TRANSCRIPT

Medincell - HY 2024-25 Earnings Call

December 10, 2025

David Heuzé
Head of corporate and financial communication

Hello, and thank you for joining us today. We published our half-year results after the close of the Paris market today. The press release is available on our website. On our website, you can also find the presentation that we will use today. You are invited to read the disclaimer concerning possible forward-looking statement on the slide three of this presentation. With me today, Christophe Douat, the CEO of Medincell. Hi, Christophe.

Christophe Douat
Chief Executive Officer

Hello, David. Hello, everybody.

David Heuzé
Head of corporate and financial communication

Stéphane Postic, our CFO. Hi, Stéphane.

Stéphane Postic
Chief Financial Officer

Hello, everybody.

David Heuzé
Head of corporate and financial communication

Dr. Richard Malamut, our Chief Medical Officer.

Dr. Richard Malamut
Chief Medical Officer

Hi, David.

David Heuzé
Head of corporate and financial communication

Hi, Richard. Christophe, before we talk financial, maybe we can talk about what happened in the last month at Medincell. First, we can talk about UZEDY®.

Christophe Douat
Chief Executive Officer

Yes, definitely. I will remind everybody that UZEDY® was approved in April '23, and so 2024 was its first commercial year. The numbers show that the ramp-up is extremely good. Our partner, Teva, for the first time disclosed revenue in November. You can see on the chart that the first three quarters had a cumulative 75 million in revenue. And Teva increased its guidance from 80 to 100 million. So very exciting numbers. Numbers that show that UZEDY® is truly a best-in-class product and also has the potential to be a blockbuster.

David Heuzé
Head of corporate and financial communication

Let's talk now about the second product with Teva Pharmaceuticals, which is the Olanzapine LAI. It was a good year for this program.

Christophe Douat
Chief Executive Officer

Yes. And a program which is extremely important for Medincell, but for Teva as well, as it is part of their pivot to growth strategy. I described UZEDY as a best in class. The second program we do with Teva can be truly described as not only a best in class, but as a first in class, because there is no other product that was commercialized with no safety issue as a Long-Acting Injectable (LAI) of Olanzapine. Early this year, in February, Teva communicated on the efficacy results from the Phase III, and then through the month, communicated on the percentage of the 3,600 injections that FDA requires with no PDSS, which is a bad side effect that Richard will tell us about in a second. This number was 99% in September, and Teva reached 100% in November. So major news. One that lead to successful completion of phase 3 by the end of the year, which should help Teva file for FDA in the first half of '25. And once that's done, the clock starts and 10 months later, Teva potentially can get approval, which means that this program, extremely important, huge potential, could be approved in the first half of '26.

Christophe Douat
Chief Executive Officer

So slightly more than a year from now.

David Heuzé
Head of corporate and financial communication

Great. Christophe, I think that the two programs we talk about, UZEDY® and Olanzapine, can have a significant impact in the future of Medincell.

Christophe Douat
Chief Executive Officer

Yes, definitely. As Stéphane will describe in a second, the first step will be reaching operational profitability in a fiscal year ending March 31st, 2027. Then within mid-term, so 3-4 years, we expect to reach revenue of 100 million. This will not be the end as the products will keep ramping up, and both combined products could reach revenue of several hundred millions, according to our analysts.

David Heuzé
Head of corporate and financial communication

Okay, Christophe, yesterday we published a press release about another program, which is in a post-operative pain management. Can you talk a bit about this program? CWM ?

Christophe Douat
Chief Executive Officer

Yes. So this press release was about more in-depth analysis of the phase 3 data and showed that on a subgroup of patients, which is actually the majority of patients, and again, Richard will tell us more in a second, patients which are naive with no previous total knee surgery, the long-term outcome is extremely favorable. This is unique. There's no other product that can do that today. So very exciting data.

David Heuzé
Head of corporate and financial communication

Christophe, if I refer to the period, there was a big announcement in May or April about a new partnership

Christophe Douat
Chief Executive Officer

Yes, April sixth, actually, as we executed this major deal with AbbVie, where we received $35 million upfront in April.

This deal is about developing for AbbVie six Long-Acting Injectable (LAI)s. We are entitled to a maximum combined of 1.9 billion in milestones plus royalties. The first program when we signed the agreement was already underway at Medincell, and it reached a major milestone in September when both parties selected what is called the lead formulation, which is the formulation which is now fixed and will enter a preclinical and clinical development.

David Heuzé
Head of corporate and financial communication

Thank you, Christophe. Christophe, a year ago, you said that we are going to enter a new era.

Christophe Douat
Chief Executive Officer

Yes.

David Heuzé
Head of corporate and financial communication

We're in now?

Christophe Douat
Chief Executive Officer

Well, yes, I think we entered that era with a lot of dynamics, with UZEDY® ramping up, with AbbVie being signed, and Olanzapine, going through all its development steps. We have shown now in all those cases that Medincell was able to really develop not only LAIs, but the best LAIs. LAIs that Jensen could not do, Eli Lilly could not do. Now, a new first in class with F14 in a total knee surgery. Things are accelerating, and we expect new partnerships coming in the next 12-18 months. Some of them are already current collaborations at feasibility stage that hopefully will transform into licensing agreements. In parallel, as our R&D team explained during the webinar, that was held a few weeks ago. We keep innovating, and actually our innovation pace is accelerating, with BEPO® Star coming on stage. BEPO® Star, as you can see on the screen, allows us to improve formulations and also increase the reach of our technology into areas where we could not go before. All our programs, new programs are migrating to BEPO® Star, as I speak, with a very long patent life as the technology is protected until in 2040.

David Heuzé
Head of corporate and financial communication

Thank you, Christophe. Now, if we look in the future, what are the next expected milestones for the company for the next year, for the year to come?

Christophe Douat
Chief Executive Officer

With UZEDY®, we will get a current news flow, quarter after quarter, revenue from Teva. That will be the first news that feed the news for Medincell as well. On Olanzapine, as I said, potential filing, first half of 25, and then potential approval, first half of 26, slightly more than a year from now, with a ramp-up that should be even faster than UZEDY because of this lack of appropriate competition. Now we know how good Teva can be at commercializing a Long-Acting Injectable (LAI) in that space. Both for the future and for Olanzapine as well. Then again, potential new partnerships, which hopefully will disclose in the next 12 to 18 months.

David Heuzé
Head of corporate and financial communication

Thank you, Christophe. Let's move now on the half-year results with you, Stéphane. Stéphane, first, can you us about what are the results of the company for the semester?

Stéphane Postic
Chief Financial Officer

Yes, sure. Thanks, David. You can see on your screen the main points to remember, and I will come back in details to those different amounts in a moment. As you can see, our revenues have increased by 23% to €8.6 million this half year. The operating income has improved by €1.5 million, leading to a loss of €7.5 million for this half year. Cash equivalence and non-risky financial investment represent €38.8 million versus 19.5 million as of March 31st, 2024, last annual closing. The first major factor is the very positive trend in the revenues, which have increased by 23% compared to last year. As a reminder, last year we achieved €9 million of sale over the full fiscal year, meaning that we have already generated 95% of what was generated during the previous fiscal year. What are the main components of those €8.6 million of revenues. First of all, you can see that we generated €2.8 million in royalties from the sales of Teva's product, UZEDY, in the States, which increased by more than fourfold compared to the same period in the previous year. You have here the historical figures by half year since the launch of the product.

It's reflecting the product's excellent sales momentum in the US, as Christophe just mentioned. Now, coming back to the green box that you have on the screen, we also generated 5.5 million of revenues from the ongoing collaboration. Out of those 5.5 million, there's 3.7 million that correspond to the first revenues from the big contract that we executed with AbbVie in April '24. Around 1.3 million comes from BMJF and Unitaid for the MDC WWM and STM programs, and 0.5 million from new feasibility studies, i. E. Studies that are early stage and are likely to eventually turn into licensing contracts, as it was the case earlier this year with AbbVie. Now, a quick snapshot on an AbbVie contract. As you may remember, we received $35 million upfront when we executed the contract, which covers the development of six injectable programs. When we signed this contract, I specified during different call that the 35 million dollars upfront or 33 million euros upfront, which has already been cashed in and is absolutely non-repayable to AbbVie under any circumstances. This upfront would not be recognized in full in the 24, 25 financial years. As it relates to the completion of the six program and that it would be spread over time according to the progress of these six programs.

For the moment, we are only working on the first program, and it was already initiated before the execution of the deal, and it's more advanced. Therefore, we have given to this program a higher value than the next five will have. At the end of the day, we have recorded €3.7 million in revenues over this half year, and the remaining €29.3 million of the upfront will appear on the balance sheet as a deferred income. The 29.3 million will be recorded as revenue over time over the next few years at a rate that will depend on the progress of the six programs.

David Heuzé
Head of corporate and financial communication

Thank you, Stéphane. What about the operating expenses?

Stéphane Postic
Chief Financial Officer

In terms of operating expenses, they are virtually unchanged compared to last year, and they represented €17 million. So thanks to this increase in the revenue and similar operating expenses, we have reduced our operating loss to €7.5 million, compared to €9 million in the previous year. And so we are on track, well on way to achieve one of our main financial targets, i. E. the operating profitability by the end of the fiscal year 26, 27 at the latest. Now, you have on your screen the income statement, and you can see that we had a loss. We incurred a financial loss of 6.9 million over this half year. This is mainly explained by the change in the fair value of the warrants that were granted to the European Investment Bank as part of the 40 million loan that was granted by the EIB to us back in 2022. What is a warrant? It's a right to buy shares in a company at a fixed price, at price fixed in advance for a given period. This means that if the stock price rises, the holder can make a profit. As part of our loan agreement, and as described in our financial documentation since 2022, the EIB has now approximately 800,000 warrants.

And because, or thanks of the sharp increase in our share price since March, the value of those 800,000 warrants has raised by approximately 4 million, meaning that we had to reevaluate their value in our balance sheet. In addition, we had the, let's say, the classical financial interest that we pay on our loans, which represented 2.5 million. There was unfavorable market conditions regarding the exchange rate between US dollars and euros over this period, leading to a €1 million loss on the deposits that we had in USD. I I'd like to remind you that indeed we are a French entity, but the vast majority of our revenues are paid in US dollar. That was detrimental on the past period. But given the more brilliant economic and climate in the US, might be something very positive in the future, will be something very positive in the future.

David Heuzé
Head of corporate and financial communication

Thank you, Stéphane. A few words about our cash position.

Stéphane Postic
Chief Financial Officer

Yeah. Our cash position is much more improved compared to what it was, as I mentioned, as of March 31st, '24, 38.8 million euros versus €19.5 at the last annual closing. This is mainly due to the cash in of the AbbVie up front of 35 million dollars. But we must also bear in mind that it integrates the rapid ramp-up of UZEDY® royalties and the fact that we have been successful in well-controlling our operating expenses. This comfortable cash position enables us to meet all the different current financial governance that we have on the EIB loan. And above all, it gives us time to continue working with serenity on the next step with the priority given to the signing of a new licensing contract such as the one we signed with AbbVie at the beginning of '24.

David Heuzé
Head of corporate and financial communication

Thank you, Stéphane. Stéphane, can you give a little bit color on our objective of operating profitability we mentioned?

Stéphane Postic
Chief Financial Officer

Yes. Christophe mentioned that already in the preambule. We are very confident in our ability to achieve operating profitability by fiscal year '26, '27 at the latest, which will close on March 31st, 2027. In the current financial year, we have already achieved revenues of €9 million in the first half, and we expect even stronger growth in the second half, which should lead to multiplication of our revenues by two or three times over the year. That's mainly, again, thanks to the royalties from UZEDY and the revenue recognition from the AbbVie contract. This will bring us pretty close to our objective of operating profitability.

David Heuzé
Head of corporate and financial communication

Thank you, Stéphane. Maybe to conclude, a few words about the long term financial trajectory of the company.

Stéphane Postic
Chief Financial Officer

Sure. To be on this operating profitability in the medium term, in probably three to four years, we should exceed the 100 million in annual revenues from UZADY and from the MDC-TJK program, the long acting injectable Olanzapine which we are developing with Teva, on which Teva has announced that it will be marketed probably in the first half of 2026, provided the FDA approval, of course.

David Heuzé
Head of corporate and financial communication

Thank you, Stéphane. Richard, we talk about it at the beginning. Yesterday, we distributed a press release, giving the results of the analysis of a subgroup representing two thirds of the Phase 3 participant of the MDC-CWM. What does this analysis show and why it is important?

Dr. Richard Malamut
Chief Medical Officer

Yeah. So thanks, David, I'm always very happy to speak of CWM. F14 is the name of the compound. We did, with our partner, AIC, present data from the completed Phase 3 study last May, but this was partial data, and happy to be able to present some additional data from that study. But to take a quick step back, CWM is an intra-articular Celucoxib, designed to treat pain and inflammation after total knee replacement, which is a very painful surgery, typically requires high doses of opioids, and unfortunately, leads to opioid addiction in 15% of patients, a high number. To be able to use a non-opioid to control pain would be quite valuable for those patients, particularly if it can be for a longer period of time than existing products. But the data we showed last May showed that we did not reach the primary endpoint on pain. However, remember that Celucoxib is a strong anti-inflammatory and did reach statistical significance in the total population on measures of inflammation like range of motion and joint swelling and a timed walking test. And these are the measures that correlate best with long-term functional improvement, ability to return to work, ability to regain normal function, ability to undergo rehabilitation.

In that study, there was a pre-specified population of patients who had had no prior knee replacement. And in that population, there was significant improvement across all measures. And this is the information we talked about yesterday. Just a quick reminder of the study. It was 150 patients. All patients received multimodal analgesia, so there was no placebo. The surgery is quite painful, ethically difficult to use placebo. And then half of the patients received CWM F14. And then endpoints were followed over a 12-month period of time. The subpopulation I mentioned, very large part of the total population, more than 70% of patients who had not had a prior total knee replacement. If you look at the data, looking at these populations, you can see on the left, the total population, which we released last year, in which, while there was numerical separation, did not reach statistical significance. But in the no prior total knee replacement, you can see continued and greater improvement at all pain endpoints with statistical significance at day 3, day 7, and improvement at two weeks. In the measures of inflammation, while the total population did show significance, it's six weeks and three months on range of motion.

You can see on the right in the no prior knee replacement group that there was additional improvement and even greater statistical significance. This was repeated for other measures of inflammation, like a fusion, a time walking test, a functional measure of pain and function after total knee replacement surgery. We mentioned opioid consumption. Here in that no prior total knee replacement subgroup, you can see from the curve that in two weeks, the control group and the F14 group were very similar. But from two weeks to three months, there was a gradual and definitive separation in patients who were using additional opioids. That's the top curve on the blue. And then in the green on the bottom, patients who received F14 did not use that many more opioids, and many more were free of opioids by three months compared to the control group. So this is very important to alleviate the concerns over the risk of opioid addiction. And so because of this, and after discussion with FDA, first quarter of next year, we plan to go forward with this subpopulation as our primary population, as well as some other questions we'll ask FDA. Very excited to see this program go forward.

David Heuzé
Head of corporate and financial communication

Thank you, Richard. A few words about UZEDY® now. In the past month, Teva Pharmaceuticals presented several posters at conferences highlighting the switch of patients to UZEDY® from other existing LAIs. Could you provide more details on these findings and explain why they are important?

Dr. Richard Malamut
Chief Medical Officer

Happy to do so. With UZEDY® was developed and prefilled syringes with four doses for a monthly, four doses for an every other monthly, which corresponded by design to the four oral doses of risperidone, 2, 3, 4, and 5 milligrams. The target was to switch patients from oral risperidone to UZEDY. With these posters, two presented in May, one just this past September, Teva is targeting and helping clinicians to switch from another Long-Acting Injectable (LAI) risperidone formulation. In May, they presented posters showing how to switch from the two-week LAI risperidone from Janssen, as well as the four-week Invega monthly. And in September, Teva presented a poster showing clinicians how to switch from Perseris, from Indivior. This turned out to be fortuitous because while Teva was preparing the poster, Indivior announced over this past summer that they were withdrawing Perseris from the market. So ultimately, these patients on the monthly Perseris will need to switch to one of the other Long-Acting Injectable (LAI) risperidone formulations, such as UZEDY. So Teva demonstrated to clinicians how to make that switch, if indicated. And it's important to note that clinicians and patients decide which therapy is the most appropriate for them. So having these posters provides more information for clinicians to provide a safe transition if that's what they choose to do.

David Heuzé
Head of corporate and financial communication

Thank you, Richard. Teva also indicated over the summer that it is currently investigating a new indication for UZEDY. Can you tell us more?

Dr. Richard Malamut
Chief Medical Officer

Yeah. Of course, schizophrenia is a very important indication for UZEDY, where schizophrenia patients stop taking their medicine 80% within the first five years of treatment. A very important addition to a clinician's armamentarium. But risperidone is also approved in several formulations for bipolar disorder. And these patients would also benefit from a Long-Acting Injectable (LAI) product, both for compliance but also for ease of use. And so Teva did announced that they will be exploring a bipolar disorder indication for UZEDY. More details to come from Teva.

David Heuzé
Head of corporate and financial communication

Yes, we hope so. Two words about Olanzapine LAI now and the phase 3. Christophe mentioned that there were no PDSS observed in November. Can you remind us why this is so important?

Dr. Richard Malamut
Chief Medical Officer

Yeah. So post-injection, delirium, and Sedation syndrome, not very common, occurs in less than 0.1% of injections with the Lilly approved LAI olanzapine, but is severe enough that the FDA put a black box warning on the label, required a REMs program where psychiatrists have to enroll, monitor, track, and then report back to the FDA on their patients on the Lilly LAI Olanzapine. This is not something that psychiatrists are used to doing. And then a requirement for every patient, for every injection, to be monitored in the clinic for three hours. So this is not what patients are willing to do. Psychiatrist offices aren't set up for that, so the product is just not being used like it could. And psychiatrists have told us that they do wish there to be an effective Long-Acting Injectable (LAI) Olanzapine on the market. So having a product that can mitigate this risk or so far, eliminate the risk of PDSS, should alleviate concerns of psychiatrists and help this product come onto the market and be used as psychiatrists wish it to be. And so far, as Christophe mentioned, no cases of PDSS. Reached the target number established between Teva and the FDA of 3,600, and zero is a very good number.

David Heuzé
Head of corporate and financial communication

A few words to conclude, Richard, maybe about our R&D pipeline, maybe, and maybe about two programs of these R&D pipelines, and this CWM and MDC-STM. Where we are, where we go.

Dr. Richard Malamut
Chief Medical Officer

As you can see, we've talked about the three programs to the right, the Olanzapine and UZADY, as well as CWM, the Celecoxib. But Medincell also has internal programs, and two of those will reach phase one in 2025. The first one is a six-month subcutaneous injection for contraception. Current available formulations only get to two, two and a half months. Beyond that, women need to use either surgical implants or devices, which is not desirable for many women. So this program is funded by the Bill and Melinda Gates Foundation. They've already contributed $23 million US dollars, not only for development in the US, where there is a need for access to contraception, but also in developing world, where access is even more limited. And we look forward to starting that program sometime in 2025. The second internal program is a program with malaria using a long acting injectable Ivermectin to kill mosquitoes, to be injected in vulnerable populations to malaria and prevent the spread of malaria, particularly in children who are most vulnerable to the spread of malaria and the accompanying symptoms. And then to the left, you see that big grey box with the number 10.

These include programs that we haven't disclosed yet, some our own internal programs, some programs that partners have asked us to work on. As they become more mature, we will disclose them in term.

David Heuzé
Head of corporate and financial communication

Thank you, Richard. Thank you. We received a few questions. The first is for you, Stéphane. It's about the debt, the EIB debt. First question, when will we have to repay the debt? And the question about the warrants. Do we know when EIB could exercise the warrants? Is it possible to know the strategy? What they plan to do?

Stéphane Postic
Chief Financial Officer

To answer to the first part of the question on the EIB loan, the principle and the capitalized interest, are repayable after a maturity of five years, meaning that we will have 20 million to reimburse in December 2027, and the rest of the 20 million will be repayable in 2028. Regarding the warrants, the exercise is at will of the EIB. We don't know when and if they will exercise the warrants, what is publicly known is that usually EIB cannot be a shareholder of their portfolio company. Probably we'll have to find some of an arrangement with them about the future of these warrants.

David Heuzé
Head of corporate and financial communication

Other question, Stéphane. Do we plan to make a share buy-back program to support the share price when we will receive a lot of royalties from our first product.

Stéphane Postic
Chief Financial Officer

It is a possibility, but I believe it's a bit too early to discuss about that now.

David Heuzé
Head of corporate and financial communication

Someone ask us if we plan to make a quarterly financial... To make quarterly financial communication in 2025. I can answer that it's not mandatory as well, at least in France. But what we know is that Teva will certainly disclose the sales each quarter for the product, but maybe we will adapt our communication with that. We'll see.

Christophe Douat
Chief Executive Officer

I think it's something to consider. We, of course, get more and more US shareholders to adapt to what is done there.

David Heuzé
Head of corporate and financial communication

Richard, someone asked us if we can explain why there will be at least one other Phase 3 for the AIC program since the results are quite good for 70% of the population. Can you explain?

Dr. Richard Malamut
Chief Medical Officer

Yeah. No. That's to be determined on discussions with the FDA first quarter. Of course, we would prefer that only one additional Phase 3 would be needed. It's possible the two more would be needed, but that's a major part of our discussion with the FDA first quarter of next year.

David Heuzé
Head of corporate and financial communication

It is usual to conduct several Phase 3 in pain?

Dr. Richard Malamut
Chief Medical Officer

Yeah. Standard is that you need two confirmatory Phase 3 studies, depending upon the formulation and the difference from the initial approved molecule. So as an example, Teva for UZEDY and also for olanzapine only was required to conduct one Phase 3 study, but the intraarticular celacoxib program, different indication, different route of administration, enough different that the pain division of the FDA has confirmed that they want two confirmatory studies. I think the question is whether the one we just reported on would be adequate, and we only need one more.

David Heuzé
Head of corporate and financial communication

Thank you, Richard. Last question about the Medincell competitors. Someone ask us if we have competitors in the field of Long-Acting Injectable (LAI) using copolymer or polymer BEPO. Christophe?

Christophe Douat
Chief Executive Officer

Using our technology, no, because our technology is patented with very strong patents. By the way, all our partners have evaluated and diligented our patents. Knowing who our partners are, you can understand that they are strong. The first generation of BEPO expires in 2033. But then on every program, we have additional patents, either composition of matter or method of use patents. Then

the new generation I talked about earlier, BEPO Star, the patents do not expire until 2040. That combination of diblocks and triblock that is at the core for BEPO® technology is Medincell. We have, of course, patented a lot of the space that is around those.

David Heuzé
Head of corporate and financial communication

We have additional pattern for each product. This is something important to understand. We explained that during the R&D webinar a few weeks ago. That was the last question. Thank you, Gentlemen.

Christophe Douat
Chief Executive Officer

Well, thank you and Merry Christmas to all. Looking forward to 2025, which should bring us a lot of good news.

David Heuzé
Head of corporate and financial communication

Thank you. Thank you all and happy holidays. Bye. Thank you.

Dr. Richard Malamut
Chief Medical Officer

Bye. Bye.