Transcript

Webcast - Medincell annual results 2024-25 - June 17,2025

David Heuzé
Head of financial and corporate communications

Hello everyone. Thank you for joining us today for this conference, following the release of our annual results. We published them earlier today with a press release that is available on our website. Today, I'm joined by Christophe Douat, our CEO, Stéphane Postic, our CFO, and Dr Richard Malamut, our Chief Medical Officer.

Before we start, I invite you to review the forward-looking statements disclaimer at the beginning of the presentation, which is available on our website. This webcast will last max 45 minutes, and we will start with a presentation followed by a Q&A session. You can send your questions at any time using the chat toolbox on the right side of your screen. Now, Christophe, It's time to start the presentation. I'll give you the floor.

Christophe Douat
Chief Executive Officer

Thank you, David. I am delighted to join you today. But before we go into this past year, let me remind you of where we are. The next couple of years will be the most transformative years of Medincell history. Why? Well, let me share our financial strategy, Shift to Growth, and its three engines which are now firing simultaneously. UZEDY will take us to operational profitability in a year. Olanzapine LAI will add exponential growth on top of UZEDY. And the rest of the pipeline, as well as our technology innovation, will extend the growth further. The timelines were UZEDY approved in 2023. Olanzapine LAI expected to be approved in 2026, and engine number three impacting the company significantly from 2029 on.

So a year ago, I told you that 2024-2025 would be a spectacular year. And we can all agree that it was. UZEDY had a great first commercial year. Olanzapine reached key milestones, no PDSS, completion of phase 3. Our R&D pipeline progressed with the great agreement with AbbVie last April, the first program already in preclinical, and the implementation of our new technology, Bioresorbable Star, throughout. It was spectacular financially as well. Our revenue was multiplied by three and our losses cut in half. Let's go back to UZEDY. So 2024-25, first commercial year, sales of UZEDY were 141 million, which translated in €6.5 million to Medincell. You can see the trend of prescriptions, very impressive. You can see the first two months of this fiscal year, April and May as well, continuing the very positive trend. What's next? Potential FDA approval for the Bipolar Disorder extension by year end, and of course, the continuation of the ramp-up in the next years.

Olanzapine. Many of you joined us because of its blockbuster potential. We can even consider Olanzapine LAI as a first in class, the dream of any pharma company. This for three reasons.

Olanzapine LAI is the most used antipsychotic in schizophrenia. It is used for most severe patients and the ones refractory to other treatments, which are the ones that need a long-acting injectable the most. And it is potentially the first long-acting Olanzapine that is appropriate. It had a great 20244-25 years. As I said, study completion, no PDSS, positive efficacy results. Our partner even had a pre-NDA meeting with FDA on April 9th. I mentioned the exact day because on this program, every day counts. The next steps will be FDA submission in the second half of '25, which will be followed by a 10-month review time by FDA, which hopefully will lead to a commercial launch in 2026, next year. This slide may be the most important financially of the whole presentation as two of the key patents on the two products were granted in the US in this 2024-2025 fiscal year, extending the patent protection to 2042 for UZEDY, 2044 for Olanzapine. I'll repeat, 2042 for UZEDY 2044 for Olanzapine. Before I let Richard describe the pipeline, I will spend a couple of minutes describing our strategy to bring partners on board. It is related to the box that you see on the left, in-house and partner programs, because here we have a double strategy.

Either we partner from scratch on a molecule that a partner would like to develop and test as a long-acting injectable, or we start the development on our own, the formulation development, on a target that we think will trigger partner interest later. This allows us to save time and also build value. The AbbVie number one program was in this category. Richard.

Richard Malamut
Chief Medical Officer

Thanks, Christophe. Starting on the right of the slide, Christophe already alluded to our engine number one and engine number two, UZEDY and Olanzapine. I'll spend a little time on both of those in just a few minutes. Then the Intraarticular celecoxib program for postoperative pain in total knee replacement surgery. I'll also spend a few minutes on in a little bit. What I want to talk about now is some of our programs that are approaching the clinic. The first of these is our first of potentially six programs with AbbVie, which had lead formulation announced last fall. While we haven't disclosed the actual target date for IND filing, it is typically 18 to 24 months after announcement of lead formulation. And currently, our CMC teams and non-clinical teams are performing activities needed to support the IND. I'm particularly excited about our long-acting subcutaneous contraceptive program, mdc-WWM. It is while owned entirely by Medincell, it's funded by the Gates Foundation, and we'll be entering phase one sometime a little later this year. And then our Ivermectin three-month program, a purely global health program designed to prevent the spread of malaria, predominantly in children in endemic areas where treatments for malaria are very much needed.

And then a few added words on the formulation slide with our 10 blue boxes. This includes programs from multiple disease areas with multiple indications and includes NCEs, where a long-acting injectable may be needed to allow for approval and then marketing. Next slide. UZEDY, we've spoken It's not a lot before. Just a reminder that UZEDY is a subcutaneous formulation, a smaller needle, less pain, reaches therapeutic levels within 24 hours of the first injection, so no need for titrating injections or oral supplementation. It comes in prefilled syringes at four doses for the monthly, four doses for the every other monthly, without need for reconstitution in the office. Then finally, you have the same effect on efficacy and safety independent of the location of the injection, whether in the arm, the abdomen, or the thigh, giving greater flexibility to clinicians. Next slide. This is some very interesting data that Teva presented last month at the Psych Elevate conference in Las Vegas, Nevada. On the left side of the slide, you're seeing data versus not placebo, as with the phase III studies, but second-generation oral antipsychotics. When we run late-stage studies, we very often see favorable results and hope that they translate and are reproduced in the real world.

Here, they very clearly were with a relapse rate of 42% less than that seen with second-generation oral antipsychotics. In the meantime, the relapse increased by 54% over second-generation oral antipsychotics, so a confirmation of the positive results of the phase III. Then on the right side of the slide, we see some of the impact of having UZEDY available for use by clinicians for patients. You can see that the inpatient rate is down by 47% for UZEDY versus second-generation oral antipsychotics. For those patients that do require hospitalization, the mean length of hospital stay is reduced by 50%, and this all translates into a mean all-cause reduction in healthcare costs by 29% versus second-generation oral antipsychotics. A reaffirmation of real-world benefits confirming the very strong data we saw from the clinical program. Next slide.

Again, to reiterate what Christophe had said, Olanzapine is the most used oral psychotic in schizophrenia, both in US and in EU. It is not a competitor for risperidone. It's typically used by clinicians for patients with schizophrenia who have more severe symptoms or who are refractory, which accounts for up to 30% of patients. Next slide.

Developing a LAI Olanzapine would be of great value to clinicians and patients. The one existing approved LAI Olanzapine, as Christophe said, has not had success, predominantly due to the risk of post-injection delirium and sedation syndrome. While not that common, 0.1% of injections, 2% of patients, the FDA put a black box warning on the label, required a REMs program, which is not that common for psychiatrists to have to follow, and every patient for every injection has to be followed in the clinic for three hours after injection. Patients are not willing to do that. Psychiatrist offices are not set up for that. When Medincell formulated the long-acting injectable Olanzapine, it was with the goal of mitigating or eliminating the risk of PDSS, which is believed to be due to a burst of Olanzapine after injection.

In fact, there were no cases of suspected or confirmed PDSS in the clinical program. This suggests that there would be no future risk of PDSS after what we hope will be an approval. Next slide.

Then mdc-CWM, this is our intraarticular celecoxib program, which has demonstrated in a completed phase III, clear differentiation from approved and investigational therapies around both duration of pain relief and measures of inflammation. In fact, it demonstrated a unique impact on long-term functional outcomes, most driven by the presence of ongoing inflammation. Examination. So Medincell and our development partner, AIC, met with the FDA earlier this

year and confirmed clear guidance for a second phase III study design, focusing on a group of patients who had not had prior total knee replacement. And AIC is actively preparing the next phase III study. Stéphane ?

Stéphane Postic
Chief Financial Officer

Thank you, Richard. Now on the financial side, some very positive news as well. First of all, Christophe already alluded to that. Indeed, we have revenues for the fiscal year 2024-2025 multiplied by three times what they were in the previous year, amounting to €25.4 million. What are the main contributors to this very strong increase in the revenues? First of all, obviously, royalties from UZEDY. We mentioned that already. €6.5 million, multiplied by almost four times compared to what they were last year. An additional milestone from Teva for €4.8 million, coming at the completion of the phase 3 study for Olanzapine LAI. €0.6 million coming from the royalties from our joint venture CMB. And the last big part is coming from the different commercial partnerships that we have with different partners, and they represented €13.5 million in total, including €9.5 million coming from AbbVie for the first program that we mentioned and that is progressing very well. That's a partial revenue recognition coming out of the $35 million up from payment that we got from AbbVie back in April '24. The rest of the $4 million from service revenues are coming from the different collaborations with the Gates Foundation, with Unitaid for the two global health programs, and also from the proof of feasibility studies that we are running for different partners.

So a very nice top line with €25.4 million.

Next slide is on income statement, where we see also a very nice improvement at all levels. I mentioned already the strong increase in revenues. This strong increase in revenues has enabled us to reduce by half the operating loss. In the meantime, operating expenses have increased by 17% at much lower pace than the improvement in revenues. Those operating expenses, as expected, they're coming from the good progress of the different programs that are in our portfolio. So 10.8 million of operating loss, an improvement of 48% compared to last year. Now on the financial result side, a loss of 7. 4 million, which correspond mainly to the interest paid on our debts, and also that include a non-cash impact related to the change in the fair value of the EIB warrants for €2. 8 million. We are actively working with the EIB to eliminate this warrants impact and the floating liability that we have on our balance sheet due to those warrants. So hopefully next year, they won't be there anymore.
At the bottom line, we end up with a net loss of €18.4 million, an improvement of 26% compared to last year. And again, we are very pleased with this result because they put us on track for our short-term objective to be profitable at operating level in the next year.
Now, another interesting and very positive news on the cash position, which is much stronger than what it was last year with 72 million in bank at the end of March 25. This is obviously coming from several nice additions, the successful fundraising that we performed in February 25 that generated €43 million of additional cash. Also, the collection of the upfront payment from AbbVie in May 24 for $35 million or €33 million, plus the quarterly royalties that we are getting from Teva for UZEDY and the milestone for the end of phase 3 study for Olanzapine that I mentioned already. So very nice cash position which will enable us to breach to operating profitability in 27.

Next, if we step a little bit back and if we look at the longer term. Obviously, the first milestones in terms of financial perspective is, again, to be profitable for the next fiscal year, ending on March 31st, '27. That's tomorrow. On the longer term, around 2030, financial analysts that are covering our stock predict several hundred of millions of dollars of annual pure profit coming from UZEDY and Olanzapine LAI products mainly, but also, obviously, from other partnerships existing or to be executed in the coming years.

Because you understood the beauty of our business model, where we don't have any additional operating expenses associated to these revenues, we are confident in saying that EBIT should represent more than 70% of the revenue in the early 2030s.

One slide now on the investor basis. We mentioned last year that it was a priority for us to expand our shareholder basis to increase the visibility of the company globally, worldwide. And indeed, we are very proud to have now on board almost 20% of shareholders that are coming from the US, the UK, and Australia. So very, very nice name that you can see here on the screen. And they started for some of them to invest directly on the Euronext market, which is quite unusual, and we can be proud of that. And they also participated very strongly in the fundraising in February. So they are coming on top of very strong, also supportive European and French investors that we have on board for a long time, like Mirova or Group Dassault or BNP, for instance. They're very, very positive support for the company. So all of that increases the visibility of Medincell globally. And also as a side effect, you can see on the right, it's improving the liquidity of the share.

Now it is trading around €2 million on a daily basis. So, it is very interesting and very promising for the next steps. Christophe?

Christophe Douat
Chief Executive Officer

Thank you, Stéphane. Thank you, Richard.

Again, last year was a great year. UZEDY had a beautiful first commercial year. Olanzapine reached key milestones. Our entire pipeline progressed. We implemented our new technology BEPO Star with record financial results.

David Heuzé
Head of financial and corporate communications

Thank you, guys. Let's move on to the Q&A session now.

The first question is about a new patent. A new patent application. So I read the question. You mentioned the improvement that BEPO Star can bring to Medincell? What are the limits in terms of molecular size? Do you have peptides and biologics in the 10 programs in house and partnership, so in the pipeline? Do you plan to address markets such as Oncology, obesity, GLP-1, immunotherapy. Christophe ?

Christophe Douat
Chief Executive Officer

Okay.

The first question limits in terms of molecular size. It's hard to answer with a given number because it really depends on the molecule, plus it's confidential information. But I would say that it is appropriate for smaller peptides, hydrophilic molecules, but not quite where we would like for larger peptides. On the second question, do we have peptides in the 10 programs? Yes.

David Heuzé
Head of financial and corporate communications

Okay, next.

Christophe Douat
Chief Executive Officer

Do you plan to address markets such as oncology, obesity, via GLP-1 immunotherapy?

The answer is yes. We will address any indication where we can make a difference, significant difference, where there is a financial return that is significant and where we can do a best-in-class treatment.

David Heuzé
Head of financial and corporate communications

Next question about, yes, a new patent published in May 25 concerning a combination of anti-neuroplastic antibody. So it refers to agents used to treat cancer. Does it mean that you have patented a formulation with a monoclonal antibody or an active part, therefore?

Christophe Douat
Chief Executive Officer

It's a great question, but I'm sorry, I cannot answer.

Richard Malamut
Chief Medical Officer

I have nothing to add.

David Heuzé
Head of financial and corporate communications

Okay. So next question. So question about AbbVie. When do you expect to provide additional updates on the AbbVie collaboration, including the timeline to initiation of clinical development for the first candidate. Maybe Richard.

Richard Malamut
Chief Medical Officer

Yeah. Again, typical industry metrics are about 18 to 24 months from identification of lead formulation. AbbVie has not opted to disclose either the API or the timing of the IND filing. We will certainly do so in advance of the IND filing. So I would just ask you to wait for that announcement.

David Heuzé
Head of financial and corporate communications

Thank you, Richard. So the next question, what is factored into your operational profitability outlook for fiscal year, 2027? And is the latest R&D spend a good proxy moving forward? Stefan.

Stéphane Postic
Chief Financial Officer

So what is basically taking into consideration for now are the existing elements, the one that are already ongoing and executed. So I will mention, obviously, royalties coming from UZEDY, which, as we mentioned, has really started well from a commercial standpoint, and we expect this to continue. We'll have also the addition of Olanzapine LAI starting from end of '26. So additional royalties. And again, we say that the first in class status of Olanzapine should lead to much higher royalties thanks to the ramp up of the sales. Also a commercial milestone that we can expect for 26-27, hopefully. And to answer to the second part of the question, basically, yes, the existing cost basis that we have just communicated for 24, 25 is a good reference. Maybe a bit of change, but nothing dramatic because again, our business model is for now to go until the IND in most cases, and especially for AbbVie. I'm thinking about AbbVie because it's among the next program to get to that stage. And so nothing much to expect in terms of additional operating expenses.

David Heuzé
Head of financial and corporate communications

Next question. How can your BEPO Star technology transform the global contraception landscape, particularly in areas with poor access to healthcare? I think it's for you, Richard.

Richard Malamut
Chief Medical Officer

Yeah, I think it is. There is value of a six-month subcutaneous contraceptive in the developed world, in the US, in the EU. But in the developing world, LMI-C countries, there's a particular need because of longer access to contraceptives, sometimes related to geography, where they live, access to clinics to receive oral contraceptives, or shorter-acting contraceptives. Having a six-month subcutaneous contraceptive, which can be stored at room temperature, would be transformative for those women who do desire and would benefit from a longer acting contraceptive.

David Heuzé
Head of financial and corporate communications

Next question maybe for you also. mdc-CWM, will this study be extend hip, shoulder, when? Will Phase 3 cover Europe?

Richard Malamut
Chief Medical Officer

The current program is focused on total knee replacement, and our next studies will use post-op pain in total knee replacement as the indication. However, it's an excellent question because the need exists, particularly in shoulder, pain and inflammation after shoulder and also hip. We do have that in mind for life cycle management. Nothing to disclose on that today. Then in regard to Europe, we're still discussing the timing of when we might wish to expand the program into Europe.

David Heuzé
Head of financial and corporate communications

Thank you, Richard. Next question. How has the funnel of new partnerships progressed over the second half? Is there a potential we could additional signing over the next 12 months with similar size deals to Teva or AbbVie. Christophe.

Christophe Douat
Chief Executive Officer

So yes, the funnel continuously progresses. As I said in our French presentation, doing a deal is very complex with a lot of steps going from evaluation of technical feasibility, which could be positive or not, and then negotiation. So yes, there is potential, but as I often say, a deal is not a deal until it is signed.

David Heuzé
Head of financial and corporate communications

Next question. What progress has been made in integrating BEPO Start technology into your formulations? Is it already being used in clinical research programs?

Christophe Douat
Chief Executive Officer

So as Adolfo described in our R&D day, it has a significant impact on viscosity, therefore on the size of the needle and as well on the burst. So it gives us more parameters to play with, which is why we've decided to switch all our new programs to BEPO Star as of 2024.

David Heuzé
Head of financial and corporate communications

Next question about risperidone, bipolar disorder. When do you think Teva will submit the dossier to the FDA? Is it likely that additional studies will be request by the FDA?

Richard Malamut
Chief Medical Officer

Yeah. So the good news is Teva has filed the supplementary NDA with the FDA. And the better news is that in February of this year, they reported acceptance of the file. Typically, that would lead to another eight months of review time. We would expect approval sometime in the end of the year. Then, did file with the strategy not to conduct additional studies and to rely on completed studies for the two-week long-acting injectable risperidone in that indication and oral risperidone, which has that indication. So no additional studies should be needed for that indication for UZEDY.

David Heuzé

Head of financial and corporate communications

Good news. Next question. You have invested 13 million in short-term financial investment. What is your approach to cash management and returns in this context?

Stéphane Postic
Chief Financial Officer

That's a good question. Don't worry, we are not investing in silly things. Those 13 million are just monetary bank deposit. But the only difference with the other deposits that we have in hand is that those ones that are issued in USD and not in euros. So for some very tricky accounting policy, because of very tricky accounting policy, they are classified as short-term investment. But They are low-risk investments. They are available very quickly if they're needed, and there's no real risk associated to those investments. We are very prudent. Just at the moment, the interest rate served on USD deposits are more interesting than on the Euro, so we do a little bit of... We take profit of that.

David Heuzé
Head of financial and corporate communications

Next question maybe for you, Christophe. Do you plan to quote made in sell on Nasdaq to unlock the value?

Christophe Douat
Chief Executive Officer

So it's a subject we evaluate continuously because of the potential, but more for access to US investors and potential growth for acquisitions in the future more than valuation. The finance department is also getting ready for it so that the day we decide, we can get there in a matter of months, not of years. However, we have not made the decision and the future will tell when we decide and whether we decide to go there.

David Heuzé
Head of financial and corporate communications

Thank you, Christophe. Richard, I know it's important for you and for everybody, but after a full year of commercialization, what is the feedback from healthcare professionals results in patients on UZEDY? Teva presented several posters, I think.

Richard Malamut
Chief Medical Officer

Yeah. So UZEDY has been on the market now for a full two years, and Teva is actively conducting post-approval research. As you've mentioned, David, there's been several posters that have been published, including the two that I referred to earlier on the presentation on impact on healthcare costs and confirmation of the phase 3 study results. Teva continuously follows these patients and also continually interviews patients as well as clinicians about their level of satisfaction. More to come on that. Look for future Teva posters and publications on the topic. I guess the thing I could say is given the strong growth and the strong prescription and sales data, I think we can assume that clinicians are quite satisfied with these heading.

David Heuzé
Head of financial and corporate communications

Christophe, last question.

Christophe Douat
Chief Executive Officer

Maybe Stéphane, what do our analysts say on the potential revenue?
The market, not the revenue, the market size in USD for olanzapine in 2030.

Stéphane Postic
Chief Financial Officer

Financial analysts have forecast between $2 billion and $3 billion in 2030, so only four years after commercialization of the product. So very nice figures that could even be higher, considering the lack of competition on the product. And that's it. So a very multi-billion market.

David Heuzé
Head of financial and corporate communications

So we can bridge with a conclusion, Christophe Douat, now? Yes.

Christophe Douat
Chief Executive Officer

Last year, I said that 24, 25 should be a spectacular year, and I think we can all agree that it was. Today, I am saying that the next two years will be the most transformative years of Medincell history so far. Thank you.

David Heuzé
Head of financial and corporate communications

Thank you, Christophe. Thank you for your attention. We appreciate your trust, and we hope to see you soon. Good night, and see you soon, guys. Thank you.