PRESS RELEASE - November 5, 2025 - 1:00 pm CET - Montpellier, France - Euronext Paris: MEDCL

UZEDY® continues strong growth; Teva setting the stage for US NDA Submission for Olanzapine LAI in Q4 2025

Medincell's partner Teva Pharmaceuticals shared today the following information:

About Olanzapine Long-Acting Injectable (TEV-749 / mdc-TJK)

1-Month subcutaneous olanzapine, the most prescribed antipsychotic for schizophrenia in the U.S.

Pivotal Phase 3 completed in January 2025 with positive Phase 3 efficacy and safety results[1] and no PDSS[2]

Anticipated opportunity

- **Estimated 20% to 30% of patients on oral olanzapine are potential candidates for LAI**
- **Absence of required monitoring expected to drive Olanzapine LAI usage growth**
- **U.S. NDA[3] submission planned for Q4 2025**
  Following an NDA submission, the FDA takes approximately 2 months to determine acceptance for review, followed by an additional 8 months for a standard review, which may lead to approval in late 2026.

Medincell is eligible for $7 million in development milestone. Provided approval, Medincell will receive mid- to high-single digit royalties on all sales and will be eligible for $105 million of commercial milestones.

About UZEDY®

1-Month and 2-Month subcutaneous risperidone for schizophrenia

Commercialized in the U.S. since May 2023

2024 sales: $117 million

- **Q3 2025 sales: $43 million, +24% compared to Q3 2024**
- **Year-to-date sales: $136 million, +82% compared to previous year**
- **Continued growth of prescriptions (MoT[4]): +119% YoY**
  (partially offset by Medicaid adjustments)
- **Reaffirmed 2025 Revenue Outlook by Teva: $190 - $200 million**
  (Q4 implied guidance: ~$55 - $65 million)

Medincell receives mid- to high-single digit royalties on all sales and is eligible for $105 million of commercial milestones.

[1] Presse Release, September 22, 2025: https://www.medincell.com/wp-content/uploads/2025/09/MDC_Psych2025_Olanzapine_EN_22092025.pdf
[2] Post-Injection Delirium/Sedation Syndrome (PDSS) is a rare but significant complication associated with existing long-acting injectable formulation of olanzapine. PDSS occurs when a portion of the injected medication unintentionally enters the bloodstream too quickly, causing sudden sedation, confusion, and potentially serious side effects such as respiratory issues. For healthcare providers and patients, PDSS remains a barrier to the widespread use of olanzapine LAI. The requirement for close post-injection monitoring limits the convenience and flexibility of this treatment option. Medincell's olanzapine LAI is designed to eliminate the risk of PDSS, potentially making it a safer and more accessible treatment option. Press release, Nov. 6, 2024: https://www.medincell.com/wp-content/uploads/2024/11/PR_MDC_Teva-earnings-Q3_2024_06112024.pdf
[3] NDA (New Drug Application): Formal request for approval to market a new pharmaceutical product, containing detailed data on its safety, efficacy, manufacturing, and labeling.
[4] MoT: Month of Therapy

Teva Q3 2025 press release: https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2025/Tevas-Innovative-Portfolio-Drives-11th-Consecutive-Quarter-of-Growth-in-Q3-2025-Increases-2025-Outlook-for-Austedo-and-Non-GAAP-EPS/default.aspx

Teva Q3 2025 earnings conference call today at 8:00am ET, webcast and replay:
https://events.q4inc.com/attendee/795276763

About Medincell

Medincell is a clinical- and commercial-stage biopharmaceutical licensing company developing long-acting injectable treatments across multiple therapeutic areas. Our innovative treatments are designed to ensure adherence to medical prescriptions, enhance the effectiveness and accessibility of medicines, and reduce their environmental impact.

These treatments combine active pharmaceutical ingredients with our proprietary BEPO® technology, which enables controlled drug delivery at therapeutic levels for several days, weeks, or months following a subcutaneous or local injection of a small, fully bioresorbable deposit.

The first treatment based on BEPO® technology was approved for schizophrenia by the FDA in April 2023 and is now marketed in the United States by Teva under the name UZEDY® (BEPO® technology is licensed to Teva under the name SteadyTeq™).

Our investigational pipeline includes numerous innovative therapeutic candidates in various stages of development, from formulation to Phase 3 clinical trials. We collaborate with leading pharmaceutical companies and foundations to advance global health through new treatment options.

Headquartered in Montpellier, France, Medincell employs over 140 people representing more than 25 nationalities.

medincell.com

UZEDY® and SteadyTeq™ are trademarks of Teva Pharmaceuticals.

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