

Transcript

Investor Webcast - WELTRUZA™ FDA Approval – October 9, 2026

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Head of Financial and Corporate Communications

Good afternoon, everyone, and thank you for joining us on this very special day for MedinCell. As you can imagine, we will discuss what WELTRUZA's U.S. approval means for MedinCell, the market opportunity and the long-term financial impact, before taking questions from analysts.

Joining me today are Christophe Douat, our Chief Executive Officer, and Stéphane Postic, our Chief Financial Officer.

Before we start, I want to remind you that today's presentation and our comments include forward-looking statements involving risks and uncertainties. Actual outcomes may differ materially. Please review the important notice on slide 2 of the presentation. All information speaks only as of today.

Christophe, over to you.

Christophe Douat

Chief Executive Officer

Thank you, David, and welcome everyone. WELTRUZA's approval is a decisive step in our Shift to Growth strategy.

Our three engines are now progressing in parallel: UZEDY, WELTRUZA, and our partnered and internal pipeline, including our first program with AbbVie. Together, they illustrate the model we are building: multiple differentiated long-acting medicines, supported by multiple partnerships and capable of generating recurring value over time.

WELTRUZA is transformational for MedinCell across three dimensions:

- > Innovation: the first and only once-monthly subcutaneous olanzapine LAI for adults with schizophrenia.
- > Financial impact: a second potential stream of recurring royalties, alongside potential milestones.
- > Platform validation: a second FDA-approved product, demonstrating the repeatability of our technology and business model.

Schizophrenia is a chronic, progressive and debilitating disorder, and long-term adherence remains a major challenge. Missed doses can lead to treatment failure and relapse.

By reducing the burden of daily dosing, long-acting injectables can support adherence and lower relapse risk. This is the patient need WELTRUZA is designed to help address for appropriate patients treated with olanzapine.

Today, Long-Acting Injectable are the core of schizophrenia innovation.

LAI penetration in schizophrenia is expected to increase from approximately 13% in 2025 to 18% beyond 2030.

Within this growing market, around 300,000 U.S. patients are already treated with oral olanzapine. Olanzapine is a well-established treatment option, including in more complex patient populations, but LAI

penetration has remained minimal because of the post-injection monitoring requirement associated with the previous option.

WELTRUZA is the first olanzapine LAI approved in the United States without a post-injection monitoring requirement. This removes a major practical barrier to the use of long-acting olanzapine.

It is administered subcutaneously once monthly, requires neither loading doses nor oral supplementation at initiation, and is available in three doses corresponding to commonly prescribed oral doses.

In Teva's Phase 3 SOLARIS program, WELTRUZA demonstrated efficacy across symptoms, illness severity, and personal and social functioning. Its systemic safety profile was consistent with oral olanzapine, and no cases of PDSS were observed during clinical development. Commercial adoption will depend on launch execution, reimbursement, physician adoption and patient access.

UZEDY and WELTRUZA are complementary treatments based on different active ingredients and addressing different clinical needs. Together, they cover the two most widely prescribed atypical antipsychotics in schizophrenia and have the potential to address roughly 75% of schizophrenia patients in the United States.

As you can see on the slide, the contrast is clear: long-acting formulations are already well established for risperidone and paliperidone, while olanzapine remains widely used orally but largely untapped in long-acting form. WELTRUZA removes a key barrier that historically limited olanzapine LAI adoption.

Teva expects to begin making WELTRUZA available in the United States in the coming weeks. Patient access will depend on market-access processes and discussions with payers, which can take time. Teva brings deep expertise in the U.S. schizophrenia market, an established commercial infrastructure, and recent experience launching and growing UZEDY. This provides a strong foundation for WELTRUZA, while outcomes will depend on execution, reimbursement, physician adoption and patient access.

Stéphane, I leave you the floor for the financial framework.

Stéphane Postic
Chief Financial Officer

Thank you, Christophe. With UZEDY and WELTRUZA, Medincell now has two approved products under the same economic terms, assessed separately for each product.

For each product, Medincell is eligible for mid- to high-single-digit royalties on net sales. Up to \$108 million of milestones remain for UZEDY and up to \$112 million are presented for WELTRUZA, including the \$4 million approval milestone. Commercial milestones depend on specified annual net-sales thresholds.

Royalties are the principal driver of long-term value. Teva currently estimates combined peak sales of up to \$2.0 billion for the UZEDY and WELTRUZA schizophrenia franchise. This is Teva's publicly stated expectation, not Medincell guidance. At that level, Medincell's annual royalties could approach \$150 million, depending on product mix and applicable rates; this is an illustration, not a Medincell forecast.

The U.S. patent portfolio covering WELTRUZA includes multiple granted patents extending to 2044. Patents may be challenged, and this should not be interpreted as guaranteed exclusivity through that date, but intellectual property and know-how provide an important foundation for the long-term value creation.

Christophe, back to you.

Christophe Douat
Chief Executive Officer

Thank you, Stéphane. I would first like to thank Teva and all the teams who contributed to this approval. It reflects years of persistence, scientific rigor and close collaboration. Let me close with three key outcomes:

- > WELTRUZA addresses a major treatment gap and opens a significant opportunity in a large, established oral olanzapine population.
- > It creates a second long-term royalty stream and expands Medincell's recurring revenue base and growth potential.
- > With two FDA-approved products, Medincell's platform is now established as a proven engine for differentiated long-acting medicines.

One last thing I want to say. WELTRUZA is more than a second approval. It opens a new growth chapter for Medincell and contributes to a broader transformation driven by execution, growth, recurring revenues, an expanding pipeline and world-class partnerships. We believe Medincell is entering the most transformative years in its history. Thank you. We are now ready to take your questions.

David Heuzé
Head of Financial and Corporate Communications

Thank you Christophe, and thank you Stéphane. We can now open the call for questions, with the first question coming from Michael from Evercore.

Michael DiFiore
Evercore

Thanks so much for taking my question and much Congrats on the approval. I know this is a long time coming and well deserved. Three questions from me. Wanted to get your thoughts on what you expect the maximum conversion from oral Olanzapine might be and how this may differ in the US versus the EU.

Christophe Douat
Chief Executive Officer

The conversion rate at Medincell, we think it could be higher than Risperidone and Paliperidone because of the higher need for compliance with the population that takes olanzapine. The second point I would make is since there is no appropriate LA of Olanzapine on the market, it's a wide-open road for WELTRUZA, which should experience a faster ramp up than UZEDY.

David Heuzé
Head of Financial and Corporate Communications

Thank you. Next question comes from Shan Hama of Jeffries. Hi Shan.

Shan Ama*Jefferies*

Thank you so much for taking my questions. I have two please.

So given that Europe is of course waiting for that decision at the moment. Could you help us understand how significant the PDSS sort of monitoring is in Europe and how that looks versus in the US just to get an idea of the potential uptake in Europe if and when it gets approved?

And then secondly, I guess earlier on Teva's call, management noted that expansion into bipolar mania, would require additional clinical studies.

And then of course, given that WELTRUZA approval without monitoring requirements has been achieved, how are you thinking about future label expansion opportunities for this asset or do you think this is a primarily severe schizophrenia asset?

Thanks very much.

Christophe Douat*Chief Executive Officer*

So when you look at the existing product which has PDSS, if you look at the existing patient population, I believe there is around 300 patients in the US as we speak that use the existing product from Eli Lilly. So there is a wide open space for WELTRUZA.

In Europe, same situation. PDSS has really scared clinicians and patients from using the existing LAI product.

So we expect a very strong significant shift from oral olanzapine to the WELTRUZA Olanzapine Long Acting in the upcoming months and years both in the Europe, in the in the US.

So we can't disclose Teva's plans on indication expansion, obviously given the very significant potential of Olanzapine LAI, something that Teva is looking at in the same manner as they looked at it for UZEDY and expanded into the bipolar disorder indication.

Nicolas Pauillac*Kepler Chevreux*

Hi guys. Congrats on the big news. It brings like 2023 memories. Big congrats.

Maybe two question on my end, 1 is going to be pretty fast, just maybe a clarification on what you said Stéphane, when you mentioned that "these are TEVA's target", where you implying they are too conservative or was it to repeat that you only get priorities on that? So just a quick clarification there.

And then the, the second question, how should we think about this ambition of Medincell to reach the operational profitability, knowing that TEVA in their call, were pretty vocal in the fact that they were highlighting that we should expect a slow ramp up into H1 27 and then probably an acceleration of the sales into H2.

So how do we think about that when we look at let's say Medincell's angle there?

Stéphane Postic*Chief Financial Officer*

OK, thank you for the question, Nicolas. So on the on the first part, indeed, I emphasized on the fact that it is Teva's guidance that was mentioning this 2 billion franchise for the two products. As you know, since you are following Medincell for a long time, all of you: we believe that there's indeed more room to play on the on the two programs.

UZEDY already is going to achieve almost 300 million this year – it means that it's on target to become a blockbuster product by the beginning of the twenty 30s.

And we all know that the the potential of WELTRUZA is even bigger than for UZEDY. All in all, 2 billion for the two products seems indeed a bit conservative, but at the moment it is indeed the public guidance from TEVA.

Now on the operating profitability, I would say that definitely the news of today is a good one because it triggers first a milestone of \$4 million. It also means that we are going to receive royalties from TEVA on the WELTRUZA net sales on top of UZEDY ones.

So things are definitely going in the right directions in terms of revenues.

Does that mean that profitability is going to happen in 27? I'm not going to comment on that.

Christophe mentioned very briefly the third engine that we have with the first Abbvie program as the first program in the pipeline. So that's definitely something that we are looking carefully at and making sure to have all the resources rightly allocated.

Damien Choplain*Stifel*

Congrats on the approval. I have one question regarding weight gain. Is there evidence of any metabolic difference versus oral Olanzapine or should we assume the same profile? And would it make sense to combine WELTRUZA with obesity drug to offset these side effects and in the end limits potential treatment discontinuation?

Christophe Douat*Chief Executive Officer*

Hello Damien. Great question.

So it is a similar profile between olanzapine and Weltruza. However, I was at the Psych Congress in New Orleans just two weeks ago and something we'll watch very closely is the impact of the use of GLP-1 on olanzapine because the early data shows that the weight gain can be mitigated by using GLP-1s.

And we know that soon like in 2031, semaglutide will get off patent and could provide a boost to the use of olanzapine.

So we plan to evaluate this potential more closely because from the early information we have, weight gain is, what is, you know, limiting the use of olanzapine.

It is still the most used antipsychotic, but it could do a lot more if it had less weight gain.

So, more to come on that subject. But it's really on top of our agenda here at Medincell.

David Heuzé*Head of Financial and Corporate Communications*

Thank you. Next question comes from Mark Goodman of Leerink. Hi Marc.

Marc Goodman*Leerink Partners*

This is Alyssa on for Mark. Congrats on the approval and thanks for taking your question. I was wondering if you could give us an update on the BEPO Star platform and when we might get some more data on how the progression is going for the next generation approaches?

Christophe Douat*Chief Executive Officer*

Yes, just to remind everybody within our three engines of growth – UZEDY is number one, WELTRUZA now number two and innovation and pipeline are the third engine.

And at the R&D day of May 12th, we said that we were switching all programs to the use of BEPO Star, which is our new generation with patent life moving from 2033 on BEPO linear to 2040 on BEPO Star.

This is just the technology patent life because of course on products like UZEDY and Olanzapine, we have additional patterns on method of use and composition of matter.

So yes, BEPO Star is moving into all our new collaborations and internal programs.

And then beyond that we also said in May that we had early innovation that was creating the most excitement I had seen at medicine in 15 years.

And today I can confirm that the excitement is growing after additional data and that we are starting to accelerate the scale up of this third generation as well.

And contemplating the use of its use in selected partnerships.

David Heuzé*Head of Financial and Corporate Communications*

Thank you. Next question is from Martial Descoutures from Oddo.

Martial Descoutures*Oddo*

Thank you very much for taking my question. Maybe just a follow up question of the one Nicolas previously asked - when do you expect royalties and milestones from WELTRUZA to become a meaningful contributor to Medincell and maybe clarification on the milestone expected.

Are they linked to the geographical expansion or is it only linked to the sales of the drug?

Stéphane Postic*Chief Financial Officer*

Okay. So to answer to your question, Martial, first, maybe on the milestone, they are -- we are entitled indeed to receive today \$4 million from Teva, thanks to the U.S. approval. We also entitled to receive \$3 million once the product gets approved in different EU countries. So that should come next year, probably end of '27, beginning of '28. And on the contribution that you mentioned, we expect to have a much faster

ramp-up on WELTRUZA than on UZEDY because of the simple absence of any competition. So probably the ramp-up to peak sales will be much faster for the second product for WELTRUZA and we'll see.

David Heuzé

Head of Financial and Corporate Communications

Thank you. I think that was the last question. There are no more questions. So, thank you, everybody. Thank you for joining us. Christophe, I leave you the floor for conclusion.

Christophe Douat

Chief Executive Officer

Well, thanks to all. We all know how important this news is for Medincell, of course, for patients, and we have been looking for this. We have been looking for the approval with no monitoring requirements, and we have it. It's amazing news, a historic moment in the life of Medincell and we'll be talking soon and watch this ramp-up of this amazing product.

David Heuzé

Head of Financial and Corporate Communications

Thank you, Christophe. Thank you, Stephane. Thank you, everybody, and see you soon.

Stéphane Postic

Chief Financial Officer

Thank you. Bye-bye.

Christophe Douat

Chief Executive Officer

Thank you.