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Myovant Sciences Ltd. NYSE:MYOV

FQ4 2022 Earnings Call Transcripts

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Presentation

Operator

Good day, everyone, and welcome to Myovant Sciences Fourth Quarter and Fiscal Year 2021 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
Chief Financial & Business Officer

Thank you, Operator. Good morning, and thank you for joining us today to discuss Myovant's corporate update and review the financial results of Myovant's fourth fiscal quarter and fiscal year 2021. 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 that will be presented during today's webcast are available on our Investor Relations website, investors.myovant.com. Today, we will be referring to our fourth fiscal quarter, representing the 3 months ended March 31, 2022, as our fourth quarter or Q4 throughout this presentation. We will also refer to our fiscal year representing the 12 months ended March 31, 2022, as our fiscal year 2021.

During this conference call, we will be making forward-looking statements. These include plans and expectations with respect to our product, 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.

David C. Marek
CEO & Director

Thank you, Uneek, and good morning, everyone. Fiscal year 2021 was a transformative year for Myovant, as we firmly advanced our commercial capabilities and maintained the financial strength to continue growing our brands while deepening our pipeline for the future. We're energized by the significant momentum that we've generated and believed Myovant is on a trajectory for substantial growth in the year ahead.

We had a strong finish to the fiscal year as we successfully drove commercial demand for both ORGOVYX and MYFEMBREE. For the quarter, we expanded utilization of ORGOVYX for men with advanced prostate cancer, with demand volume growth of 18%, demonstrating continued adoption across a broad range of patient types and treatment setting. With MYFEMBREE, we've already achieved market leadership in new-to-brand prescription share while substantially growing the GnRH antagonist class for the treatment of uterine fibroids. And outside the U.S., RYEQO is more widely available for women with uterine fibroids, now launched in 17 European countries. As we close out our fiscal year, Myovant recorded $231 million of total revenue, including net product revenues of $94.3 million. Of that, $32.4 million of net product revenues were recorded in the fourth fiscal quarter.

Moving to regulatory and business development updates. As it relates to our MYFEMBREE sNDA for endometriosis-associated pain, the FDA has extended the review period to allow for review of additional analyses if requested and we've provided regarding bone mineral density. The extended PDUFA goal date is August 6 of this year. We remain

confident in the clinical profile of MYFEMBREE and its potential to become a meaningfully differentiated therapeutic option for the management of endometriosis-associated pain. We'll continue to work closely with the FDA to support the advancement of our sNDA. We're also pleased to announce the results of our SPIRIT long-term extension study of MYFEMBREE in women with endometriosis, where we are the only GnRH antagonist, who have demonstrated a consistent efficacy and safety profile through 2 years.

Moving to our oncology business, I'm excited to share 2 important developments. As we announced in April, the European Commission approved ORGOVYX as the first and only oral androgen deprivation therapy for adult patients with advanced hormone-sensitive prostate cancer. And on the heels of this approval, we just announced a highly anticipated exclusive license agreement with Accord Healthcare for the commercialization of ORGOVYX in Europe. Once launched in Europe, patients will have the ability to rapidly reduce testosterone without hormonal flare in a convenient oral form. We believe that over time, ORGOVYX has the potential to change the standard of care in Europe, for men with advanced hormone-sensitive prostate cancer. We entered this fiscal year in a strong financial position with cash and committed financing of just over $475 million, enabling us to fully support ORGOVYX and MYFEMBREE commercialization activities while seeking to expand our pipeline.

Now let's review the exclusive license agreement with Accord Healthcare that was just announced yesterday. In Accord, we have found the ideal partner with the existing capabilities already in place and importantly, the passion and the commitment to unlock the commercial potential of ORGOVYX in Europe. Accord is one of the fastest-growing pharmaceutical companies in Europe and has one of the largest market footprints in oncology with over 40 oncology-related treatments. We're delighted to join forces with Accord to make available ORGOVYX in Europe as the first and only oral androgen deprivation therapy for men with advanced hormone-sensitive prostate cancer.

Under the agreement, Accord obtains rights to commercialize ORGOVYX in Europe and potentially other select markets. We're very pleased with the favorable deal economics with a total value of up to $140.5 million, where Myovant will receive an upfront payment of $50 million and up to $90.5 million in milestone payments, including $15 million of near-term milestones. In addition, Myovant will receive tiered royalties from the high teens to the mid-20s on net sales. We're excited with our new partnership with Accord and look forward to European launches of ORGOVYX beginning later this year.

So as you can see, we've had a number of recent positive developments, which position Myovant for a strong 2022. Now for a more in-depth review of our commercial performance, I'll turn the call over to Lauren.

Lauren Merendino
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 performance. ORGOVYX showed continued momentum in Q4, further advancing our progress in establishing it as an androgen deprivation standard of care. Since launching in January 2021, approximately 14,500 men have been treated with ORGOVYX, demonstrating continuing growth of patient and prescriber demand. ORGOVYX delivered $83 million of net revenue for the fiscal year with $29.4 million in fiscal Q4. We're proud to report that in this quarter, we also drilled 18% sequential commercial demand growth over the prior quarter, demonstrating the continuing expansion of ORGOVYX use.

ORGOVYX's new patient starts grew significantly this quarter, with an additional 3,500 men initiating ORGOVYX in Q4, representing a 32% increase compared to last quarter and bringing the total estimated patients treated since launch to 14,500. It's important to note that these patients represent a broad range of patient types. Recent analyses of our specialty pharmacy and claims data shows that ORGOVYX is being used broadly in both ADT naive and transition patients as well as across patients with different stages of disease.

We also see that about 20% of patients have used ORGOVYX in combination with other prostate cancer therapies, which is consistent with combination used in the ADT market overall. This confirms that prescribers see the benefit of the ORGOVYX clinical profile across a spectrum of prostate cancer patients.

In fiscal Q4, we saw 21% quarter-over-quarter growth of net sales despite the typical January seasonality due to the annual reset of the Medicare Part D benefit and commercial payer deductible. When we look at month-to-month refill rates, there was an impact in January, but they returned to normal levels above 90% in February and March. During the same time period, the new patient starts trend continued and was not impacted by this payer dynamics.

In addition to this typical seasonality, there was an Omicron surge in January that impacted our access to physicians' offices and may have had an impact on patient flow. Despite these short-term dynamics, the underlying fundamentals of our business remains strong, including the broad coverage we've established to enable patient access and important leading indicators like the new patient starts trend, the breadth of use across patient types, the breadth and growth of account adoption and increasing prescriber satisfaction. The combination of these factors gives us conviction in our future growth trajectory.

So let's explore each of these further. Just as we saw ORGOVYX being used across the breadth of patient types, we're also seeing use across the range of treatment settings. About 80% of ORGOVYX business comes from the dispensing clinics and academic and IDN 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 the Academic/IDN segment, primarily driven by oncologists, is driving 35% of our business and is one of the fastest growing segments. Most importantly, we're seeing double-digit growth across all segments with almost 20% volume growth overall. This demonstrates that our business is well balanced across prescriber account types as well as across the spectrum of patients.

A key driver of the growth we've seen to date is the differentiated clinical profile of ORGOVYX. For the first time, prescribers have a treatment that provides fast-on, fast-off profound and sustained control of testosterone in a convenient 1 pill once a day dose. This profile is unique and compelling, and as prescriber experience is growing, so is their satisfaction, which has now risen to 73%. Overall, this growing prescriber satisfaction, coupled with our growth to date and the breadth of our business gives us further confidence that the growth trajectory for ORGOVYX will continue in the year ahead. With 300,000 men being treated with ADT each year, there continues to be tremendous opportunity for us to expand our impact and establish ORGOVYX as the new standard of care in advanced prostate cancer.

Now turning to the launch update for MYFEMBREE, fiscal Q4 was a milestone quarter for MYFEMBREE as we surpassed our competitor to become the market leader for uterine fibroid patients new to GnRH therapy, capturing 59% new-to-brand prescription share. Over 3,400 women have been treated with MYFEMBREE since launch, more than doubling the number of patients treated through fiscal Q3 and reflecting the growing momentum we're seeing with this brand.

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 the GnRH antagonists in uterine fibroids has grown by 137%. This demonstrates that MYFEMBREE is expanding the patient population that prescribers believe will benefit from this class of treatment. In fiscal year 2021, we recognized $6.4 million of net revenue with $2.2 million in fiscal Q4. MYFEMBREE commercial demand nearly doubled in Q4 versus Q3, but this growth was offset by a lower net price due to the January reset of commercial payer deductibles, increasing copay card benefits. This seasonality is a dynamic seen across our industry, and we expect it to improve in subsequent quarters as patients work through their annual deductible.

The new brand prescription share trend shows how quickly MYFEMBREE has established market leadership in uterine

fibroids. 6 months post launch, half of patients initiating GnRH therapy were receiving MYFEMBREE, and within 8 months, we surpassed our competitor to become the preferred treatment for these patients. We attribute this rapid growth trajectory to MYFEMBREE's differentiated clinical profile and our focused commercial strategy, which we believe will continue to expand our market leadership in the future. MYFEMBREE's compelling clinical profile and our strategic approach is also accelerating overall growth of the GnRH antagonist class for uterine fibroids.

On our last earnings call, we were proud to show the GnRH antagonist market has grown by 81% since MYFEMBREE launch. And now we're happy to report that growth has further expanded to 137%, demonstrating an acceleration of adoption of the class. In addition to increasing the overall class volume, MYFEMBREE is also attracting new prescribers to the class. Over 1,700 HCPs have prescribed to date and for 60% 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 momentum in the market is showing that MYFEMBREE is leading the mindset shift that will continue to expand this market over the long term.

From the start, we knew that providing a positive first experience for prescribers and patients was essential in this market, and that starts with access. We've now secured coverage for 93% or 165 million commercial lives, an increase of nearly $17 million lives since January. With this, we can proudly say that we have established broad access well in advance of our expectations. While access enables prescribing, it's really MYFEMBREE's differentiated clinical profile that's driving the increasing momentum around this brand.

MYFEMBREE provides substantial and sustained reduction in menstrual blood loss in a convenient 1 pill once a day dose, a profile that is clearly resonating with OB/GYN. 9 out of 10 HCPs are now aware of MYFEMBREE, and even more importantly, nearly 90% of our priority customers intend to prescribe MYFEMBREE in the next 3 months. This indicates that physicians are finding the MYFEMBREE clinical profile compelling and aligned with their treatment goals. With 5 million women seeking treatment for urine fibroids and 3 million of them being failed by their first-line therapy, we believe there is a tremendous opportunity for MYFEMBREE to make a difference for these women. Based on our progress to date and the building momentum, we believe that we are poised to evolve this market and ultimately redefine the treatment paradigm in uterine fibroid.

And now I'll turn it over to Juan Camilo to provide a clinical and regulatory update. Juan Camilo?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Thank you, Lauren. As announced last week, the FDA extended the review period for the MYFEMBREE sNDA for management of moderate to severe pain associated with endometriosis. This extension will allow the agency time to review additional analysis of bone mineral density data we provided upon their request. No new clinical data was requested by the agency. The submission of this additional analysis has been determined by the FDA to constitute a major amendment to the sNDA, resulting in an extension of the PDUFA goal date to August 6.

As is our policy not to discuss ongoing interactions with regulatory agencies during the review of an application, we are not able to provide additional details at this time. We remain confident in the efficacy and safety profile of MYFEMBREE in women with endometriosis-associated pain and its potential to become an important treatment option, and we'll continue to work closely with FDA to support the review of the sNDA.

Now let me share with you the top line results of the second year of treatment in the SPIRIT long-term extension study. Remember that relugolix combination therapy is the only GnRH antagonist for which 2-year efficacy and safety data have been reported. As you may remember, we met with moderate to severe pain associated with endometriosis, who participated and completed 1 of the 2 pivotal studies, SPIRIT 1 or SPIRIT 2 and who met all entry criteria were eligible to participate in an 80-week extension study in which all women received relugolix combination therapy, regardless of the treatment they received during the pivotal studies.

The co-primary endpoints for the long-term extension study were the proportion of responders on dysmenorrhea or menstrual pain and non-menstrual pelvic pain or NMPP and were assessed at week 52 and week 104. Responders were defined as those achieving a mean reduction in NRS scores of greater than or equal to 2.8 points for dysmenorrhea or greater than or equal to 2.1 points for NMPP, and no increase in use of analgesic medications. The initial analysis at week 52 was conducted after all patients have completed 28 weeks of treatment. Data from this analysis were previously presented and were included in the sNDA.

At the end of the first quarter of 2022, we completed the second year of treatment, which we are briefly summarizing here. Therefore, these 2-year data are not part of the sNDA currently under the review. As you can see, at week 52, 84.8% of women who received relugolix combination therapy continuously from baseline, met the definition of responder for dysmenorrhea and 73.6% met the definition of responder for NMPP. At week 104, 84.8% and 75.8% met the definition of responder for dysmenorrhea and NMPP respectively. These results demonstrate durability of treatment effect for after 2 years.

Safety data collected over after 2 years of treatment confirmed the safety profile of relugolix combination therapy previously reported with no new safety signals identified with an additional year of treatment. The most frequently reported adverse events remain headache, nasopharyngitis and hot flush. 2 additional pregnancies were reported in the relugolix combination therapy group during the second year of the long-term extension study.

Lastly, as shown by the orange line, bone mineral density remained stable through week 104 in women treated with relugolix combination therapy after minimal, non-clinically meaningful bone loss observed through week 24. In women treated with placebo for the first 24 weeks in charcoal, small gain was observed after week 24, which was followed by stabilization after initiation of relugolix combination therapy after week 104. In women treated initially with relugolix monotherapy for 12 weeks in blue, bone density decreases of about 2% were observed by week 12, which were followed by stabilization of an initiation of relugolix combination therapy and a trend towards recovery observed after week 24.

We are very proud of these results and look forward to presenting them with additional details at a scientific conference this summer, depending the outcome of the sNDA review, we plan to submit these data to the FDA in the first half of 2023. Once the protocol mandated post-treatment follow-up is completed.

I'll now turn the call over to Uneek to provide a financial review. Uneek?

Uneek Mehra
Chief Financial & Business Officer

Thank you, Juan Camilo. My comments today will focus on the highlights of our financial performance in the fourth fiscal quarter and fiscal year 2021. Please refer to our press release issued earlier today for additional information.

Let's begin with revenue. Myovant recorded $57.6 million in total revenues in the fourth quarter. Q4 net product revenue was $32.4 million. ORGOVYX net revenue was $29.4 million, reflecting 18% sequential demand volume growth and net price favorability. The gross to net deduction for ORGOVYX in fiscal fourth quarter was approximately 40%. We expect ORGOVYX gross to net to be in the low to mid-40% for the foreseeable future.

MYFEMBREE net revenue was $2.2 million for fourth quarter, reflecting nearly doubling of MYFEMBREE commercial demand volume compared to Q3, offset by a lower net price driven by higher copay card benefits. We recorded $25.1 million of Pfizer collaboration revenue, consisting of $21 million related to the partial recognition of the upfront payments received from Pfizer and $4.1 million related to the partial recognition of $100 million uterine fibroids regulatory milestone payment.

In future quarters, we will continue to amortize these milestones at the same amounts through the end of calendar year 2026 when the amortization period is scheduled to end. For the fiscal year 2021, we recorded $231 million of total revenue. Net product revenue was $94.3 million, consisting of net revenues from sales of ORGOVYX of $83 million, MYFEMBREE of $6.4 million and Richter's product supply and royalties of $5 million.

For the fiscal year 2021, Pfizer collaboration revenue was $105 million and consisted of $83.9 million related to the upfront payment received from Pfizer and $21.1 million related to the uterine fibroids regulatory milestone. For the fiscal year 2021, we also recorded $31.7 million of license and milestone revenue from Gedeon Richter, consisting of a $15 million regulatory milestone payment for the European Commission approval of RYEQO for uterine fibroids and $16.7 million related to the remaining portion of the upfront and initial milestone payment.

Moving on to other highlights of our income statement, cost of product revenue for the fourth quarter and fiscal year 2021 was $3.6 million and $11.5 million, respectively, largely comprised of expenses related to the cost of goods sold as well as the royalty on net sales of relugolix payable to Takeda. Collaboration expense for the fourth quarter and fiscal year 2021 was $14.1 million and $40 million, respectively, reflecting Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S.

R&D expense in the fourth quarter was $24.5 million compared to $21.6 million for the comparable prior year period. The increase in R&D expenses primarily reflects an increase in expenses associated with the hiring of Myovant's medical affairs organization and other personnel to support the U.S. launches of ORGOVYX and MYFEMBREE. For fiscal year 2021, R&D expense was $107.4 million compared to $136.7 million for the prior year. The decrease in R&D expenses primarily reflects a reduction in clinical study costs as a result of the completion and wind down of Myovant's Phase III clinical programs.

SG&A expense in the fourth quarter was $67.2 million compared to $78 million for the comparable prior year period. The decrease primarily reflects lower share-based compensation, partially offset by increased spending on commercial activities to support the U.S. launches of ORGOVYX and MYFEMBREE. For the fiscal year 2021, SG&A expense was $259.4 million compared to $181.4 million for the prior year, reflecting higher expenses to support the U.S. launches of ORGOVYX and MYFEMBREE.

Myovant generated a net loss of $59.3 million in the fourth quarter and $206 million for the fiscal year 2021. On a per share basis, net loss was $0.63 for the quarter and $2.22 for the full year. Looking ahead, we expect fiscal year 2022 R&D expenses to increase as compared to fiscal year 2021, driven largely by spending on relugolix life cycle opportunities such as the Phase III setting study as well as our post-marketing requirements as agreed upon with the FDA.

SG&A expenses in fiscal year 2022 are expected to increase as compared to fiscal year 2021 due to increased marketing and promotional expenses to support the ongoing commercialization of ORGOVYX and MYFEMBREE in the U.S., including annualization of the MYFEMBREE marketing and promotional spend and targeted patient activation for both brands.

We ended fiscal Q4 with total cash, marketable securities and committed financing of $475.5 million, comprised of $434.2 million of cash and marketable securities and $41.3 million of capacity remaining under the low-cost loan facility extended to us by Sumitomo Pharma, our majority shareholder. Additionally, we expect to receive an upfront payment of $50 million from Accord Healthcare in the first quarter of fiscal 2022. This coupled with additional potential future milestone payment, scaling 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 execute our commercial strategies while at the same time expanding our pipeline.

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

David C. Marek
CEO & Director

Thank you, Uneek, Juan Camilo and Lauren. We believe Myovant is positioned well for near-term and long-term sustainable growth. We have 2 differentiated brands in markets with high unmet needs, demonstrating substantial demand growth and supported by a strong collaboration with Pfizer in the U.S. Outside the U.S., our partnership with Gedeon Richter, coupled with our new partnership with Accord will continue to expand our patient impact globally.

Our strong balance sheet allows us to maximize our launches while enabling targeted investment in pipeline opportunities. And looking ahead, we remain confident in our sNDA for MYFEMBREE for endometriosis-associated pain and look forward to working with the FDA to potentially bring this meaningful therapy to patients. In addition, we have multiple opportunities to expand our global reach in both women's health and oncology. And later this year, we intend to share details of potential new pipeline programs.
Thank you for your attention, and I'll turn it over to the Operator to begin the Q&A session.

Question and Answer

Operator

[Operator Instructions] We will take our first question from Phil Nadeau with Cowen and Company.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

First question is commercially, you called out seasonality for both ORGOVYX and MYFEMBREE. I'm curious if you can quantify the impact on reported revenue of the seasonal factors. How much of a dollar size headwind was there in the quarter to those seasonal factors?

David C. Marek
CEO & Director

Yes, Phil, thanks for joining us. We haven't really put the math on specifically calling out what part of seasonality versus just general trends that are happening based on seasonality. So we did see significant demand growth, as we've mentioned across both ORGOVYX and MYFEMBREE. And so our patient volumes and new starts continue to grow. A little bit of the economics as it relates to pulling through on the revenue was clearly impacted to some degree by copay cards, et cetera, that were mentioned. But we're really encouraged by the overall continual generation of demand that we're seeing that's very consistent with prior quarters.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

Okay. Fair enough. And then I guess, a follow-up, which is somewhat unrelated, on the sNDA in endometriosis, I know you said you don't want to go into much more detail on the interactions, but you have disclosed that the FDA identified deficiencies and you've disclosed that you've submitted analysis on bone marrow density. So we're curious if you can give us any more information on either the deficiencies that were indicated by the FDA or exactly which analysis the agency requested?

David C. Marek
CEO & Director

Yes. Juan Camilo, do you want to take that?

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes. Phil, as we mentioned in our prior call, the FDA didn't specify in the first letter what deficiencies where they were referring to. And then as part of our ongoing review of the -- our discussions with the FDA as part of the review, we received their request for additional BMD analysis on data they already had. So we just provided those analyses. But we don't know how those 2 are related, and FDA has not communicated more details of that to us.

Philip M. Nadeau
Cowen and Company, LLC, Research Division

So you still actually haven't been specifically informed of the deficiencies that the FDA was referring to?

Juan Camilo Arjona Ferreira
Chief Medical Officer

No. We have not received the specifics beyond the request for the additional analysis that we received.

Operator

We will take our next question from Brian Skorney with Baird.

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

I have a question on the Accord Healthcare deal, just interested in hearing a little bit more about the capabilities here. It seems that they're largely a generics company. I was wondering, do you know how many branded drugs that they have on the market that are branded exclusive? And I know it's a bit of a different market, but I think they just launched leuprolide brand in the U.S. So I was just curious if you know if they had any intention of launching that in Europe and how that sort of efforts in prostate cancer in the U.S. drove at all your decision to partner with them?

David C. Marek
CEO & Director

Yes. Well, I'll take part of that, and then I'll turn it over to Lauren. Yes, certainly, there -- we are very impressed with their footprint in oncology. The brand that you mentioned is U.S. brand and not currently available in Europe. It could be available down the road. But right now, we are looking at really having a priority role within their oncology portfolio, which is really exciting. Lauren, do you want to talk about their portfolio?

Lauren Merendino
Chief Commercial Officer

Yes. So they have -- currently have 6 branded products across 3 therapeutic areas, with oncology being their primary focus. And I'll just add to Dave's comments, they have tremendous reach in Europe with 95% of the -- reaching 95% of the European population. And with their experience already in prostate cancer have made them a really desirable partner for ORGOVYX.

Operator

We will take our next question from Eric Joseph with JPMorgan.

Eric William Joseph
JPMorgan Chase & Co, Research Division

So just one on ORGOVYX commercial, I'm curious to know if you have a sense of what duration of therapy is among the legacy patients, I guess those that weren't new to brand in calendar Q1. I guess any insight on potential discontinuation rate? And I guess, what can be done for the short things up there. And I guess, with now having a little bit over a year's worth of experience into launch, are you in a place where you might be able to offer or start providing guidance for the full year? And then one modeling question as it relates to the Accord deal, can you just clarify how you're going to be reflecting the -- or treating the $50 million loss on payment on the earnings system?

David C. Marek
CEO & Director

Well, Eric, I'll start with; Lauren, if you could take the discontinuation rate for ORGOVYX and then the other 2 questions were for you Uneek. Lauren?

Lauren Merendino
Chief Commercial Officer

Yes. Thanks, Eric, for the question. So from a duration of therapy perspective, it can be challenging for us, as you know, with the limitations of our data, but also with the different ways that physicians utilize ADT. So of course, it can be used as a long-term therapy in which case, we do not have the tail of the data yet. So any estimation at this point would be an underestimation. But also some physicians use ADT products intermittently or can use it in the case of radiation for a shorter duration. So between limitations of our data, the time on market and the variability in the way that our product is used, it's very difficult to be able to give a duration of therapy estimate at this point.

David C. Marek
CEO & Director

And Uneek, you want to cover the guidance and how we'll record upfront?

Uneek Mehra
Chief Financial & Business Officer

Yes. Thanks, Eric, for the questions. On the guidance for ORGOVYX, I think you're seeing impressive growth both on new patient stats as well as on the demand, the broad account adoption as well, still relatively early, despite us now having also given guidance on the gross to net to give a formal guidance on the overall revenue numbers, I think we would need a few more quarters under our belt to be able to do that. Regarding your question on the accord milestone, so the $50 million, we expect -- we haven't finalized the revenue recognition with our auditors as yet. But I think given the service obligations under 606, we do expect the majority of that revenue to be recognized in fiscal year 2022.

Operator

We will take our next question from Madhu Kumar with Goldman Sachs.

Unknown Analyst

This is Rob on for Madhu. I was just wondering for the endometriosis PDUFA, do you -- do any of the bone mineral density questions from the FDA effective current approval in U.S.?

David C. Marek
CEO & Director

I'll let Juan Camilo take that.

Juan Camilo Arjona Ferreira
Chief Medical Officer

Yes, Rob. The request for additional analyses are to inform the review of the endometriosis associated pain indication that we've submitted. So we will continue to work with the FDA on that review, and look forward to the next steps with them between now and August 6.

Operator

We will take our next question from Roanna Ruiz with SVB Securities.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

A couple for me. For ORGOVYX, could you remind us how the gross to net dynamic evolved from fiscal 3Q to 4Q? And are you seeing any signs of stabilization, or could it still increase into the next couple of quarters?

Uneek Mehra
Chief Financial & Business Officer

Yes, Roanna. I can take that question. So between fiscal Q3 and Q4, I mean largely, we've seen approximately 40% gross to net in ORGOVYX and this is consistent with our guidance that we've given that it's around the low 40s to mid-40s, and that's the same we expect for the coming fiscal year. So I think we remain with that guidance on gross to net.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Okay, great. And still on ORGOVYX, I wasn't sure if I missed it. What has the reorder rates look like in the recent quarter? And I noticed you mentioned, there's a little bit of recent growth among academic or oncologist prescribers. Just curious what might be driving that as well?

David C. Marek
CEO & Director

Yes. I'll turn it over to Lauren here in just a second. I think that, with the academic, we're very happy with that -- with the growth that we're seeing across the different treatment settings. With the academic and IDNs as we may have mentioned that we see a predominant use with oncologists in that setting. So when we think of those within office dispensing that we mentioned, that's largely urologists, where this section is largely oncologists. So we're really happy to see substantial growth in both of those largest sectors, which combined make up about 80% of our overall volume. And Lauren?

Lauren Merendino
Chief Commercial Officer

Yes. And from the perspective of reorder rates, what I'll say is, when we look at the top 50 accounts for ADT volume, all 50 accounts are currently using ORGOVYX, and all of them are ordering on a regular basis, so on a monthly basis. So we see high reorder rates in our biggest customers, and that's really where we're focused.

Roanna Clarissa H. Ruiz
SVB Leerink LLC, Research Division

Okay, great. And last one for me, for my. I was curious, how your payer interactions gone so far? And are you exploring extra rebating strategies and to help get preferred status, things like that?

David C. Marek
CEO & Director

Lauren?

Lauren Merendino
Chief Commercial Officer

Yes. So obviously, we've made great progress on the payer front in our discussions to date in establishing our payer coverage, much quicker than we expected actually. So those discussions have gone extremely well. We've been very careful around rebating strategies, and we've tried to establish parity coverage. That has been our goal from the beginning, and that's where we've been successful.

The danger is going down the rebating route is that it becomes a competitive rate to the bottom. So we're not looking to start that, but rather to be competitive, and then we believe our clinical profile will have us come out on top, as you've seen from the NBRx data that's playing out as we expected.

David C. Marek
CEO & Director

Yes. Another point of reference, Roanna, when you think of the step through that some payers require, it step through oral contraceptives. And remember, there are 3 million women with uterine fibroids who have already been failed by their first-line therapy, which is typically uterine fibroids.

So while we could spend a lot of time trying to take that away, there are so many women who are already -- who've already stepped through those -- the initial therapy anyway. And so now it's really how do we capture those women that have already been through either unfortunately, many times -- one or 2 courses of oral contraceptives. So there is still tremendous headroom for us with our current contracting strategy, and we don't see that as what's getting in the way. It's really making sure that OB/GYNs understand the outstanding coverage that we have and the outstanding co-pay assistance that Lauren and her team have put in place.

Operator

[Operator Instructions] We will take our next question from Gavin Clark-Gartner with Evercore ISI.

Gavin Clark-Gartner
Evercore ISI Institutional Equities, Research Division

Multi-part. So you've heard from prescriber calls that there's strong interest in using ORGOVYX in combination with the second and third Gen AR block with a considerable market opportunity. But there is still some hesitations over the lack of data generated to date. So I just wanted to ask about the development about Phase I. I think there was Phase I trial, you sponsored testing Erleada and abiraterone combos. Wondering, if you can see the [indiscernible]. Secondly, I see there's a Janssen sponsored Phase II also testing Erleada plus ORGOVYX. Wondering what's your involvement in this trial? Third, I just wanted to hear any next steps on the ADT combo program, including potential XTANDI co-formulation type?

David C. Marek
CEO & Director

Okay. We'll see if we can get through those. And hopefully, we will not miss any of those parts of that -- of those. I think let me kick off just by saying the combination therapy data that we discussed earlier today, where we have around 20% of our patients that we're estimating are on combination therapy. So when we look across the ADT broader market, that seems to be about consistent.

Now we know that's not a huge sample size. It's market research that we're looking at the claims data. But at least right now, it feels like we are in the neighborhood of what ADT therapies utilization would be in combination. Regarding generating additional combination information, I'll turn that over to Juan Camilo.

Juan Camilo Arjona Ferreira

Chief Medical Officer

Yes, Gavin, for combination therapy data, we have multiple sources that we've already presented are in the process of publishing data from our HERO study, where patients who had progressive disease were allowed to take enzalutamide or docetaxel. And we have a fair number of those that will be -- have been presented and will be published relatively soon.

We are, as you pointed out, running a Phase I study in which we are exploring transition of patients that are already on an ADT abiraterone, apalutamide or docetaxel in 3 different parts of the study and then transition their ADT to ORGOVYX, we're following them initially for 12 weeks and then up to a year afterwards. So we are very excited about that program, and we look forward to start reporting results of that study later this year on a part by part basis as we complete those parts.

With regard to the Janssen study, we are not directly involved in that study, but we are excited to see that other companies see the value of using ORGOVYX as their ADT of choice for their development programs for their assets. And in terms of co-formulation with XTANDI or other drugs, we are, as you know, very interested in looking at all potential cycle opportunities and opportunities, particularly with ORGOVYX. So this is one that we are exploring among others, but we don't have anything else to report at this point.

Operator

And we have no further questions at this time. I will turn the program back over to Dave Marek for any additional or closing remarks.

David C. Marek
CEO & Director

Well, thank you. Look, fiscal year 2021 has been really a transformational year for Myovant as we evolve into a successful commercial stage company. And we'll use the momentum from 2021 and these recent positive announcements as catalysts for further advancement of our business, and we're on a trajectory for substantial growth in the year ahead. So thank you for joining us today, and I look forward to keeping you updated on our progress. Have a great day.

OperatorThis does conclude today's program. Thank you for your participation. You may disconnect at any time, and have a wonderful day.