once a day that can simultaneously address their uterine fibroids and their endometriosis -- or their endometriosis and simultaneously be an oral contraceptive. That's a tremendous unlock in terms of value and really helps to serve those patient needs in a much more effective or certainly efficient way.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So kind of following from that, given all of these forward stream, can you remind us kind of the key trial design aspects, endpoint sizing as better as you can say towards powering? Just kind of give us some details about the SERENE study.

David C. Marek
CEO & Director

Well, the key is kind of the efficacy endpoint that we're looking at in SERENE is really what we call the Pearl Index, it's been used in other contraception studies. And that's really looking at the percentage of pregnancies that you get across 100 treatment years of the study drug. So that's going to be the primary evidence for efficacy.

And remember, we already had one trial that demonstrated 100% ovulation inhibition prior to SERENE. So we go into SERENE with tremendous confidence that -- and we certainly look forward to the outcomes. But we believe that's a significant unlock for value and serves women better than with the options that they have today.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay, great. Let me shift gears over to ORGOVYX, the other kind of lead commercial franchise. And so -- well, obviously, the first thing that comes to mind for people is how to think about the accord partnership in Europe. And so can you walk us through some of the factors that came into play in choosing to partner with Accord in Europe for ORGOVYX?

David C. Marek
CEO & Director

Yes. I think we mentioned we had multiple partners potentially that raise their hand. Uneek led that process. So I'll let you describe why we chosen...

Uneek Mehra
Chief Financial & Business Officer

We ran -- do we ran a structured process on our main criteria in that process was to look at firms with commercial capabilities in Europe. Europe, similar size than U.S. in terms of patients, but has a very different sort of commercial process. The timing of the EU5 launches and the cadence of that requires different capabilities, especially pricing and reimbursement. So we looked at multiple parties who had those capabilities who had launched similar products with that cadence and especially in the EU5.

Many parties were interested. It was a very competitive process. Accord came to the lead given that they cover about their fully integrated pharmaceutical company originally in chemotherapy, but now they have moved into branded biosimilars as well as they have new chemical entities as well. They cover almost 95% of the European population.

They have ran such launches with the timing in multiple products. So that's the reason why we felt that Accord was a great partner. They're hungry. They are eager to get started. As soon as we sort of sign the bill, they were ready to kick off and get going in the market. So those were some of the criteria, and we are very happy due to the fact that we've now got Accord as our partner.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So to that end, it's obviously like the European decision, you had the pump favorable opinion, pretty close to the kind of the approval there. You mentioned EU5, but you also mentioned that Accord is in 95% of Europe. So to what extent can you talk towards what Accord strategy is going to be? Are they really focusing on EU5? Or are they focusing on all of your -- like how should we think about kind of that framework [indiscernible]

Uneek Mehra
Chief Financial & Business Officer

I think the initial focus will be EU5, but they -- the contract and the agreement goes beyond that into Turkey, into Switzerland. They have the right of first negotiation in other countries outside of Europe into Middle East, Africa, India.

So it's a pretty broad partnership, especially in the sort of Europe, Middle East area. To begin with, I think, in the first 12 months, the focus will clearly be on the EU5.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. And just a reminder, what do you believe is the kind of market opportunity for ORGOVYX in Europe relative to the U.S.?

Uneek Mehra
Chief Financial & Business Officer

When you look at patient numbers, we -- our estimate is about 1.5 million men who have -- compared to about $3 million in the U.S. It's a very large opportunity. It's, of course, different in terms of pricing. So we all know that Europe has a very different pricing model compared to the U.S. But from a volume perspective, there's tremendous opportunity in growth that we see in that market.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Yes. So on that point, how is -- to what extent does Accord kind of led you in [hub] their strategy for kind of achieving rapid patient access and rapid payer reimbursement like the big national health payers from EU5?

Uneek Mehra
Chief Financial & Business Officer

Yes. I think the typical launch process that we've seen and Accord is no different in terms of their plan to start with Germany as the first market because that sets the reference pricing. It's also one of the biggest markets.

And then to systematically sort of go through the cadence of the rest of the EU5, but it's -- I think, they have a well-defined plan, they walked us through that. And it goes all about the EU5 launch cadence right now.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. So moving beyond Accord, how should we think about in the U.S., your launch of ORGOVYX in fiscal '22 in terms of launch maturation, and where do you think you guys are right now?

David C. Marek
CEO & Director

Yes. Well, we feel really enthusiastic about the momentum that we've seen in the first year of ORGOVYX. We're already at more than 14,000 patients who have tried ORGOVYX. We're seeing growth quarter-on-quarter in terms of the patient numbers.

And what's exciting is we're seeing broad adoption. We're seeing 60% of the patients are treatment-naive to ADT therapy. But that means 40% are transitioning from other ADT therapy to ORGOVYX. So we're seeing a good blend there. We're seeing patients along the treatment continuum prescribed ORGOVYX. We're seeing about 20% of our patients are being used -- it's being used in combination with other therapies. And that mirrors a lot of the current treatment landscape. So it shows broad utility in terms of patient types, but also in terms of treatment setting.

So those with in-office dispensing, those offices that don't have in-office dispensing, academic centers, we're seeing double-digit growth across each of those treatment settings. So we feel really comfortable with the momentum we're seeing with the continued uptake and it's really exciting to see the kind of growth that we've had this early in the launch.

And then we're also seeing the plateau of our gross to net, which Uneek has talked about in multiple settings that we're -- so we're seeing continued growth in terms of patient volume and adoption with clinicians while our gross to net has leveled off.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Let's speak to that last piece. So with the gross to net leveling off, do you -- remind us where that is. Can you kind of speak to -- do you feel that, that's kind of a real permanent stabilization? Is there any risk of that kind of bearing in the future because of various macro headwinds? Or like where do you think we are right now with that?

Uneek Mehra
Chief Financial & Business Officer

Yes. So I think what we saw in Q4, fiscal Q4, around 40% and our guidance has been that I think for fiscal year 2022, it will be around the low to mid-40s. So we see that -- it's to be pretty range-bound right now.

And the reasons are, I think, all our peer contracts, our GPO contracts are largely done. So we feel pretty comfortable with the range that we are indicating. Now the slight increases that we expect are all due to just inflation on the rebates that you would expect as some of these contracts come on for renewals. But other than that, we don't envisage any other major sort of macroeconomic factor to change that sort of range right now.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. Great. So to the point you made earlier about that a lot of patients who are ADT-naive, but you have patients who are switching. When you speak to about prescribers and like look at your market research, why are people switching ADT therapies to ORGOVYX specifically?

David C. Marek
CEO & Director

Yes. I think when you look at the value proposition of ORGOVYX, it -- with the rapid onset without testosterone surge, that's one of the key areas that clinicians tell us that they like, but they also like the rapid off that in very short order, we have patients that are returning back to their levels after discontinuation of treatment.

And then there's also the tolerability and safety profile. We know there is a lot of focus on cardiovascular. I think that's one of the areas that people are looking more at -- or physicians are looking more at the profiles of us, and they're looking at that profile for leuprolide. So they're making their own conclusions. So I think that's one of the areas we hear about.

And then the oral nature, the administration being oral, we know there's tremendous momentum in oncology of moving to oral agents. Combination therapy very often is going to be or has been oral therapy. So from a patient perspective, we know that their preference is -- the majority of patients prefer oral therapies as well.

So there's plenty of reasons why a physician would consider making a transition from one of the older agents to ORGOVYX.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So following from that, are there -- how should we think about kind of life cycle management strategies, both -- is there any indication expansion opportunities for ORGOVYX but also just other things you're doing to kind of manage the life cycle of the drug in prostate cancer?

David C. Marek
CEO & Director

I think they're -- we look at it through kind of 2 different areas. The first is enriching the data that we already have for ORGOVYX in prostate cancer. So for example, adding to the wealth of data we already have would be looking at combination therapy, the safety of combination of ORGOVYX with enzalutamide, apalutamide, et cetera. And so those are already underway. So we would expect results towards the end of this year or early next year.

So that helps enhance kind of the confidence that clinicians would have. We don't have any limitations of use in the label, but we just know that, that could help add to the wealth of data. When we think about other areas to enrich our current indication, we're exploring some of those with Pfizer.

But then we're also looking at other hormone-sensitive oncology areas. And you can imagine a number of areas that we would be talking to Pfizer about and trying to align on what the next priority is of development.

So when you think of relugolix, both in oncology and in women's health, you can really think of it as a platform therapeutic. It's a portfolio just within relugolix itself. And we're very excited about opportunities within the indications we have and the potential for future indications.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So those are both really interesting. So when do you think kind of we can get greater visibility on -- so I mean, obviously, the combination stages of their AR pathway drugs in prostate cancer and then kind of the association of other androgen-dependent cancers. I wonder if -- can you guys provide more visibility and kind of like the broader strategy there? Because I think you're -- it's really interesting to kind of like layer that out in a really broad way.

David C. Marek
CEO & Director

Yes. We certainly are -- have had great collaboration with Pfizer as our co-development partner. We have an embarrassment of riches of opportunities, I think, with relugolix, as I mentioned. So it's really going through the prioritization and the design of how we would approach some of these opportunities. And as we continue through that process, I would look to later this year, detail -- beginning to detail out some of those areas of exploration.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Sounds good. And then on -- coming back to the enzalutamide, apalutamide combinations. To what extent do you feel that success there could expand the market opportunity for ORGOVYX beyond where

it is today? Or is it more about kind of enforcing the drug's kind of broad utility in the setting is already approved for.

David C. Marek
CEO & Director

Yes. Well, I think, look, expansion of utilization happens as confidence grows and confidence grows in a number of ways. It grows in terms of treatment experience, feedback from patients, watching how those patients respond.

Early on, it was about access and making sure that we kind of knock down some of those barriers and over time, as we layer in more data, it just helps with the confidence that physicians have in their clinical profile. So we're already seeing broad utilization. We're already seeing 20% of the patients in combination. More data, we think will help instill even greater confidence for those physicians who may be selective about combination therapy today. So it's certainly, we think it will open up the opportunity with more physician prescribers, but also more patients.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. Great. So then to ask a more granular and frankly, more direct question you get from investors all the time. What is the path to providing guidance for ORGOVYX revenues? [indiscernible] now the gross to net seems to have stabilized for fiscal '22.

Uneek Mehra
Chief Financial & Business Officer

Yes. No, I mean I think we are sort of encouraged that the gross to net has stabilized. There are a couple of trends that we are still watching before we start to think about guidance. One is, as you know, ORGOVYX is distributed through -- limited model through GPOs. So we don't have access to patient-level data.

Second Medicare population as [part d] is about 60%. They go through their annual resets, typically which causes some seasonality in the brands. So we would expect to at least go through 2 full years of execution as these trends sort of stabilize before we start considering giving guidance.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

It's a guidance [indiscernible] as potentially more of a fiscal '23.

Uneek Mehra
Chief Financial & Business Officer

[indiscernible]

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So -- okay, cool. That's good to know. All right. So moving beyond ORGOVYX. Let's think about some of the pipeline products. So let's think about MVT-602 in female infertility, when can we expect your next steps in terms of clinical studies from that program? And can you also just give us for a level set everybody walk through the program, walk through the opportunity.

David C. Marek
CEO & Director

Yes, certainly. So when we think of MVT-602 it's a kisspeptin-1 receptor agonist. So we're very excited about the potential of that asset in terms of fertility. When you think about it, think about it as, I guess, kind of the master controller along that kind of HPG kind of access, so to speak, so there are multiple potential...

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Do you mind, what is HPG?

David C. Marek
CEO & Director

So hypothalamus, pituitary gland, gonadal gland. So when you think about the opportunity there, there are multiple points of entry where kisspeptin can play a role. And so as we look at that, you could almost think of MVT-602 as another potential platform therapeutic with multiple applications along that axis related to fertility.

And we are looking at a number of those different opportunities, and we're going through kind of our prioritization and again, how we would design certain approaches to kind of prosecuting those. And we would expect to begin announcing some of those later in the year as well.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. And so following to that, where do you see 602 fitting in the current treatment landscape for female infertility?

David C. Marek
CEO & Director

I think it kind of depends on where we pick within that kind of HPG axis. There are multiple potential entry points that we think has utilization. And could be a kind of differentiated offering if we're able to prosecute some of these potential targeted areas. So we'll need to see how that plays out in terms of our prioritization and how we kind of prosecute 602. But we think there are multiple shots on goal, so to speak, that we think kisspeptin -- the role that kisspeptin can play there.

Uneek Mehra
Chief Financial & Business Officer

And just to add on that, I think, the initial work seems to suggest that we do have a pathway of triggering the oversight maturation. It is just such a natural part of the fertility cycle that we believe MVT-602 could play a role in that. So that's just one of the first sort of pathways that we are exploring within the whole HPG axis.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. So let's -- let me step back and have some more high-level discussion. So one, obviously, like biotech is going through a really rough patch, and a lot of it comes on too many companies who don't have capital to kind of fund themselves efficiently.

Obviously, you all are not in that bucket. We can talk about that in a little bit. But the other kind of question that comes from that, particularly, as we were discussing actually before, was commercial versus pre-commercial companies, like commercial companies have this kind of intrinsic value now because of -- versus companies that are just burning cash and there's no way forward beyond that.

How do you think about the kind of balancing of wanting to expand opportunities, wanting to do life cycle management and kind of increasing pipeline investment versus I'm sure like you've had the drum-beating investors were like, what's the path to profitability? What's the path to a dividend? All those kind of questions are just like strip things down to these commercial products that you can do well and make them profitable. Like how do you balance those concerns in this kind of macro environment for small-cap biotech?

David C. Marek
CEO & Director

Yes. Well, our first priority is to continue to drive uptake and the value we're bringing to patients with both ORGOVYX and MYFEMBREE. And we have a very strong commercial presence, not only with ourselves but in the collaboration with Pfizer. And that allows us a lot of optionality, as I mentioned earlier, but it also allows us to look at working very efficiently and driving continued momentum that we've seen. So that is clearly our first priority.

And then when we think of now how do we look at expanding kind of the pipeline, so to speak, we can expand very efficiently with the therapies we currently have. So I mentioned some of the SERENE study and other areas that we can unlock value with the therapies we have. We believe those are very efficient investments that can lean significant value on the back end.

So looking at relugolix and expanding the labels, expanding the opportunities, there is a very efficient way for us to continue to build kind of our future without taking our eye off on delivering for today in 2022.

And then we do have the resources to be able to target additional opportunities as they come our way. But that's after we make sure that we deliver on the opportunities that we have right here in front of us.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So then is there a case we made for like moderating R&D spend outside of the core expansion opportunities for relugolix so with that you can kind of do both. You can take advantage of the commercial opportunity you have and making that stronger, but kind of streamline down on R&D to kind of help towards that path to profitability. Like how do you win that possibility?

David C. Marek
CEO & Director

Well, I think, we already have been very efficient in our selection of which programs that we're moving forward. And certainly, as we look at other things outside of our pipeline business development, we've been very choiceful in looking at what the various opportunities are out there.

But right now, when you look at the prioritization that we have and the programs that we've announced, we think that those are going to really glean value for the amount of investment that we're putting forth.

And with the amount of capital we have, roughly $0.5 billion, we're going to be able to do both. We're going to be able to fuel our continued momentum with our commercial launches while being choiceful on the R&D side.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. And then another structural question we get a fair bit is especially after a few weeks ago with Biohaven, how should we think about kind of the acquisition opportunity for you guys as a commercial company, particularly with Pfizer is a partner of people are putting one and one together and maybe getting 3.

But one of the natural question that emerges, if Pfizer buys its partners, people -- everyone made that list of like who are the partners that Pfizer has and you are clearly among the top of them. So how do you think about kind of M&A generally at the current levels and M&A from specific partners as such?

David C. Marek
CEO & Director

Well, the good news around whether we're an M&A target or we want to stay in the path that we are is that what you do for success is the same thing. It's driving commercial performance. It's investing in the right opportunities to drive value for shareholders.

So we stay focused on delivering for today. We stay focused on being choiceful with our R&D selection. Our focus is really driving shareholder value today and into the future. And we really don't spend a lot of time thinking about the M&A activity as it might come our way.

We would be responsible with opportunities that come our way to see if that was the right move for the company and for shareholders. But the way we do that is by staying focused on delivering.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

So on the other end of that equation, are you looking at any kind of external business development opportunities? I know Uneek has spoken previously about kind of searches but being selective. So where are you guys now in? Because I would say like, obviously, kind of the classic problem of like everything has gotten a lot cheaper in the last 6 to 18 months or so. So where are you guys now on?

Uneek Mehra
Chief Financial & Business Officer

Certainly. Yes. No. I mean I think, look, markets are -- given the state of the market, the assets are pretty key right now. But we stay focused on our areas of hormone-sensitive cancers as well as women's health. Should there be an opportunity that is both practical and pragmatic for us to invest in.

Our capital allocation, as Dave has alluded to, is focused first on commercial launches as well as the sort of life cycle extensions. But we are. We consider to prosecute opportunities externally to the extent that it makes sense. And as they come about, we will surely sort of mention those publicly.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Okay. Great. So a final question, the question we're asking every company at the conference. What is the reason to own Myovant stock in the next 12 months?

David C. Marek
CEO & Director

Well, look, I think, Myovant is in pretty exclusive class of companies. So if you look at the companies that are in the $1 billion to $3 billion range and I look across 3 key areas: the first, you mentioned already, do you have brands that you're already commercializing that have already made it over the line at FDA.

In the last 18 months, we have 2 of those. And these are highly differentiated therapies in markets that are growing and we're showing success. We've shown tremendous uptake in terms of the first year in the launch. And that's fueled by our partnerships.

Fueled by our partnership with Pfizer in the U.S. and as we mentioned, ex-U.S. partnerships as well. And we have sustainable opportunity there. Remember, our patent life goes through 2037. So differentiated therapies in high-growth marketplaces that we think can provide significant value over time.

So that's the first category. We don't think there are as many companies out there that match that characteristic. And the second is pipeline. And we talked about the different areas of pipeline, relugolix as a potential platform therapy. You can look at MVT-602, and we have the resources beyond that to look strategically at additional things that we could add in.

So we have -- even what we already have in-house, we have a bright future, we believe, in terms of the pipeline. And then the third is the resources to deliver on the business plan. Again, with $0.5 billion, we can fully fund our commercial endeavors and make sure that we're being smart about those investments and continue that growth while looking strategically at building our pipeline.

So when you look across those 3 characteristics, we think, there's just a very, very short list of companies that can match up to Myovant.

Madhu Sudhan Kumar
Goldman Sachs Group, Inc., Research Division

Great. Well, thanks so much [indiscernible] for joining us today, and thanks everyone for joining us at the conference. So have a good one.

David C. Marek
CEO & Director

Thank you.

Uneek Mehra
Chief Financial & Business Officer
Thank you.