

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 results¹ and no PDSS²

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. NDA³ 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 (MoT⁴): +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/Teva-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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This press release contains forward-looking statements, including statements regarding Company's expectations for (i) the timing, progress and outcome of its clinical trials; (ii) the clinical benefits and competitive positioning of its product candidates; (iii) its ability to obtain regulatory approvals, commence commercial production and achieve market penetration and sales; (iv) its future product portfolio; (v) its future partnering arrangements; (vi) its future capital needs, capital expenditure plans and ability to obtain funding; and (vii) prospective financial matters regarding our business. Although the Company believes that its expectations are based on reasonable assumptions, any statements other than statements of historical facts that may be contained in this press release relating to future events are forward-looking statements and subject to change without notice, factors beyond the Company's control and the Company's financial capabilities.

These statements may include, but are not limited to, any statement beginning with, followed by or including words or phrases such as "objective", "believe", "anticipate", "expect", "foresee", "aim", "intend", "may", "anticipate", "estimate", "plan", "project", "will", "may", "probably", "potential", "should", "could" and other words and phrases of the same meaning or used in negative form. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that may, if any, cause actual results, performance, or achievements to differ materially from those anticipated or expressed explicitly or implicitly by such forward-looking statements. A list and description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the Autorité des Marchés Financiers (the "AMF") pursuant to its regulatory obligations, including the Company's registration document, registered with the AMF on September 4, 2018, under number I. 18-062 (the "Registration Document"), as well as in the documents and reports to be published subsequently by the Company. In particular, readers' attention is drawn to the section entitled "Facteurs de Risques" on page 26 of the Registration Document.

Any forward-looking statements made by or on behalf of the Company speak only as of the date they are made. Except as required by law, the Company does not undertake any obligation to publicly update these forward-looking statements or to update the reasons why actual results could differ materially from those anticipated by the forward-looking statements, including in the event that new information becomes available. The Company's update of one or more forward-looking statements does not imply that the Company will make any further updates to such forward-looking statements or other forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements.

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