

## UZEDY® Continues Strong Momentum in 2025; Olanzapine LAI on Track for FDA Filing in H2 2025

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

### About UZEDY®

- 1-Month and 2-Month subcutaneous risperidone for schizophrenia
- Commercialized in the U.S. since May 2023
- 2024 sales: \$117 million,
- **Q1 2025 sales: \$39 million, 2.6x increase compared to Q1 2024**
- **Continuous growth of prescription: 2.8x increase compared to Q1 2024**

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

### 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 results<sup>1</sup> and no PDSS<sup>2</sup>
- **Preparation for filing and launch on track**
  - **Productive Pre-NDA<sup>3</sup> meeting with FDA held on April 9, 2025**
  - **Safety data to be presented at Psych Congress Elevate, May 28-31, 2025, Las Vegas**
  - **NDA submission planned for H2 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.

**Teva Q1 2025 press release:** <https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2025/Teva-Reports-Ninth-Consecutive-Quarter-of-Growth-in-Q1-2025-With-Key-Innovative-Medicines-Growing-40-2025-Profit-Outlook-Improved/default.aspx>

**Teva Q1 2025 earnings conference call today at 8:00am ET, webcast and replay:**

<https://events.q4inc.com/attendee/984311609>

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<sup>1</sup> Press Release, May 8, 2024: [https://www.medincell.com/wp-content/uploads/2024/05/PR\\_Solaris\\_08052024\\_EN\\_Final.pdf](https://www.medincell.com/wp-content/uploads/2024/05/PR_Solaris_08052024_EN_Final.pdf)

<sup>2</sup> 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](https://www.medincell.com/wp-content/uploads/2024/11/PR_MDC_Teva-earnings-Q3_2024_06112024.pdf)

<sup>3</sup> NDA (New Drug Application): Formal request for approval to market a new pharmaceutical product, containing detailed data on its safety, efficacy, manufacturing, and labeling

## About Medincell

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Medincell is a clinical- and commercial-stage biopharmaceutical licensing company developing long-acting injectable drugs in many therapeutic areas. Our innovative treatments aim to guarantee compliance with medical prescriptions, to improve the effectiveness and accessibility of medicines, and to reduce their environmental footprint. They combine active pharmaceutical ingredients with our proprietary BEPO® technology which controls the delivery of a drug at a therapeutic level for several days, weeks or months from the subcutaneous or local injection of a simple deposit of a few millimeters, entirely bioresorbable. The first treatment based on BEPO® technology, intended for the treatment of schizophrenia, was approved by the FDA in April 2023, and is now distributed in the United States by Teva under the name UZEDY® (BEPO® technology is licensed to Teva under the name SteadyTeq™). We collaborate with leading pharmaceutical companies and foundations to improve global health through new treatment options. Based in Montpellier, Medincell currently employs more than 140 people representing more than 25 different nationalities.

*UZEDY® and SteadyTeq™ are trademarks of Teva Pharmaceuticals*

**medincell.com**

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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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