Webinar Transcript – Medincell Half-Year results 2025-26 (December 9,2025)

David Heuzé

Hi everyone, and thank you for joining us today for this conference following the release of our half-year results, which were published earlier today. The press release is available on our website. Today, I'm joined by Christophe Douat, our CEO. Hi Christophe.

Christophe Douat

Hi David. Hi everyone.

David Heuzé

Dr. Richard Malamut, our CMO. Hi Richard.

Richard Malamut

Hi David.

David Heuzé

And by Stéphane Postic, our CFO. Hi Stéphane.

Stéphane Postic

Hi David. Hi everyone.

David Heuzé

Before we start, I invite you to review the forward-looking statements disclaimer at the beginning of the presentation available on our website. This webcast will last 45 minutes max. We'll start with a presentation session followed by a Q&A session if we receive questions. You can send your questions at any time using the chat tool on the right side of your screen. A similar session in French was held earlier, and both replays will be available shortly on our website. But now I leave the floor to you, Christophe.

Christophe Douat

Thank you, David. Hello everybody. We are delighted to have you join us and celebrate the filing of olanzapine LAI. It's a major event for the company, so lots of emotions and excitement at Medincell today. Last June, I told you that Medincell was entering the most transformative years of its history, mostly thanks to olanzapine. And here we are. Our partner Teva filed the olanzapine LAI at the FDA today, and so the clock will start ticking since FDA has ten months to get back to Teva with the potential approval sometime in

Q4 2026 for a product that is a major product, a priority at our partner, and of course a priority at Medincell.

Let me remind you of our strategy Shift to Growth. You can see that UZEDY, and we'll come back to UZEDY in a second, is the first engine of growth of Medincell. Olanzapine will accelerate growth, and then the third engine is made out of the pipeline with AbbVie number one leading the way.

Let's step back a bit and look at our strategy in schizophrenia. On the left, you have risperidone. On the right, olanzapine. Risperidone was a drug of Johnson & Johnson. Olanzapine, Eli Lilly. Both were significant blockbusters for both companies, respectively. Both companies followed the same strategy, lifecycle management with long-acting injectables. You can see on the left that Johnson & Johnson was highly successful, building a franchise which is now 4.8 billion dollars a year. But you can see on the right that there is no big green box. Eli Lilly failed commercially with a long-acting injectable. Richard will tell us why in a couple of minutes. And we at Medincell gave our partner Teva the keys to grab some of that potential, with a real appropriate long-acting injectable of olanzapine.

Let me remind you of the metrics that we have on both products. We are eligible to mid- to high-single-digit royalties, eligible for a 4 million dollar milestone at approval of olanzapine LAI, plus 105 million dollars of commercial milestones for UZEDY and 105 million dollars for olanzapine LAI. Richard, could you tell us why olanzapine, from a medical standpoint, has such a large potential, why Eli Lilly failed, and why tiny Medincell in the south of France succeeded?

Richard Malamut

I could do all of that, Christophe, and I will. So first, as a reminder, oral olanzapine is the most prescribed oral antipsychotic, and that's mostly because it's currently used for the more severe patients with schizophrenia, the patients who are refractory, which can be up to 30% of patients. But unlike the risperidone franchise, there is only one approved long-acting injectable olanzapine product, and it's not being used for reasons that we'll talk about. The unmet need is very, very high here to have something in a long-acting injectable form to improve compliance for patients who are exactly the patients you don't wish to have stop their medications. For these reasons, the unmet need is quite high.

Now, on the next slide, a reminder of the safety finding that has limited the use of the Eli Lilly drug, and that's Post-Injection Delirium and Sedation Syndrome, PDSS. Not very common, seen in less than 0.1% of injections, but it is severe enough that the FDA put rather onerous monitoring requirements on the label, including a REMS program, which US psychiatrists are not used to following, and most impactful, every patient on every injection has to be monitored in the clinic for three hours. That's not happening and is largely the reason why the product is not being used.

PDSS is thought to be due to a burst of olanzapine in the blood. On the next slide, you can see how Medincell formulated our LAI olanzapine to eliminate that risk of burst, and therefore PDSS. What you can see here is that on the top, the Lilly product, when injected directly into human plasma, almost completely releases within the first 24 hours. You can imagine that that would correlate with a burst and then PDSS. But on the bottom, the Medincell product, subcutaneous, where there are very few blood vessels, even if injected directly in the human plasma, does not release right away, thereby eliminating the risk of PDSS.

Our partner Teva did negotiate with the FDA the number of injections needed to fully explore the risk of PDSS. That number was 3,600. As you can see, Teva has conducted more than 4,000 injections in the clinical program with no cases of PDSS. Here, zero is a really good number and bodes well for not needing those onerous monitoring requirements that really limited the use of the Lilly drug.

On the next slide, you can see the safety data for the Phase III study that Teva conducted using LAI-olanzapine. This was released in September of this year. The key point is that there were no cases of PDSS and no unexpected or surprising adverse events, and all was comparable to the oral and LAI formulations of olanzapine. Based on this, as you heard, the exciting news is that Teva has filed the NDA today. We should expect a 10-month review time, approval sometime in the fourth quarter of next year, with commercial launch before the end of 2026, and that's to be followed by submission in Europe, as Teva has already announced.

Christophe Douat

So let's go back to our growth engines. We've discussed, and I think you can all understand now why olanzapine is such a strategic, significant product. But let's go back to our risperidone LAI, which is important both because it is bringing us revenue, but also because it is a proof of concept of Teva's ability to get a product to market, which bodes well for olanzapine as well.

You can see that prescriptions keep growing and growing in a very nice, regular fashion. This translates into sales. And you can see on the next slide that Teva confirmed their guidance of 190 to 200 million dollars for 2025, which is the second full commercial year. You can notice as well that Q3 had lower sales than Q2. Teva explained that this was a one-time adjustment of Medicaid gross-to-net.

Now, maybe Richard, you could explain to us why UZEDY is doing so well and why it is such a great drug, both for patients and clinicians.

Richard Malamut

Yeah, I'd be happy to do that. A reminder that when we formulated UZEDY, long-acting injectable risperidone, we were looking to address some of the challenges faced by patients, clinicians, and even payers with the Johnson & Johnson portfolio of risperidone and paliperidone products.

First of all, UZEDY is subcutaneous, with a smaller needle, more comfortable for the patients, whereas the Johnson & Johnson products are intramuscular, more painful, larger needle. UZEDY reaches therapeutic levels within the first 24 hours after injection, making it easy to transition from oral risperidone, whereas the Johnson & Johnson products require either oral supplementation or titrating injections over several weeks before they reach therapeutic levels.

UZEDY comes in prefilled syringes: four different doses on a monthly regimen, four different doses on an every-other-month regimen, which correspond to the four usual doses of risperidone in schizophrenia, 2, 3, 4, and 5 mg. Whereas the Johnson & Johnson products are converted to paliperidone and require reconstitution in the office, which can be somewhat cumbersome for a psychiatrist.

Finally, Teva had asked US psychiatrists what one feature of a long-acting injectable product they would desire. The number one feature was flexibility to inject in different areas of the body. In fact, UZEDY, whether it's injected in the arm, the abdomen, or the thigh, has the same efficacy and safety, whereas the Johnson & Johnson product, intramuscular, has variable exposure with different PK up to 30%. For all these reasons, UZEDY has done very well and very quickly.

As you would expect, Teva has been collecting real-world data after the launch of UZEDY in May 2023. Here you can see on the left a reaffirmation of the primary endpoint in the Phase 3 study, which was relapse rate and time to relapse. In that study, compared to placebo, but here on the left, showing significant differences between UZEDY and a second-generation oral antipsychotic on relapse rate and time to relapse.

But remember that in schizophrenia, 80% of those patients do not take their medicines, and when they don't take their medicines, they relapse and end up in the hospital. So part of the value here is to keep patients out of the hospital. And in fact, on the right side of the slide, you can see that there was an almost 50% reduction in hospitalization rate, a 50% reduction in time spent in hospital if they needed to be admitted, and a correlation with a reduction in health care cost, which is of great interest to US payers, of course.

On the next slide, we can see two additional pieces of news that Teva announced this quarter. First of all, UZEDY has been approved for the treatment of Bipolar I disorder in the United States. Bipolar I disorder is much more common in the US. While the adherence rate is better than the 80% non-adherence rate seen in schizophrenia, still, 50% to 60% of those patients are non-compliant. We know that over 300,000 US patients are already taking a risperidone product for their Bipolar I disorder.

The second bit of news is that Teva has announced approval of long-acting injectable risperidone in Korea and in Canada. More to come, but those are the two countries that Teva has announced.

Christophe Douat

Thank you, Richard. Quite exciting on the UZEDY side as well. Just to give you some numbers, Teva estimates the cumulative peak sales of UZEDY and the olanzapine LAI to be between 1.5 and 2 billion dollars. Medincell's analysts are above 3. Of course, it could be higher; the future will tell. And we are looking forward to getting olanzapine out there as well.

Now, let's discuss the third engine. UZEDY was engine number one, olanzapine engine number two. And the leading program of the third engine is the first program we do with AbbVie. There's some piece of news today, as we are happy to announce that it will be ready to launch into Phase 1 in 2026. A very strategic program for both companies. Lead formulation was chosen in September 2024. Medincell did all pre-IND activities. AbbVie will conduct clinical development, and we are eligible to 315 million dollars of potential milestones, with royalties that now get into the low double digits.

But beyond AbbVie, we have a pipeline of products. Richard, maybe you could tell us about that?

Richard Malamut

Sure. We've talked about the two programs on the right, the partner programs with Teva in psychiatry, but we also have another late-stage program, this an intra-articular celecoxib to treat pain and inflammation in patients who have had total knee replacement surgery. We've been discussing with the FDA this year the design of our next Phase III study as well as endpoints, and we look forward to starting that study in the coming year.

Then moving to the left, you can see two other programs that we run internally. The first one is a six-month subcutaneous contraceptive to differentiate from existing shorter-term subcutaneous contraceptives. It is funded by the Gates Foundation, and we do plan to start Phase 1 sometime in 2026.

Then we also have another global health program to prevent the spread of malaria through the use of ivermectin, which kills mosquitoes and is effective in preventing the spread of malaria in endemic areas, particularly in children who are most vulnerable. Some news on that: we've just announced that that program is also funded by the Gates Foundation.

Then we have one more global health program we've recently disclosed, and that's a program in tuberculosis using a novel molecule, which in long-acting injectable form will improve the adherence in these patients, who don't tend to take their pills as many months as they need to, and reduce the risk of drug resistance. We're very excited about that program as well.

Then we also have 10 to 15 or so additional programs, undisclosed. They're early in development, so we typically don't disclose until a little later. But these are both internal programs as well as programs that can be already-approved drugs, but can also be

NCEs, where you need a long-acting formulation to enable use. Again, we're agnostic to therapeutic area and are developing these in more than five separate therapeutic areas.

David Heuzé

Thank you, Richard. Let's talk about financials.

Stéphane Postic

Yes, certainly. With pleasure. I'm going to comment on the financials for the half year that was closed on September 30th, 2025.

The first slide is on the revenue growth over the period. So, very nice improvement in the revenues for the period, an increase of 50% compared to the same half year for the past fiscal year. Three main items are contributing to the revenues.

First, obviously, the UZEDY royalties, which account for approximately one-third of the 14 million. I'll come back to that in more detail in a minute.

Then we have about half of it coming from the R&D partnerships. Obviously, we mentioned earlier the AbbVie first program, and that represents a big part of these R&D partnerships. On top of that, we mentioned with Rick the Gates Foundation program, or the malaria program, that were performed on behalf of foundations. The third item falling into these R&D partnerships is the 10 to 15 boxes that we saw on the pipeline. Some of them are proof-of-feasibility studies that we are running for undisclosed partners at the moment, but they might be the future licensing deals that we will execute over time. They're very important as well.

Third item in these revenues is a 2.5 million euro research tax credit that we are benefiting from. Again, it is another proof of the maturity of the pipeline and of the different programs, and it explains why this amount has increased largely compared to the previous year.

Very quickly, on the royalties from UZEDY. As Christophe mentioned, UZEDY is doing very well. You've seen the prescription curve, which is progressing very nicely. Teva has confirmed their guidance for 2025 to 190 to 200 million dollars of sales. Despite a slightly weaker Q3 2025 than expected, the sales have increased by 65% in USD compared to what they were in the same period last year. Once converted in euros, the increase is a bit lower than the 65%. It's only 50%, but it's still very good. It is very nice to have those 4.2 million euros on our P&L.

On the next slide, you have the operating expenses of the company, showing a 22% increase compared to last year. I remind you, 50% of increase in revenues and only 22% increase for operating expenses. What's important is that two-thirds of the operating expenses relate to R&D activities. Again, it is proof and evidence that the pipeline is progressing and that the programs in the pipeline are getting more and more mature. It is good news for the future. I remind you that also most of these R&D costs are covered

by partnerships and revenues. It is the case for the AbbVie first program, also for the Gates Foundation programs, and again for the proof-of-feasibility studies.

On the next slide, you have a view of the income statement. If you combine the 50% increase in income with the 22% increase in operating expenses, you end up with an improved operating loss by 13% to 6.6 million euros over the half year. It is good. It could have been even better without this negative impact of the US dollar, the weak US dollar over the period, which has impacted us badly. If this situation with a weak US dollar was to persist over time, it might delay our return to profitability, which we plan for fiscal year 2026–2027, but we have time to see how this evolves.

Another comment on the income statement regarding the financial results. We have again a non-cash impact due to the change in the fair value of the EIB warrants. This impact represents 6.8 million euros for the period. It is linked to the fact that the Medincell stock price has performed very well over the period, with a 65% increase. Again, on that topic, negotiations are progressing, but too slowly compared to what we were expecting, with the EIB. We're hoping to find a definitive agreement with them that will enable us to waive the put option that exists with the EIB. Without this non-cash adjustment to the fair value of the warrants, the net loss would have been drastically reduced to 9 million euros.

Finally, a word on the cash position. At the end of September, we had 53 million euros in bank. That's a bit lower than what we had at the end of March, which was just after the capital raise that we performed at the end of February, so it was probably a peak in our cash position. That said, it is a comfortable cash position that is sufficient to respect all the covenants that we have towards our banks, and especially the EIB, and it gives us sufficient visibility for the next two years at least, because we obviously will be getting additional royalties on a quarterly basis from UZEDY and hopefully from olanzapine at the end of 2026, plus potentially commercial milestones as well.

That's it for me.

David Heuzé

Thank you. Thank you, Stéphane. Now, let's move on to the Q&A session.

First question for you, Christophe, maybe. What does progress beyond 2026 look like: number of approved products, revenue scale or global partnerships? And how do you plan to maintain technological leadership as competitors enter the LAI space, potentially including big pharma?

Christophe Douat

On the first question, the best educated guess can be done by looking at the pipeline. So, 2026 should be approval of olanzapine. And then you can see in the pipeline, you have a celecoxib, potentially another program, which has commercial potential, AbbVie number one, and then the rest of the pipeline in formulation.

As far as technology leadership, that's a very good question, and I will give a bit of context here. Ten years ago, Johnson & Johnson was probably doing about a billion in schizophrenia. That became 5 billion worldwide ten years later. So every single company now in schizophrenia and bipolar wants to do a long-acting injectable of their drug. And we believe that the number of indications with long-acting injectables will increase in the next ten years. Some analysts believe that the global long-acting injectable market will go from about 15 billion today to 50 in ten years. And we want to be best positioned to do that.

To do that, I predict that at the end of the day, half of our innovation will come from internal innovation, half from external. We already have people scouting the world for new technologies, in either academic settings or small companies. And we will probably do alliances at some point. We are also working hard at developing the new generations of BEPO, and that is a very significant effort to keep maintaining our lead. We've shown that in our space, we are the best positioned company. We could do things that Johnson & Johnson could not do. We could do things that Eli Lilly could not do. We were the first company that could maybe meet the dream of Melinda Gates. And so we want to maintain that lead for sure, and we'll keep investing in technology.

David Heuzé

Thank you, Christophe.

Stéphane, next question. What are the revenues linked to the joint venture with Corbion for H1?

Stéphane Postic

For H1, they're fairly limited, less than 100K. That's because, when you understand the business model of the JV, at the moment, the orders that the JV is receiving from their different partners are not linear because we are at the beginning of the commercialization. There can be big orders one half-year and smaller ones on the next one. Over time, it will increase and become more stable. But for the moment, it's limited.

David Heuzé

Okay. Next question also for you, Stéphane. Opex has gone up quite notably, largely due to R&D spend. How should we anticipate this to look for the full year and in outer years?

Stéphane Postic

So indeed, it has increased for the first half year. As I mentioned, it is evidence that we are gaining credibility and enriching the company portfolio: more programs, more mature programs. I would say that it's good news if we are continuing to invest in these R&D costs, because it is the future of Medincell and the future licensing deals that are there.

David Heuzé

Okay, next question. The press release that we issued today states that Medincell has decided to accelerate certain activities related to technological innovation to further extend its capabilities in terms of formulation. Is this perhaps related to peptide or protein capabilities?

Christophe Douat

Yes, but not only. There are three directions we could work on. First is highly hydrophobic molecules. Second is the dose, because sometimes we are limited by the dose because you don't want to have a depot which is too big subcutaneously. And then the highly hydrophilic. Yes.

David Heuzé

Thank you, Christophe. Next question. Last winter, you indicated the first AbbVie program was targeting IND in 18–24 months. Where are we on that clock today, from the CMC readiness? Can you share more about the timeline? When do you expect IND filing and clinical start? And what remaining gating items could push IND beyond mid-2026?

Christophe Douat

I think we answered that question during the presentation, as we stated that, yes, we were expecting the start of clinical activities during 2026, which means that all other pre-IND activities, including CMC, are on track.

David Heuzé

Thank you, Christophe. Next question. You framed the deal as up to six programs, the deal with AbbVie. Have AbbVie and Medincell already selected a second and third candidate? If so, what's the rough scheduling for CMC and preclinical starts across 2026–2027? Are the candidates adjacent categories or therapeutic areas, or differentiated?

Christophe Douat

As I said, I think in our French presentation, I can't comment on the status of our discussion with AbbVie. I'll go back to the first product, which is on track to go into a clinical stage in 2026.

David Heuzé

We're just going to add that we stated when we announced the collaboration that it can be in different therapeutic areas. That's the only thing we can say today.

Next question. The Board of Directors of Medincell has been strengthened with additional appointments of prominent industry leaders. Do you see partnerships arising from operations tied to these individuals' potential, including Intracellular or Novartis?

Christophe Douat

Obviously, we select board members for their competencies and experience, and the two new board members have incredible experience and competencies. If they can help us, like other board members, using their networks, we would love to use that capability.

David Heuzé

Thank you, Christophe.

Next question for you, Richard. Is it feasible for both MDC-STM and MDC-WWM to enter clinical development in 2026, or are you prioritizing one of the programs?

Richard Malamut

Yeah. So we expect all our programs to succeed, and the timelines are based on the data accumulation on the programs. As of today, we're looking for the WWM program to enter Phase 1 sometime towards the end of 2026. STM, we think maybe a little later.

David Heuzé

Thank you, Richard.

Next question, Stéphane. Outside of the 4 million dollars for the potential approval of olanzapine next year, are there any other milestones to anticipate for 2026?

Stéphane Postic

So I'm not sure I can disclose much on that, but we hope indeed to have more milestones in 2026–2027. You know that we are eligible to several types of development and commercial milestones from Teva on one side and also from AbbVie. So there are different sources of milestones that can be achieved in 2026–2027, and there's a probability to it.

David Heuzé

It looks like the last question. You've indicated that you currently have multiple collaboration deals ongoing. Could you please comment on the pace for future partnerships that might materialize and get announced in the next five years?

Christophe Douat

Obviously, I can't comment on the current collaborations, but I can comment on what we are building here. And the image I will take is a string of pearls, “pearls” meaning blockbuster potential drugs. We have UZEDY, then olanzapine, AbbVie number one. And now all our focus and efforts are trying to work on the next pearls after those programs.

David Heuzé

Thank you, Christophe, and thank you all for your questions. It was a very good discussion. Before we leave, Christophe, I will give you the floor for a final word.

Christophe Douat

Thank you for being with us tonight and sharing this amazing news. You can see that it's quite emotional. We've been working on olanzapine LAI for over 10 years, against all odds. Our team here really knew we could solve it, and we did. But we also convinced Teva that we could. Teva has been a formidable partner on this, taking the product through clinicals. And here we are with a major, major first-in-class product that could be launched in about a year. So, exciting news.

As I said in our French meeting just earlier today, here we'll be drinking champagne tonight to celebrate this news. And we are looking forward to our next discussions and following all the progress. You see that even beyond olanzapine, UZEDY is progressing well and the rest of the pipeline as well. The three engines are really performing well.

David Heuzé

Thank you. Thank you, guys. Thank you, everybody, for joining us today. We truly appreciate your trust and your interest in Medincell, and hope to see you soon. Thank you. Bye. Have a good day.