

REFINITIV STREETEVENTS

EDITED TRANSCRIPT

Q1 2023 Myovant Sciences Ltd Earnings Call

EVENT DATE/TIME: JULY 27, 2022 / 9:00PM GMT

CORPORATE PARTICIPANTS

David C. Marek *Myovant Sciences Ltd. - CEO & Director*
Juan Camilo Arjona Ferreira *Myovant Sciences Ltd. - Chief Medical Officer*
Lauren Merendino *Myovant Sciences Ltd. - Chief Commercial Officer*
Uneek Mehra *Myovant Sciences Ltd. - Chief Financial & Business Officer*

CONFERENCE CALL PARTICIPANTS

Brian Peter Skorney *Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst*
Eric William Joseph *JPMorgan Chase & Co, Research Division - VP & Senior Analyst*
Gavin Clark-Gartner *Evercore ISI Institutional Equities, Research Division - Analyst*
Madhu Sudhan Kumar *Goldman Sachs Group, Inc., Research Division - Research Analyst*
Philip M. Nadeau *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*
Roanna Clarissa H. Ruiz *SVB Securities LLC, Research Division - Director of Infectious Disease, Endocrine & Cardiovascular Disorders & Senior Research Analyst*

PRESENTATION

Operator

Good day, everyone, and welcome to Myovant Sciences' First Quarter of Fiscal Year 2022 Earnings Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Uneek Mehra, Chief Financial and Business Officer at Myovant. Please go ahead.

Uneek Mehra *Myovant Sciences Ltd. - Chief Financial & Business Officer*

Thank you, operator. Good afternoon, and thank you for joining us today to discuss Myovant's corporate update and review the financial results of Myovant's First Quarter for Fiscal Year 2022. Joining me for today's call are Dave Marek, Myovant's Chief Executive Officer; Lauren Merendino, Chief Commercial Officer; and Dr. Juan Camilo Arjona, Chief Medical Officer.

In addition to the press release issued earlier today, the slides presented during today's webcast will be available on our Investor Relations website, investors.myovant.com after today's call. Today, we will be referring to our first fiscal quarter, representing the 3 months ended June 30, 2022 as our first quarter or Q1 throughout this presentation. During this conference call, we will be making forward-looking statements.

These include plans and expectations with respect to our products, product candidates, strategies, opportunities and financials, all of which involve certain assumptions of risks and uncertainties that are beyond our control and could cause actual results to differ materially from these statements. A discussion of these risks can be found in our SEC disclosure documents. In addition, Myovant does not undertake any obligation to update any forward-looking statements made during this call.

I will now turn the call over to Dave Marek, Myovant's Chief Executive Officer. Dave?

David C. Marek *Myovant Sciences Ltd. - CEO & Director*

Thank you, Uneek, and good afternoon, everyone. Myovant's 2022 fiscal year is off to a strong start, marked by significant volume-driven growth for both ORGOVYX and MYFEMBREE and with regulatory advances that enable us to reach more patients with our differentiated medicine. In our first quarter, Myovant recorded \$116.5 million of total net revenues, including \$41.4 million of net product revenue. We continue to reach more men with advanced prostate cancer through continued adoption of ORGOVYX across a broad range of patient types and treatment settings, resulting in quarterly sequential demand volume growth of 26%.

With MYFEMBREE, we continue to grow the GnRH antagonist class for the treatment of uterine fibroids, and we're proud that MYFEMBREE is now the number 1 prescribed GnRH therapy with leadership in both new-to-brand and total prescription shares. Outside the U.S., RYEQO is now launched in 19 European countries, making it more widely available for women with uterine fibroids. And we've made great progress with our regulatory efforts. We are pleased to be in labeling discussions with the FDA with respect to our MYFEMBREE sNDA for endometriosis-associated pain and expect a decision from the FDA by the PDUFA goal date of August 6.

We remain confident in the clinical profile of MYFEMBREE and its potential to become a meaningfully differentiated therapeutic option for women with endometriosis. We'll continue to work closely with the FDA to support the advancement of our sNDA. In June, we announced that the FDA accepted for review our sNDA for MYFEMBREE based on 2-year safety and efficacy data from the Phase III LIBERTY randomized withdrawal study. These study results show the longer-term benefit MYFEMBREE can potentially have on treating women's uterine fibroid symptoms. The FDA set a PDUFA goal date of January 29, 2023.

Moving to Oncology, I'm excited to share that ORGOVYX is now approved in the United Kingdom as the first and only oral androgen deprivation therapy for adult patients with advanced hormone-sensitive prostate cancer. This approval, coupled with the European Commission approval in April, will bring this meaningful therapy to more patients across Europe. And finally, our strategic partnerships continue to be a value driver for Myovant.

This includes the \$50 million upfront payment received from Accord in Q1 for its exclusive license agreement to commercialize ORGOVYX in Europe. And despite the challenging macroeconomic environment, we ended the quarter in a strong financial position with cash and committed financing of \$400 million, enabling us to fully support ORGOVYX and MYFEMBREE commercialization activities while also seeking to expand our pipeline.

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

Lauren Merendino Myovant Sciences Ltd. - Chief Commercial Officer

Thank you, Dave. Today, I'll provide an update on the performance of ORGOVYX and our progress on the MYFEMBREE launch in the U.S. Let's start with ORGOVYX's performance. ORGOVYX continued to demonstrate strong growth on multiple fronts in fiscal Q1, further advancing our progress and establishing it as an androgen deprivation standard of care for advanced prostate cancer. Since launching in January of 2021, approximately 18,000 men have now been treated with ORGOVYX, illustrating continued growth of patient and prescriber demand.

ORGOVYX delivered \$36 million of net product revenues in Q1, and we're proud to report that this quarter, we also drove 26% sequential commercial demand volume growth, demonstrating the expansion of ORGOVYX utilization. As we look at the quarterly net sales trend, you can see the revenue we achieved in Q1 represents 22% quarter-over-quarter growth. The broad coverage we've established for ORGOVYX continues to play an important role in the brand's success by enabling affordable patient access. In fact, 3 out of 4 patients on ORGOVYX are paying less than \$60 out of pocket per month.

Our gross to net remained within the previously stated range of low to mid-40s, and we expect to stay within this range this fiscal year. Due to quarterly fluctuations, we were near the upper end of this range for this quarter. Leading indicators such as new patient starts and account growth continue to be strong, giving us confidence that we will continue to see growth with this brand in the future. Let's talk a bit more about these factors. ORGOVYX new patient starts grew this quarter with an additional 3,500 men initiating ORGOVYX in Q1, representing a 24% increase compared to last quarter and bringing the total estimated patients treated since launch to 18,000.

It's important to note that these patients represent a broad range of patient types. Recent analysis of our specialty pharmacy and claims data shows over half of ORGOVYX patients have clinically localized disease, while 30% have metastatic prostate cancer, which is consistent with what we see in the ADT market overall. This analysis confirms that prescribers see the benefit of the ORGOVYX clinical profile across a spectrum of advanced prostate cancer patients. As you can see in the pie chart, our account volume distribution is very similar to what we reported last quarter, with about 80% of ORGOVYX business coming from the dispensing clinics, academic and integrated delivery network accounts combined.

And this is consistent with what we see from the ADT market overall. Almost half of our volume comes from dispensing clinics, which are primarily driven by urologists, and we've seen accelerated growth in this segment with 26% growth this quarter versus the 11% we reported last quarter. The academic IDN segment is driving 34% of our business and is primarily driven by oncologists. This segment also continued to see substantial growth with 22% in Q1. Most importantly, our growth overall across all segments has accelerated with 26% volume growth this quarter versus the 18% we reported last quarter.

We're seeing continued expansion of the number of accounts as well with over 2,000 treatment centers having utilized ORGOVYX to-date. This collectively demonstrates that our business is well balanced across prescribers and account types as well as across the spectrum of patients. And remember, with 300,000 men being treated with an ADT each year, there continues to be tremendous opportunity for us to expand our impact and to help many more men experience the benefits of ORGOVYX in the future.

Now turning to the launch update for MYFEMBREE; Q1 was another milestone quarter. Within the class of GnRH therapies approved for treatment of uterine fibroids, we continue to be the market leader in new-to-brand prescriptions and have now also become the market leader in total prescriptions, capturing 51% total prescription share. Over 5,800 women have been treated with MYFEMBREE since launch, reflecting the growing momentum we're seeing with this brand. As we've previously stated, we believe that in order to change the treatment paradigm, it's imperative that we grow the GnRH class.

Since the launch of MYFEMBREE in June of 2021, the total prescription volume for GnRH antagonists in uterine fibroids has grown by 180%. This demonstrates that MYFEMBREE is expanding the patient population that prescribers believe will benefit from this class of treatment. In our first quarter, our commercial demand increased by over 50%, and we recognized \$4 million of net revenue. MYFEMBREE has now been used to treat 5,800 patients since launch with about 2,400 new patients starting treatment with MYFEMBREE in Q1, which represents a sequential quarterly increase of 71%.

Of these patients, 95% are new to receiving GnRH therapy, indicating that MYFEMBREE's differentiated clinical profile and our commercial execution is broadening the patient population receiving this class of treatment. A key part of our strategy since launch has been making MYFEMBREE easy to access. We continue to benefit from the broad coverage we've established with 94% of commercial lives covered and 75% of these commercial patients are paying \$5 or less out of pocket per month. Last quarter, we announced that we became the market leader in new-to-brand prescriptions for GnRH therapies approved for uterine fibroids.

As you can see in the graph on the left, we have continued our leadership in NBRx. And on the right, you can see that we have now crossed the threshold to become the market leader in total prescriptions as well with a 51% share of TRx. The speed with which MYFEMBREE has become the market leader is impressive. It took 6 months post approval to cross the 50% threshold in NBRx. And now at a year post launch, we have crossed the threshold on TRx as well. This demonstrates that our differentiated profile is resonating with our customers and that our commercial strategy and field execution have been impactful.

For these reasons, we remain steadfast in our belief that we will continue to change the treatment paradigm and provide more women with uterine fibroids and effective treatment for their heavy menstrual bleeding in the future. In addition to leading on market share, MYFEMBREE is helping to drive the expansion of use of GnRH antagonist overall in uterine fibroids. In our last earnings call, we reported that the GnRH antagonist market had grown by 137% since MYFEMBREE launch, and now we're proud to report that growth has further expanded to 180%.

In addition to increasing the overall class volume, MYFEMBREE is also continuing to attract new prescribers to the class. Over 2,400 HCPs have now prescribed MYFEMBREE, which is a 41% increase over what was reported last quarter. And for 61% of these prescribers, MYFEMBREE was the first GnRH antagonist they had written for uterine fibroids. Ultimately, it's class growth that will lead to reaching far more women who can benefit from this product, and the market trend shows that MYFEMBREE is continuing to serve as a catalyst for continued class expansion in uterine fibroids.

ACOG guidelines emphasize the importance of gynecologists utilizing shared decision-making with their patients when making a treatment decision. And our research shows that many women with uterine fibroids want to play an active role of selecting a treatment but lack the information needed to do so. Additionally, our research shows that when a patient requests a specific treatment, the majority of gynecologists are likely to fulfill that request. With this in mind, in mid-June, we launched a multichannel consumer campaign, leveraging targeted media to drive increased patient awareness and engagement.

The Perfectly Imperfect Life campaign is designed to efficiently reach those who most resonate with these messages and are most likely to take action. While very early, initial indicators are already showing an impact on consumer activity and we believe that patient

activation is an important part of our strategy to redefine care in uterine fibroids. We expect that patient activation through this campaign will continue to drive patients to engage with their HCP partners on treatment options for uterine fibroids and accelerate MYFEMBREE utilization and further growth in the class overall.

As we've discussed, MYFEMBREE is already evolving the uterine fibroids market and changing the treatment paradigm. Our progress to-date and the building momentum drives our continued confidence that over time, we will be able to advance and redefine care for women with uterine fibroids. Shifting gears now to endometriosis. As you know, our MYFEMBREE sNDA is currently under review for endometriosis-associated pain. Endometriosis is a significant opportunity given the unmet need that remains for these patients.

It impacts approximately 8 million women in the U.S., of which 6 million experience often debilitating symptoms, which can significantly impact their quality of life. This underscores the high unmet need for this disease. When we ask gynecologists and patients what they're looking for in a treatment for endometriosis-associated pain, they say that they want medical treatments that are effective, perhaps reducing the need for opioids, reduce the need for surgery, have a tolerable safety profile and are affordable and easy to access.

Should the FDA grant approval by the PDUFA date, we are prepared to launch MYFEMBREE in endometriosis in August. This launch will have significant synergies, both from a strategic and execution perspective with our current uterine fibroid efforts, enabling us to accelerate quickly into this new market while continuing to shape the treatment paradigm in uterine fibroids as well.

I will now turn the call over to Uneek to provide a financial review.

Uneek Mehra Myovant Sciences Ltd. - Chief Financial & Business Officer

Thank you, Lauren. My comments today will focus on the highlights of our financial performance in the first quarter. Please refer to our press release and Form 10-Q issued earlier today for additional information. Let's begin with revenue. Myovant recorded \$116.5 million in total revenues in the first quarter. Q1 net product revenue was \$41.4 million. ORGOVYX net revenue was \$36 million, reflecting 22% quarterly sequential net sales growth and 26% quarterly sequential commercial demand volume growth. The gross to net deduction for ORGOVYX in the first quarter was approximately 44%, which was near the upper end of our expected range due to quarterly fluctuations in the timing of Medicare Part D rebates.

As Lauren mentioned, we continue to expect ORGOVYX gross-to-net deductions to be in the low to mid-40% for this fiscal year. MYFEMBREE net revenue was \$4 million for the first quarter, reflecting 54% quarterly sequential commercial demand volume growth. Consistent with the prior quarter, we recorded \$25.1 million of Pfizer collaboration revenue, representing \$21 million related to the partial recognition of the upfront payment received from Pfizer and \$4.1 million related to the partial recognition of \$100 million uterine fibroid regulatory milestone payments.

For the first quarter, we also recorded \$50 million of Accord license revenue, which consisted of the upfront payment we received from Accord in May 2022. Moving on to the other highlights of our income statement; cost of product revenue for the first quarter was \$4.9 million, largely comprised of expenses related to the cost of goods sold as well as royalties on net sales of relugolix payable to Takeda. Collaboration expense for the first quarter was \$18 million, reflecting Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S.

R&D expense in the first quarter was \$23.9 million compared to \$30.9 million for the comparable prior year period. The decrease primarily reflects a reduction in clinical study costs due to the completion and winddown of Myovant's Phase III, LIBERTY, HERO, and SPIRIT clinical studies. SG&A expense in the first quarter was \$79 million compared to \$61.2 million for the comparable prior year period. The increase primarily reflects higher expenses to support the ORGOVYX and MYFEMBREE commercialization activities in the U.S., including higher personnel-related costs, patient activation costs, particularly for MYFEMBREE as well as a banker fee associated with the Accord license agreement.

Income tax expense in the first quarter was \$8.2 million compared to \$900,000 in the comparable prior year period. The increase was driven primarily by the implementation of the amendments to Internal Revenue Code Section 174 pertaining to the amortization of R&D expenditures. These amendments became applicable for Myovant during the first quarter. We expect our total tax expense for fiscal

2022 to be approximately \$23 million to \$25 million. Myovant generated a net loss of \$21.2 million in the first quarter. On a per share basis, net loss was \$0.22 for the quarter.

Looking ahead, we expect R&D expenses in the future quarters of fiscal 2022 to be higher than the first quarter, driven largely by spending on relugolix life cycle opportunities such as the Phase III SERENE study as well as on post-marketing requirements as agreed upon with the FDA. SG&A expenses in future quarters of fiscal 2022 are expected to be higher than the first quarter, driven largely by marketing and promotional expenses to support the ongoing commercialization of ORGOVYX and MYFEMBREE in the U.S., including annualization of MYFEMBREE marketing and promotional spend and targeted patient activation primarily from MYFEMBREE.

Despite the challenging overall macroeconomic environment, Myovant's balance sheet remains strong. We ended the first quarter with total cash, marketable securities and committed financing of \$400 million comprised of \$358.7 million of cash and marketable securities and \$41.3 million of capacity remaining under the loan facility extended to us by Sumitomo Pharma, our majority shareholder.

Our current liquidity position, coupled with additional potential future milestone payments from our collaboration and commercialization partners, sharing of certain relugolix-related development and commercial expenses with Pfizer as well as the anticipated increase in ORGOVYX and MYFEMBREE revenues puts Myovant in an excellent financial position to successfully deliver on our key growth drivers.

I will now turn it back over to Dave for key closing remarks.

David C. Marek Myovant Sciences Ltd. - CEO & Director

Thank you, Uneek and Lauren. We believe Myovant is well-positioned to demonstrate strong performance throughout 2022. We're focused on delivering for today as we continue to drive broad adoption of ORGOVYX across patient types and treatment settings as we advance our aspiration to create a new standard of care in advanced prostate cancer. For MYFEMBREE, our differentiated clinical profile and commercial execution are helping us to extend market leadership while expanding the GnRH antagonist class as we look to redefine care for women with uterine fibroids.

Our strategic partnerships outside of the U.S. will continue to expand our patient impact globally as we grow our reach in Europe and Canada. And our strong balance sheet allows us to continue driving commercial execution while building for tomorrow. We're engaging with the FDA in labeling discussions for MYFEMBREE for endometriosis-associated pain and look forward to the FDA's decision on our sNDA by its August 6 PDUFA date.

We remain confident in our application and if approved, we look forward to bringing this meaningful therapy to patients later this quarter. We have additional exciting milestones ahead. And as previously mentioned we intend to share details on potential new pipeline programs later this year.

Thank you for your attention, and I'll turn the call over to the operator to begin the Q&A session.

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions) Your now first question coming from the line of Phil Nadeau with Cowen.

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

Congrats on progress. First, David, one on the endometriosis label expansion that you just referred to. Has Myovant got any more information on the deficiencies that the FDA had identified in its prior communication? And in light of the labeling negotiations, does it now seem like any deficiencies have been resolved?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Thanks, Phil. I'll let Juan Camilo address that.

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

Yes. Phil, as you know, we don't usually consider appropriate commenting on our ongoing discussion with the FDA. What we are reporting is that we've entered labeling negotiations. We continue to collaborate with the FDA through the review. Remain very confident in the profile of MYFEMBREE in the new indication and look forward to the FDA making their final decision on the PDUFA date.

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

And then second, on the launch, assuming approval in August, the rate at which you captured number 1 share in uterine fibroids has been impressive. Could we expect a same trajectory of share gains in endometriosis? Are there any unique features of the endometriosis market that would make the uptake of MYFEMBREE either faster or slower?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Well, I think, Lauren, I'll let you address this, but just as kind of a lead-in -- we're really excited about the potential if we do get approved in endometriosis. We think a lot of the same characteristics that the customer base is looking for in uterine fibroids parallels to what they're looking for in endometriosis. Lauren, I'll let you add some additional color to that.

Lauren Merendino Myovant Sciences Ltd. - Chief Commercial Officer

Yes. We're very excited about the opportunity should the FDA grant our approval and our team is prepared for that launch. We believe it's a different market. But our clinical profile is favorable in that market. So we're excited about the opportunity. Additionally, because we have already established MYFEMBREE for uterine fibroids we think there are some factors that are beneficial that set us up positively in endometriosis. And that is, number one, from a payer perspective, we already have payer coverage established for uterine fibroids and this would be considered a line extension.

So we believe we can move quickly to secure payer coverage. Secondly, we've got a base of prescribers that have experience with MYFEMBREE now, and we think that -- since their experience has been positive that, that will translate well to treating their endometriosis patients. And then finally, we think that there's tremendous synergy here across both indications because there's high overlap of the prescribers. And so therefore, from a field perspective, there's tremendous synergy and that we'll be able to realize the opportunity quickly.

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

That's great. One last financial question from us on the taxes. I think you said \$23 million to \$25 million in taxes in 2022. Can you remind us why you owe taxes in 2022? I missed it in the prepared remarks and whether we should model taxes for future years even if Myovant has not achieved profitability?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Yes. Uneek?

Uneek Mehra Myovant Sciences Ltd. - Chief Financial & Business Officer

Yes. Thanks, Phil. I mean, I think, look, as per the prepared remarks, and I think you will be seeing this across companies that now with the Section 174 amendments being more a possibility, there's still legislation that could defer this amendment to later years, but we've taken the sort of conservative and prudent approach to book the taxes per that. We also have a policy of doing sort of our deferred tax.

We have a full sort of a valuation reserve for that. When you combine those 2, Phil, we thought it's appropriate to start booking the taxes for fiscal '22 in line with sort of our exposure. Now as regards to the outer years, we still have to determine that depending on these amendments, applicability as well as our sort of taxable income in those years, but at least we thought we should give the guidance for this year that we have visibility to right now.

Operator

And our next question coming from the line of Brian Skorney with Baird.

Brian Peter Skorney Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst

I was hoping you can help us understand how important you think the sNDA to include the 2-year safety data from Liberty is? Maybe you could just talk through how you think that could potentially differentiate ORGOVYX and Orion and just how you think that impacts any sort of near-term commercial ramp up?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Yes. Why don't I start with Juan Camilo and then Lauren, if you could add on.

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

Yes. Thanks, Dave and Hi Brian. I think that for -- maybe we should just remember what the data from the randomized withdrawal study showed. This was the second year of our LIBERTY program. And in this study, we re-randomized patients into continuing on therapy with MYFEMBREE or taking placebo. And we demonstrated how stopping therapy and the placebo group led to returning of heavy menstrual bleeding and how retreating these patients where we regain the control that we have already seen, therefore, demonstrating that the long-term treatment with MYFEMBREE provides efficacy.

We've submitted this data. We also generated additional safety data for the long term, including bone mineral density. So we provided this data to the FDA and of course, pending the review, we look for capturing some of those concepts about efficacy and safety for the longer term in the label. I'll also remind you that this is the only program that has at least showed for now showed 2-year data in uterine fibrous for a GnRH antagonist.

David C. Marek Myovant Sciences Ltd. - CEO & Director

Yes. I think -- and also when you look at that, Brian, in terms of how it matches to uterine fibroids, we know that's a chronic condition. And therefore, from the very outset, we were looking to establish a program that would help clinicians understand if they were going to treat longer term -- if they could have a therapeutic option that could extend that. So -- and then from a competitive perspective, Lauren?

Lauren Merendino Myovant Sciences Ltd. - Chief Commercial Officer

Well, I mean, we're always careful when things are under review with the FDA, but I would say that it would be a differentiator from a competitive perspective where we could get this in our label and enable us to speak to the long-term use of the product and the efficacy and safety profile that comes along with that.

Brian Peter Skorney Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst

Maybe just as a quick follow-up. I mean it's obviously a 2-year study, so maybe it doesn't address the question in terms of the limitation on label. But is there any thought about a way to eventually get around the 24-month limitation of use? Do you think that's feasible or do you think the continued bone loss is a risk enough that limits that?

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

Yes. Of course, that is top of mind to us, Brian. And we are looking at how we could potentially get to that. We certainly provided the 2-year data for the uterine fibroids study. We will, in the future, as we've said before, provide the 2-year data for the endometriosis if we were to get approved by the FDA for endometriosis in the coming weeks. But we also are, as you know, running now or will start running a post-marketing requirement by FDA that will get us up to 4 years of data, BMD data with MYFEMBREE. And we believe that all that data combined may potentially in the future allow us to have an impact on the duration of use. But again, it's hard to speculate what the FDA will think until we have the data and we're able to provide it. But it's something we think constantly on how to potentially address it.

Operator

And our next question coming from the line of Eric Joseph with JPMorgan.

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

Just a couple on MYFEMBREE. It sounds like you're expecting a shorter payer review cycle in endometriosis assuming approval. How quickly if approved do you expect endometriosis to be a contributor to total MYFEMBREE uptake? And will you have visibility on uptake

between these 2 indications, endometriosis and uterine fibroids. And then if I could try to follow up on what a label might look like and these ongoing labeling discussions. Like the current U.S. label already has warnings for fatigue and the duration limitation. Is it safe to assume that this -- the current label is sort of the floor in terms of sort of warning language? Is it possible that endometriosis might lead to a more restrictive or conservative label or is it really more of trying to create some relaxing of these criteria in endometriosis?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Yes. Well, thank you, Eric. I think regarding any speculation on the label, as you know, we really don't want to anticipate where FDA might go. As Juan Camilo mentioned, discussions are underway with FDA, and they'll make their assessment on endometriosis. If we were to get endometriosis approved, as mentioned, we think that there's really a strong foundation of prescribing that already exists. Remember, one of the key benefits in our plan regarding MYFEMBREE was the same brand, the same dose, the same one pill, once-a-day simplicity that physicians are accustomed to in uterine fibroids, if approved, could be applied to endometriosis. We think that's a huge advantage for gynecologists who really value simplicity of dosing and the experience that they've gained on uterine fibroids, we believe, can easily transfer over to endometriosis. So we're very excited about the launch potential if we get to that point. And we think the opportunity to really help women with uterine fibroids is very significant for us.

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

Okay. And in terms of, I guess, visibility on uptake, between uterine fibrosis and endometriosis is there sort of the ability to do that?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Yes. I mean I think from the standpoint of physician awareness of MYFEMBREE, it's already very high for uterine fibroids, and that will translate over pretty significantly to endometriosis. Lauren, maybe you want to talk about discussions with payers and other potential levers for uptake.

Lauren Merendino Myovant Sciences Ltd. - Chief Commercial Officer

Well, Eric, just to clarify, is this a question around the data, the transparency of the data between the indications? Is that what you're asking? I believe that's what you're asking. So we will have the ability to separate out the data, but it will require more analysis than it has so far. So of course, having one product with a single indication, every prescription, we know is for that indication. In the future, we'll need to do additional claims analysis and then apply that to the prescription data, but we will be able to have visibility. Does that answer your question? We may have lost there?

Operator

And our next question coming from the line of Madhu Kumar with Goldman Sachs.

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

First one is really on cash runway. So how are you thinking about kind of the ongoing cash burn through the potential launch into endometriosis and kind of the runway given the burn this quarter kind of excluding the Accord recognition of revenue?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Yes. I'll start, and then I'll turn it over to Uneek. I think one thing to remember, if we are approved for endometriosis, the efficiencies that we really have with our current MYFEMBREE promotion, given it's the same -- largely the same physician pace. We have no plans to expand the field force or any other significant activities around that. So when you reference endometriosis just remember that's a very efficient or would be a very efficient launch for us and fit within our commercial engine that we have now. Uneek?

Uneek Mehra Myovant Sciences Ltd. - Chief Financial & Business Officer

Yes. And Madhu, just to give color, I think you will notice a net cash burn of about \$75 million from the financials. Of course, we benefited from the receipt of the Accord upfront payment -- so if you sort of take that back, it's about \$120 million or so cash burn. Now typically, in the first quarter of the fiscal year, we have a higher cash burn because that's when we have personnel-related payments go out. When I look at the remainder of the year, I think we feel pretty comfortable with the cash that we have that we will be able to resource allocate both for endometriosis, uterine fibroids and then, of course, ORGOVYX.

And then we do want to flag that I think should endometriosis get approved in August, we would expect \$100 million milestone coming

from Pfizer our way. So that is also factored into our overall cash flow forecast. But with the Pfizer cost share, with the milestone payments we have, we again, feel very comfortable in our financial position, our balance sheet strength for continuing on our key drivers for this fiscal year.

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

Great. So another question was around ORGOVYX in kind of the current quarter. So how do you think the kind of go-forward trajectory of ORGOVYX growth, given what you've seen in the last few quarters and kind of like the rate of revenue growth over the next few quarters?

David C. Marek *Myovant Sciences Ltd. - CEO & Director*

Well, we haven't provided guidance for the remainder of this year, as you know, Madhu, but we're very excited about the continued quarter-to-quarter new patient starts we see. As Lauren mentioned, we took another significant step up to 18,000 patients for ORGOVYX for this quarter. We're adding more accounts, and we continue to see broad adoption across both treatment settings as well as patient types. So we are very optimistic about the continued momentum that we have, and we're very excited about how this year is shaping up for ORGOVYX.

Operator

And our next question coming from the line of Roanna Ruiz with SVB Securities.

Roanna Clarissa H. Ruiz *SVB Securities LLC, Research Division - Director of Infectious Disease, Endocrine & Cardiovascular Disorders & Senior Research Analyst*

So one question for MYFEMBREE and then I'll switch to ORGOVYX. So for MYFEMBREE, could you give us a little more detail on how its gross to net might evolve for the remainder of the year, particularly assuming the August PDUFA goes through and MYFEMBREE gets approved for endometriosis?

David C. Marek *Myovant Sciences Ltd. - CEO & Director*

Lauren, do you want to take that?

Lauren Merendino *Myovant Sciences Ltd. - Chief Commercial Officer*

Yes. So from a gross to net perspective, our gross to net is primarily driven by our strategy to make our product easy to access. And that's great first experience for both physicians and for patients. And so we continue to have that strategy and believe that's important at this point in our growth trajectory in order to continue to gain physician experience with the product in uterine fibroids today and hopefully in endometriosis tomorrow. So as far as guidance on the actual gross to net, I'll leave that to Uneek.

Uneek Mehra *Myovant Sciences Ltd. - Chief Financial & Business Officer*

Yes. And Roanna, MYFEMBREE is still sort of just covering up, getting beyond one year. So we don't feel comfortable giving a guidance as yet. There are still fluctuations that are happening. The only color I'll add to what Lauren said is, as you can imagine, MYFEMBREE right now, the big drivers of gross to net unlike ORGOVYX are commercial rebates and our co-pays. And as Lauren said, our focus right now is on sort of patient accumulation, making sure patients are satisfied and over time that those elements should improve, but we still need more time to be able to sort of see through the trends of that and then come with a guidance which we have done for ORGOVYX, but not yet for MYFEMBREE.

Roanna Clarissa H. Ruiz *SVB Securities LLC, Research Division - Director of Infectious Disease, Endocrine & Cardiovascular Disorders & Senior Research Analyst*

And for ORGOVYX, I was also curious, I know you walked us through the distribution of account types that are using and prescribing ORGOVYX like academic centers, IDNs, dispensing clinics, etcetera. I was curious, in your view, do you think the relative share of these different stakeholders could stay the same or could it shift going forward?

Lauren Merendino Myovant Sciences Ltd. - Chief Commercial Officer

Yes, very good question. We continue to see -- I mean, I provided the growth rates for the quarter. I will say that as far as where we see the strongest trajectory would be with our urology dispensing clinics. So I don't have a crystal ball. I can't tell you what the share will look like in the future. But the dispensing clinics and the academic IDN are our biggest growth drivers, but dispensing clinics might outpace in the longer term.

David C. Marek Myovant Sciences Ltd. - CEO & Director

Yes. And Roanna, when you think about the utilization by urologists for a lot of the new start patients -- we really are very pleased that we're having such strong uptake with new starts, men who are just starting ADT therapy because we really believe that will pull through from urologists to oncologists over time. So we think that will help us not only with urologists now but even help accelerate with oncologists over time.

Operator

Our next question coming from the line of Gavin Clark-Gartner with Evercore ISI.

Gavin Clark-Gartner Evercore ISI Institutional Equities, Research Division - Analyst

Just had 2. First on MYFEMBREE. So last year, the SERENE trial was put on hold as you adjusted the BMD monitoring and the protocol. Can you just remind us what changes the FDA wanted?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Juan Camilo?

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

Yes. Gavin, there were a couple of things. You may remember that initially, we were running the trial in an otherwise healthy population of women seeking contraception. After discussion with the FDA, we've changed that population to women with uterine fibroids or endometriosis, which is the target population for that indication in the context of our current and, hopefully, future label if endometriosis is approved. And then we added the monitoring for BMD that the FDA was requiring. Those are the major changes that we made to the study design.

Gavin Clark-Gartner Evercore ISI Institutional Equities, Research Division - Analyst

Got it. And then on ORGOVYX, we noticed that you changed the specialty pharmacy network last month, which has made the IQVIA script capture pretty poor, though Symphony seems to be consistent. I'm just wondering if you can elaborate on the rationale for making that switch?

David C. Marek Myovant Sciences Ltd. - CEO & Director

Absolutely. Lauren?

Lauren Merendino Myovant Sciences Ltd. - Chief Commercial Officer

Yes. So back in April, CVS acquired U.S. Bioservices, which was one of the 2 SPs in our network. And so in order to maintain our distribution model through the independent SPs, we needed to transition our business from U.S. Bioservices and we switched over to Onco360 at the beginning of July. The transition has gone very smoothly. There's been no disruptions or significant complications and the customer feedback has been tremendously positive. In fact, they have a lot of experience with Onco360 on other products than in the past. So we've heard nothing but positive feedback on the transition.

Operator

Thank you. I will now turn the call back over to Mr. David Marek for closing remarks.

David C. Marek Myovant Sciences Ltd. - CEO & Director

Thank you, operator. We remain committed to our mission to redefine care for the patients that we serve in women's health and in hormone-sensitive cancers. We're well-positioned. We have 2 differentiated therapies generating significant growth. We have pipeline

opportunities not only now but into the future. And we have a strong balance sheet to enable our efforts to deliver sustainable long-term value. So thank you very much for joining us. I look forward to keeping you updated on our progress. Have a good day.

Operator

Ladies and gentlemen, this concludes Myovant Sciences first fiscal quarter 2022 earnings conference call. Thank you for your participation. You may now disconnect.

DISCLAIMER

Refinitiv reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Briefs are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT BRIEFS REFLECTS REFINITIV'S SUBJECTIVE CONDENSED PARAPHRASE OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT BRIEF. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2022 Refinitiv. All Rights Reserved.