

## MedinCell publishes its consolidated half-year financial results April 2023 - September 2023

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**Commercial launch by Teva of UZEDY™, the first product based on BEPO® technology, in the United States, and collect of first royalties representing €635K (June-September 2023).**

Christophe Douat, CEO of MedinCell, said:

*"Commercial revenues will transform MedinCell for the long term, especially as the first trends in UZEDY prescriptions and feedback from professionals and patients are very promising. Another good news is that revenues from UZEDY could soon be complemented by those from mdc-TJK, with phase 3 results now expected in 2024.*

*Considering these factors, our goal is to achieve operational profitability as soon as possible and to generate additional revenue with new partnerships to extend our cash visibility until this horizon."*

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### Other key highlights in the first half of fiscal year 2023-24

- Acceleration of the phase 3 clinical trial of mdc-TJK, the second antipsychotic developed with Teva, with results now expected in the second half of 2024
- End of recruitment for the phase 3 clinical trial of the mdc-CWM program (post-operative pain), with analysis of efficacy results expected in the first quarter of 2024
- Progress in the rest of the portfolio, with clinical trials of several programs scheduled to start in 2024
- Financing:
  - €23.2 million net of costs from the capital increase of May 12, 2023
  - €10.0 million representing the final tranche of the European Investment Bank loan

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### Consolidated financial statements for the first half of the 2023-24 financial year

- **Income from ordinary activities: €8.2 million** (+6.1% vs. first half of previous year, of which €7.0 million in revenue, +15.9%)
- **Operating expenses: €17.1 million** (-11.5% vs. first half of previous year)
- **Net result: €-8.2 million** (vs. €-13.7 million in first half of previous year)
- **Available cash: €26.8 million** (of which €15.0 million in non-risky current financial assets)

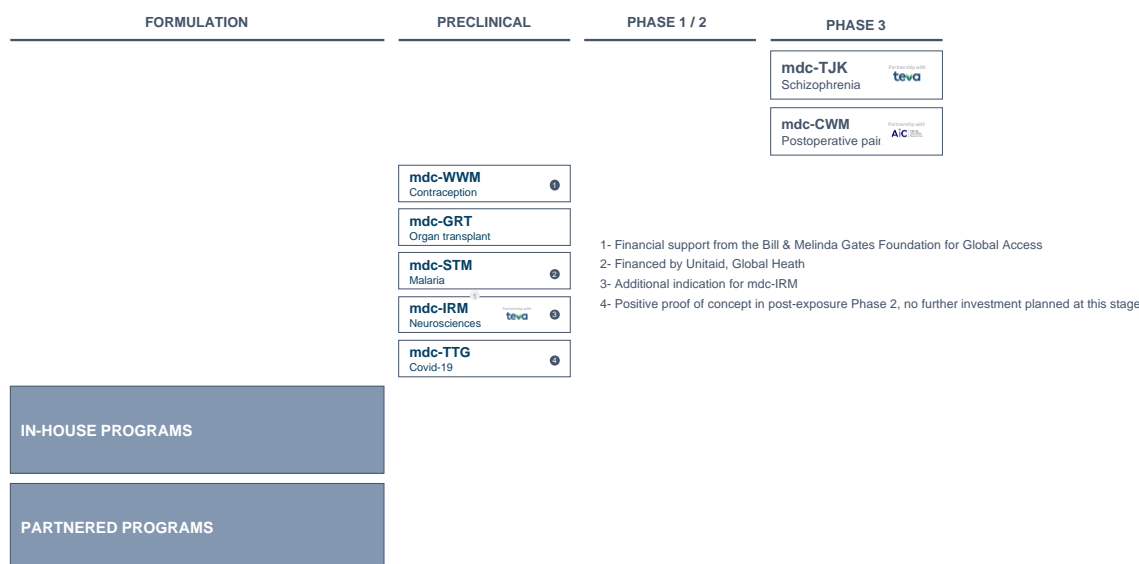
*Main cash payments received after the closing  
+€4.2 million from the 2022 Research Tax Credit  
+€2.7 million from the Gates Foundation for collaboration on the mdc-WWM program*

## Marketed product: UZEDY (risperidone – schizophrenia)

UZEDY is the first product based on MedinCell's long-acting injection technology, BEPO, to reach commercial stage

- US marketing authorization obtained from the FDA on April 28, 2023
- Commercial launch under the UZEDY brand by our partner, Teva, in the United States in May 2023
- Teva's positive comments on the commercial launch:
  - On the basis of agreements already concluded and ongoing negotiations with US private and public insurance systems, our partner expects to be well positioned for market access in 2024
  - Feedback from healthcare professionals and patients has been very positive about the product's features: subcutaneous injection, immediate action, pre-filled, ready-to-use syringe, etc.
  - Teva anticipates significant sales growth in 2024
- During the first half, UZEDY generated a €3.6 million milestone payment following FDA approval, as well as the very first royalties of €0.6 million, calculated on Teva's net sales from mid-May to end of September.

## Development of product portfolio based on BEPO technology



R&D portfolio as of September 30, 2023

### Programs in clinical Phase 3

#### mdc-TJK (olanzapine - schizophrenia)

If approved by the FDA, mdc-TJK would be the first long-acting injectable olanzapine product with a favorable safety profile potentially elevating this product to "first-in-class" status. mdc-TJK offers a complementary treatment solution to UZEDY for patients with more severe forms of schizophrenia.

- The Phase 3 clinical trial conducted by our partner, Teva, began in the United States in January 2023.
- On November 13, 2023, Teva announced that it had reached an agreement with Royalty Pharma to accelerate the development of mdc-TJK.
- On November 29, 2023, Teva reported that over 600 patients (out of 640 planned in the study) had already been enrolled, and that no post-injection delirium/sedation syndrome (PDSS) had been observed on over 1400 injections. Teva also announced that all data (collected after 3600 injections) are expected in the second half of 2024 (as opposed to the previous expectation of H1 2025). These data will include the study's primary endpoints and safety data.

#### mdc-CWM / F14 (celecoxib - postoperative pain)

Conducted and funded by MedinCell's partner, Arthritis Innovation Corporation (AIC), the first Phase 3 clinical trial of this locally administered treatment to relieve patients' pain for a prolonged period after surgery began in November 2022.

- Recruitment of the 151 patients was completed in August 30, 2023 with the last patient completing the 3 month follow-up period end of November 2023.
- Data base lock and topline results are expected in the first quarter of 2024.

### Programs in formulation and preclinical

- Progress in preclinical activities for three programs with a view to starting clinical trials in 2024: mdc-GRT (immunosuppressant/organ transplant), mdc-WWM (contraception) with support from the Bill & Melinda Gates Foundation and mdc-STM (malaria) with support from Unitaid.
- Several collaborations with pharmaceutical partners are currently in formulation.
- MedinCell continues to expand its portfolio of in-house programs.

### Selected financial information for the first half of the 2023-2024 fiscal year

Consolidated key figures - IFRS (In thousands of €)

PROFIT AND LOSS ACCOUNT	09.30.2023 6 months	09.30.2022 6 months
Revenue	6 985	6 027
Other income from ordinary activities (Research Tax Credit)	1 195	1 682
Current operating profit	(8 957)	(11 652)
Operating profit	(8 981)	(11 657)
Financial result	823	(2 090)
Net result	(8 158)	(13 747)

CASHFLOW	09.30.2023 6 months	09.30.2022 6 months
Net cashflow from operating activities	(11 759)	(9 962)
Net cashflow flow from investing activities	(190)	(230)
Net cashflow from financing activities	32 260	(2 700)

BALANCE SHEET	09.30.2023	03.31.2023
Equity of the consolidated group	(25 747)	(42 294)
Total non-current liabilities	56 414	14 608
Total current liabilities	19 821	57 025
Total non-current assets	11 093	9 772
<i>Of which financial assets and other non-current assets</i>	3 262	1 460
Total current assets	39 397	19 568
<i>Of which cash and cash equivalents</i>	26 779	6 467

FINANCIAL DEBT	09.30.2023	03.31.2023
Financial debt, non-current portion	53 659	11 708
Financial debt, current portion	9 418	42 812
<b>GROSS FINANCIAL DEBT</b>	<b>63 077</b>	<b>54 520</b>
Cash and cash equivalents	26 779	6 467
<b>NET FINANCIAL DEBT</b>	<b>36 298</b>	<b>48 053</b>

## Profit and loss account

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### Income from ordinary activities: €8.2 million

Increased by 6% compared to the previous period, revenues for the first half of the 2023-2024 financial year were generated by (i) a milestone payment of €3.6 million for UZEDY's marketing approval by the US FDA, (ii) services rendered as part of the Company collaborations, (iii) royalties received from Teva on the first sales of UZEDY (€0.6 million) and from CMB for the supply of copolymers.

The Company's research and development (R&D) activities are eligible for the Research Tax Credit. It has decreased compared to last year by 29% due to lower R&D expenses, particularly for expenses with CDMO and clinical CROs.

### Current operating expenses in line with the development of the Company's portfolio: €17.1 million

Operating expenses were down by 12% compared to the same period last year. This was mainly due to lower R&D expenditure, which accounted for 65% of operating expenses. This is the consequence of the reorganization of teams and optimization of internal skills, and of the nature of outsourced activities, which differ from the previous year.

Marketing and sales expenditure was up by almost 8% on the same period last year, due in particular to the promotional campaign launched after the approval of UZEDY.

Overheads, meanwhile, rose by 37% over the period, mainly due to the increase in salaries and bonuses for members of the Executive Board, higher legal and accounting fees, and the deployment of our investor strategy in the United States.

### Net financial income: €0.8 million

The change in the financial result is explained by the renegotiation of the EIB loan on November 22, 2022, which led to an increase in the average indebtedness following the issuance of tranches B and C and to a reduction in the interest rate from 16.28% to 13% on tranche A, and to the re-estimation of the variable remuneration and the fair value variation of the BSA put options linked to the EIB loan as of September 30, 2023.

## Consolidated cash flow statement

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(In thousands of €)	09.30.2023 6 months	09.30.2022 6 months
Net cash from operating activities	(11 759)	(9 962)
Net cash flow from investing activities	(190)	(230)
Net cash flow from financing activities	32 260	(2 700)
<b>CHANGE IN NET CASH AND CASH EQUIVALENTS</b>	<b>20 312</b>	<b>(12 889)</b>
Cash and cash equivalents – opening balance	6 467	24 617
Cash and cash equivalents – closing balance	26 779	11 728

As of September 30, 2023, MedinCell had cash and cash equivalents of €26.8 million, of which €15.0 million in non-risky current financial assets, compared with €6.5 million in cash and cash equivalents at March 31, 2023.

The Company completed a capital increase of €23.2 million net in May 2023 and received the final €10 million tranche of the loan from the European Investment Bank.

During the first semester, the Company also received the first royalties calculated on Teva's net sales of UZEDY. The Company expects these royalties to increase progressively over the next few years, until this first product reaches peak sales. In addition, MedinCell is still eligible to receive up to \$105 million in commercial milestones related to UZEDY.

MedinCell's cash position has also been strengthened since the year-end by several significant incomes, including €4.2 million of the 2022 Research Tax Credit and €2.7 million under the grant awarded by the Bill & Melinda Gates Foundation for the mdc-WWM program.

In the Company's baseline forecast scenario, MedinCell is fully able to meet its contractual financial commitments to the EIB within the next twelve months in terms of projected cash flow. This time horizon could increase considerably with the signature of new licensing agreements currently under discussion. The pace of UZEDY sales ramp-up, which depends in particular on Teva's commercial strategy, as well as the date of eventual approval of mdc-TJK and its launch on the market, may also have a significant impact on the Company's financial visibility.

## About MedinCell

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MedinCell is a clinical and commercial-stage biopharmaceutical company developing long-acting injectable drugs in a wide range of therapeutic areas. Our innovative treatments aim to ensure compliance with medical prescriptions, improve efficacy and accessibility of medicines, and reduce their environmental footprint. They combine already known and used active ingredients with our proprietary BEPO® technology which controls the release of a drug at a therapeutic level for several days, weeks or months from the subcutaneous or local injection of a simple, fully bioresorbable deposit measuring just a few millimeters. The first treatment based on BEPO technology, intended for the treatment of schizophrenia, was approved by the U.S. 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, France, MedinCell currently employs over 140 people representing more than 25 different nationalities.

*UZEDY™ and SteadyTeq™ are registered trademarks of Teva Pharmaceuticals.*

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These statements may include, but are not limited to, any statements beginning with, followed by or including words or expressions such as "objective", "believe", "anticipate", "aim", "intend", "may", "anticipate", "estimate", "plan", "project", "will", "may", "probably", "should", "could" and other words or expressions of similar meaning or used in the negative. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control which may cause actual results, performance or achievements of the Company to differ materially from those anticipated or implied by such statements.

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