**PRESS RELEASE** - June 10, 2024 - 8:00 am - Montpellier, France - Euronext: MEDCL

# Medincell publishes its consolidated annual financial results

*(April 1st, 2023 - March 31st, 2024)*

## Highlights

**Commercial launch by Teva Pharmaceuticals ("Teva") of UZEDY® (risperidone) in the U.S., the first product using Medincell BEPO® technology**

- Successful commercial launch and market access negotiations with U.S. private and public health insurance systems
- Receipt of a €3.6 million milestone payment for U.S. FDA approval and €1.7 million in royalties received on first net sales
- Sales ramp-up in line with forecasts: $80 million in revenue anticipated by Teva in 2024

**Acceleration of phase 3 clinical trial of mdc-TJK (olanzapine, schizophrenia), second antipsychotic developed with Teva**

- End of recruitment in January 2024, 9 months earlier than originally planned

  *Post-closing*
  - *Announcement of positive phase 3 efficacy results in May 2024*
  - *No post-injection delirium/sedation syndrome (PDSS) observed after administration of approximately 80% of the number of injections required by the FDA, as of May 8, 2024*

**End of phase 3 clinical trial of mdc-CWM (intraarticular celecoxib, post-op pain, developed in partnership with AIC)**

- Recruitment of 151 patients completed in August 2023

  *Post-closing*
  - *Encouraging phase 3 results paving the way for future developments announced in May 2024*

**Financing**

- €23.2 million net received following the capital increase in May 2023
- €10.0 million corresponding to the final tranche of the European Investment Bank loan received in August 2023

**Christophe Douat, CEO of Medincell:** *"2023 has been a transformative year, marked by the FDA approval and successful commercial launch of UZEDY in the United States by our partner Teva. The anticipated rise in UZEDY royalties and the expected revenue from the olanzapine LAI will generate net profit to fuel Medincell's sustainable growth. We have entered a new era, demonstrating our ability to innovate and develop the enabling technologies to design innovative therapeutic solutions. We are now excited to welcome new partners, such as AbbVie, with whom we have recently signed a significant strategic agreement."*

## Consolidated financial statements for the year 2023-24

**Operating result: €(21.0) million, a 13% improvement vs previous year**

- Revenues and other income: €11.9 million
- Operating expenses: €(32.9) million

**Net result: €(25.0) million, a 22% improvement vs previous year**

**Cash consumption from operating activities: €11.9 million, a 43% decrease vs previous year**

**Closing cash position: €19.5 million** (of which €5.2 million in the form of non-risky financial assets)

**Main post-closing cash-in: €32.5 million** (AbbVie initial payment)

*Audit procedures on the Company's 2024 consolidated accounts were completed. The statutory auditors report on the 2024 consolidated financial statements will be issued after the completion of the procedures required for the filing of the Universal Registration Document with the French Financial Markets Authority (Autorité des Marchés Financiers or AMF).*

**Strategic co-development and licensing agreement with AbbVie** *(April 2024, post-closing)*

On April 16, 2024, Medincell announced a collaboration with AbbVie to co-develop and commercialize up to six therapeutic products across multiple therapeutic areas and indications. Medincell will use its commercial-stage long-acting injectable technology platform to formulate innovative therapies. Medincell will conduct formulation activities and preclinical studies, including supportive CMC work to advance candidates into clinical trials. AbbVie will finance and conduct the clinical development for each program and will be responsible for regulatory approval, manufacturing, and commercialization.

The first LAI program candidate has been selected and formulation activities are underway.

Under the terms of the co-development and licensing agreement covering up to 6 programs, Medincell has received a $35 million upfront payment and is eligible to receive up to $1.9 billion in development and commercial milestones ($315 million for each program). Medincell is also eligible to receive mid-single to low-double-digit royalties on net sales.

**Product portfolio and R&D Portfolio**


**Successful commercial launch of UZEDY® (1-month and 2-month risperidone, schizophrenia)**

UZEDY® is the first product based on Medincell long-acting injectable technology to reach the commercial stage:

- U.S. market authorization obtained from the U.S. FDA on April 28, 2023
- Commercial launch under the brand name UZEDY® by Teva in the United States in May 2023
- Teva's comments on the commercial launch:
  - Based on the agreements already reached and ongoing negotiations with US government, private and public health insurance systems, Teva expects market access to continue to improve in 2024;
  - Feedback from healthcare professionals and patients has been well-received related to the product's attributes, such as its subcutaneous injection and pre-filled, ready-to-use syringe;
  - Teva forecasts sales of $80 million in 2024, in line with sales acceleration forecasts.
- Over the past fiscal year, Medincell received €3.6 million in milestone payments following FDA approval of UZEDY®, as well as the first royalties of €1.7 million, calculated on Teva net sales in the U.S.

**mdc-TJK (olanzapine, schizophrenia): recruitment finalized 9 months earlier than planned**

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 aims at offering an additional treatment solution for UZEDY for patients with more severe forms of schizophrenia.

- On November 13, 2023, Teva announced that it had entered into a financing agreement with Royalty Pharma to accelerate the program's development.
- Recruitment of the 640 study participants was completed in January 2024, 9 months earlier than initially planned.

  On May 8, 2024, Medincell and Teva announced positive efficacy results for the SOLARIS phase 3 trial: meeting its primary endpoint across all three dosing groups, with mean difference in change in the Positive and Negative Syndrome Scale (PANSS)[1] total score from baseline to week 8 of -9.71 points, -11.27 points, and -9.71 points versus placebo for the high, medium, and low dose groups, respectively. These differences from placebo were clinically meaningful and statistically significant with adjusted p-values of <0.001 for each comparison. Key secondary endpoints of CGI-S (Clinical Global Impressions – schizophrenia) and PSP (Personal and Social Performance Scale) total score were also statistically significant after adjusting for multiplicity. No cases of post-injection delirium/sedation syndrome (PDSS) have been reported to date, after administration of approximately 80% of the target injection number requested by FDA.

  [1] *The PANSS is composed of 3 subscales: Positive Scale, Negative Scale, and General Psychopathology Scale. Each subscale is rated with 1 to 7 points ranging from absent to extreme. Each of the 30 items is accompanied by a specific definition as well as detailed anchoring criteria for all seven rating points. These seven points represent increasing levels of psychopathology, as follows: 1- absent 2- minimal 3- mild 4- moderate 5- moderate severe 6- severe 7- extreme; the PANSS overall total score ranges from 30 to 210, with a higher score indicating greater symptom severity. The primary efficacy endpoint was measured by change from baseline to week 8 against the PANSS total score.*
- The complete safety database should be available in the second half of 2024.

**mdc-CWM (intra-articular celecoxib, post-operative pain): end of phase 3 clinical trial and encouraging results paving the way for future developments**

- Recruitment of the 151 participants in the study conducted by Arthritis Innovation Corporation (AIC) was completed in August 2023.
- The results of the study conducted by AIC were released on May 14, 2024. The study did not meet its primary endpoint of time-weighted AUC[1] of pain intensity over 14 days when comparing treatment with multimodal analgesia (MMA) alone to MMA concurrent with a single dose of F14 administered in the knee at the time of Total Knee Replacement (TKR). The MMA control analgesia that every patient received was defined by the protocol as standard of care periarticular infiltration with bupivacaine, oral acetaminophen and opioid rescue medication.

  A numerical improvement favoring F14 was observed for the primary endpoint. Secondary endpoints of time-weighted AUC of pain over 3 and 7 days also demonstrated numerical improvement favoring F14. The safety profile for F14 was consistent with the prior Phase 2 study, and no new safety signals were identified, and no SAEs[2] were reported as related to F14 treatment.

  Substantial improvement was observed for F14-treated patients for the key secondary endpoint of knee range of motion (ROM) at 6 weeks, as well as at 3 months ($p<0.005$ and $p<0.0005$ respectively; unadjusted for multiplicity). Treated-knee effusion (i.e., swelling) showed highly improved outcomes for the F14-treated patients compared to MMA at 6 weeks and 3 months ($p<0.005$ and $p<0.05$ respectively, unadjusted for multiplicity). The widely used clinical-performance based measure of lower extremity function, the Timed-Up-and-Go (TUG) test was also improved for the F14 group at 6 weeks. Notably, far greater improvements were observed for the endpoints of time-weighted AUC of pain, ROM, effusion, and TUG in a sub-group of patients representing over 70% of the trial population (108/151) who had not previously undergone TKR in their contralateral (non-study) knee. This subset analysis was pre-specified in the protocol, but not alpha-controlled for formal statistical testing. AIC intends to discuss the results from this trial with regulators and explore alternative approval pathways for F14 in this sub-group of patients.

  *[1] Time-weighted Area Under the Curve (AUC) of pain is a statistical measure used in clinical trials and pain management studies to quantify the overall experience of pain over a specified period. It integrates both the intensity of pain and the duration for which that pain is experienced.*

  *[2] SAE: Severe adverse event*

**Progressing the preclinical pipeline**

- Progress in preclinical activities for two programs to prepare initial of clinical trials: mdc-WWM (contraception) with support from the Bill & Melinda Gates Foundation and mdc-STM (malaria) with support from Unitaid (the international health agency has granted Medincell an additional envelope of $6 million to advance the mdc-STM program into clinical phase in April 2024, *post-closing*)
- Launch of feasibility studies and formulation activities for several in-house or partnered programs
- Discontinuation of two preclinical programs for strategic reasons: mdc-ANG (antipsychotic, developed with Teva) and mdc-GRT (transplantation, in-house program).

**Other Research and Development activities**

In parallel with the advancement of the R&D pipeline, Medincell teams have continued to strengthen the Company's technological portfolio, to increase its capacity to formulate innovative treatments with different types of molecules and different therapeutic objectives.

## Selected financial information for fiscal year 2023-2024

**Key consolidated figures - IFRS (in thousands of €)**

| INCOME STATEMENT | March 31, 2024<br>12 months | March 31,2023<br>12 months |
|---|---|---|
| Revenues | 9 032 | 9 889 |
| Other income | 2 913 | 3 766 |
| Current operating result | (20 940) | (24 025) |
| Operating result | (20 977) | (24 046) |
| Financial result | (3 973) | (7 964) |
| Net result | (25 038) | (32 010) |

| CASHFLOW | March 31, 2024 | March 31,2023 |
|---|---|---|
| Net cashflow from operating activities | (11 922) | (21 005) |
| Net cashflow from investing activities | (613) | 1 298 |
| Net cashflow from financing activities | 25 528 | 1 556 |

| BALANCE SHEET | March 31, 2024 | March 31,2023 |
|---|---|---|
| Equity of the consolidated group | (40 824) | (42 294) |
| Total non-current liabilities | 61 304 | 14 608 |
| Total current liabilities | 16 466 | 57 025 |
| Total non-current assets | 9 690 | 9 772 |
| *Of which financial assets and other non-current assets* | *1 792* | *1 460* |
| Total current assets | 27 258 | 19 568 |
| *Of which cash and cash equivalents* | *19 460* | *6 467* |

| FINANCIAL DEBT | March 31, 2024 | March 31,2023 |
|---|---|---|
| Financial debt, non-current portion | 50 541 | 11 708 |
| Financial debt, current portion | 5 518 | 39 757 |
| Non-current derivative liabilities | 5 745 | - |
| Current derivative liabilities | - | 3 055 |
| **GROSS FINANCIAL DEBT** | **61 804** | **54 520** |
| Cash and cash equivalents | 19 460 | 6 467 |
| **NET FINANCIAL DEBT** | **42 344** | **48 053** |

## Consolidated cash flow statements

| (In thousands of euros) | | March 31, 2024 12 months | March 31,2023 12 months |
|---|---|---|---|
| A | Net cashflow from operating activities | (11 922) | (21 005) |
| B | Net cashflow from investing activities | (613) | 1 298 |
| C | Net cashflow from financing activities | 25 528 | 1 556 |
| | Impact of non-monetary items and foreign exchange rate changes | - | - |
| | **Change in net cash position** | **12 993** | **(18 150)** |
| | Cash and cash equivalents - opening balance | 6 467 | 24 617 |
| | Cash and cash equivalents - closing balance | 19 460 | 6 467 |

### A- Net cashflow from operating activities

Cash expenses from operations decreased compared to previous year, in particular due to lower current operating expenses and the receipt of the first royalties from UZEDY® net sales.

### B- Net cashflow from investing activities

Net cashflow from investing activities was down €1.9m on the previous year. The latter included the termination of a capitalization contract in the first quarter of 2023 for 2.6 M€, which was not repeated in the year ended March 31, 2024. In the year ended March 31, 2024, net cashflow from investing activities included the acquisition of laboratory equipment and instruments, and improvements to the Jacou site for €0.3 million, and the acquisition of intangible assets relating to intellectual property for €0.9 million, partially offset by the receipt of €0.5 million in income from cash interests on investments.

### C- Net cashflow from financing activities

The €24 million increase over the previous year relates to proceeds of €23.2 million from capital raise in May 2023, net of issuance costs, and the receipt of the last 10 M€ tranche of the EIB loan in July 2023. The Company continued to repay its outstanding loans during the fiscal year.

**Consolidated income statement**

| (In thousands of euros) | March 31, 2024 12 months | March 31,2023 12 months | Value Variance | Variance % |
|---|---|---|---|---|
| Revenues | 9 032 | 9 889 | (857) | -9% |
| Other income | 2 913 | 3 766 | (853) | -23% |
| **REVENUES AND OTHER INCOME** | **11 945** | **13 655** | **(1 710)** | **-13%** |
| Research and Development Expenses | (21 076) | (27 925) | 6 849 | -25% |
| Sales and Marketing Expenses | (2 639) | (2 588) | (51) | 2% |
| General and Administrative Expenses | (9 170) | (7 167) | (2 003) | 28% |
| **TOTAL OPERATING EXPENSES** | **(32 885)** | **(37 680)** | **4 795** | **-13%** |
| **CURRENT OPERATING RESULT** | **(20 940)** | **(24 025)** | **3 085** | **13%** |
| Other non-current operating income and expenses | (37) | (21) | (16) | 76% |
| **OPERATING INCOME** | **(20 977)** | **(24 046)** | **3 069** | **13%** |
| Financial interest income | 553 | 41 | 512 | 1249% |
| Cost of gross financial debt | (4 617) | (3 932) | (685) | 17% |
| Change in fair value of financial liabilities | (53) | (5 206) | 5 153 | -99% |
| Other financial expenses | (1) | (57) | 56 | -98% |
| Other financial income | 145 | 1 190 | (1 045) | -88% |
| **FINANCIAL RESULT** | **(3 973)** | **(7 964)** | **3 991** | **50%** |
| **PROFIT BEFORE TAX** | **(24 950)** | **(32 010)** | **7 060** | **22%** |
| Income tax (expense)/income | (88) | - | 88 | N/A |
| **NET RESULT** | **(25 038)** | **(32 010)** | **6 972** | **22%** |
| *- Attributable to Medincell shareholders* | (25 038) | (32 010) | 6 972 | 22% |
| *- Attributable to non-controlling interests* | - | - | - | - |

**Revenue and other revenue: 11.9 M€**

For the year ended March 31, 2024, Company revenues include the following items:

- Medincell has received a milestone payment of €3.6 million from Teva following FDA approval of UZEDY®.
- Royalties on net sales from UZEDY® were invoiced to Teva for €1.7 million, and royalties on intellectual property to the CMB joint-venture for €0.6 million.
- As part of the collaboration with the Bill & Melinda Gates Foundation to develop a contraceptive long-acting injectable and an HIV preventive product, Company revenues amount to €1.8 million for the 2023-2024 financial year.
- The collaboration with Unitaid to develop a long-acting injectable product to fight malaria in LMICS (low- and middle-income countries) generated revenue of €0.6 million.
- Sales from services, including feasibility studies, represented €0.7 million.

Other income consists mainly of the Research Tax Credit for €2.8 million.

**Current operating expenses: €32.9 million**

Current operating expenses decreased by €4.8 million (13%) compared to the previous year.

R&D expenses decreased from €27.9 million in the previous year to €21.1 million, to represent 64% of the total operating expenses. Subcontracting expenses relating to CDMOs and CROs decreased following the end of phase 2 trial of the mdc-TTG program and because of reduced polymer purchases.

General and administrative expenses increased by €2.0 million (or 28%) compared to the previous year, due to various fees (consulting concerning the Research Tax Credit, lawyers, audit, investors relations in the United States), as well as higher personnel expenses (notably bonus, profit-sharing and free shares related expenses).

**Net financial result: €(4.0) million**

Net financial loss reduced by €4.0 million year-on-year. This variance is explained by the renegotiation of the EIB loan on November 22, 2022, which led to an increase in the average debt after the issue of tranches B and C of the loan, and to a reduction in the effective interest rate from 16.3% to 13.0% on tranche A, by the re-evaluation of the variable remuneration due to EIB and by the change in fair value of the warrants put options attributed to EIB as of March 31, 2024.

Net financial charge is mainly composed of interest payable on the EIB loan of €(4.4) million as of March 31, 2024, compared with €(3.5) million as of March 31, 2023. The change in fair value of the EIB loan amounted to €(0.1) million and comprises the following items:

- The change in the estimate of variable remuneration had a positive impact of €1.5 million on financial income,
- The fair value of the put options on the warrant components of the EIB loan had a negative €1.5 million impact on financial charges.

## About Medincell

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.



**www.medincell.com**

## Contact

**David Heuzé - Head of Corporate and Financial Communications, and ESG**
david.heuze@medincell.com / +33 (0)6 83 25 21 86

**Grace Kim - Head of US Financial Strategy and IR**
grace.kim@medincell.com / +1 (646) 991-4023

**Investors Relations France**
**Louis-Victor Delouvrier/Alban Dufumier**
medincell@newcap.eu / +33 (0)1 44 71 94 94

**Media Relations**
**Nicolas Mérigeau**
medincell@newcap.eu / +33 (0)1 44 71 94 94