PRESS RELEASE – December 10, 2024 - 5:45pm CET - Montpellier, France - Euronext Paris: MEDCL

Medincell publishes its consolidated half-year financial results

(April 1st, 2024 - September 30, 2024)

Key highlights

Sales growth of UZEDY® in the United States

- €2.8 million in royalties invoiced by Medincell over the period
- Upward revision of Teva's 2024 net sales forecast from $80 million to $100 million
  - U.S. net sales year-to-date 2024: $75 million
  - U.S. net sales in Q3 2024: $35 million

Olanzapine LAI (mdc-TJK): positive results from the pivotal phase 3 trial

- Positive efficacy results announced in May 2024
- No cases of post-injection delirium/sedation syndrome (PDSS) observed after 100% of injections planned for regulatory submission
- Submission of the US marketing application by Teva expected in the first half of 2025

Christophe Douat, CEO of Medincell, said: *"Eighteen months after its launch, UZEDY is experiencing strong success in the United States, with sales expected to reach $100 million in 2024, its first full year of commercialization. Phase 3 of olanzapine has concluded with positive results, paving the way for a market authorization submission in the coming months. These two products, based on our technology, are fully benefiting from the dynamism of our partner, Teva. Together, they could represent more than $100 million in annual revenues for Medincell within three or four years, with much greater potential thereafter."*

R&D Portfolio progress

- Results of the mdc-CWM Phase 3 study (post-operative pain after knee replacement)
  - The study did not meet its primary endpoint but demonstrated quantitative improvements on several key endpoints
  - Particularly remarkable improvements were observed after analysis of a subgroup of patients representing more than 2/3 of study participants (108/151): pain reduction, reduction in opiate consumption and improvement in motor function
  - This subgroup of patients will be the focus of the next stages of clinical development, planned for 2025
- Progress on preclinical and CMC activities (Chemistry, Manufacturing & Control) for mdc-WWM (contraception) and mdc-STM (malaria), with clinical trials to start in 2025
- Launch of new feasibility studies and formulation activities for several programs, including some in partnership

Strategic co-development and licensing agreement with AbbVie (April 2024)

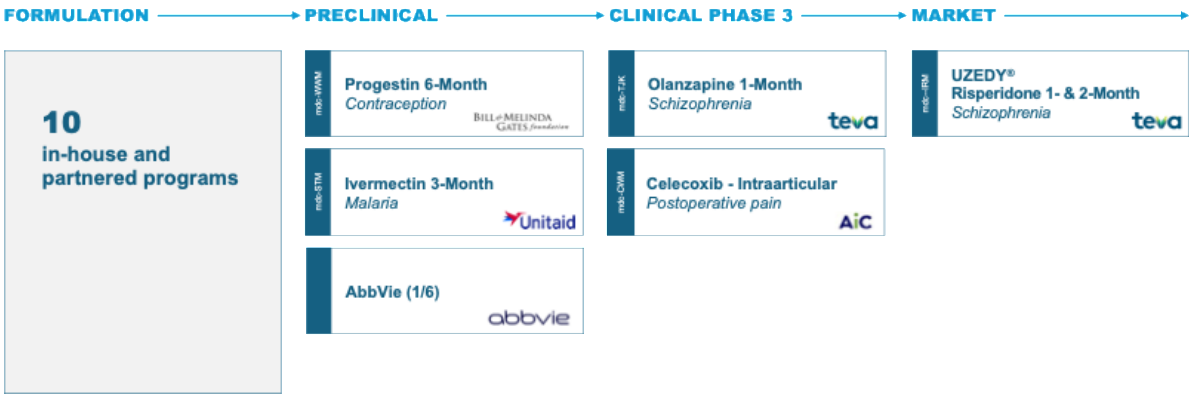
- Up to six long-acting injectable therapies in different therapeutic areas and indications
- Upfront payment of $35 million received in May 2024
- Up to $1.9 billion in milestone and commercialization payments ($315 million for each program) and mid-single to low double-digit royalties on net sales
- Start of preclinical and CMC activities prior to entry into clinical development of first drug candidate

Consolidated financial statements for the first half of the 2024-2025 fiscal year, ending September 30, 2024, (IFRS standards)

- **Operating and other income: €9.4 million**, up 15% compared with the first half of the previous year
  including sales of €8.6 million, up 23% on the first half of the previous year
- **Operating expenses: €17.0 million**, stable compared with the first half of the previous year
- **Operating profit: €(7.5) million**, a 16% improvement on the previous year
- **Cash and cash equivalents at the closing: €31.6 million (excluding €7.2 million in non-risky financial investments)** vs. €19.5 million at March 31, 2024

Stéphane Postic, Chief Financial Officer of Medincell, said: "*Halfway through our fiscal year, our revenue has already reached 95% of the total revenue from the previous year, which amounted to €9 million - highlighting Medincell's strong momentum in 2024. We anticipate closing the year with a 2- to 3-fold increase in revenue and a significant improvement in operating profit compared to last year. This performance marks a key milestone on our path to achieving operating profitability, targeted no later than the 2026-2027 financial year."*

Product and R&D portfolio



Commercialized product

UZEDY® (risperidone - schizophrenia): €2.8 million in royalties invoiced by Medincell over the period

During its earnings call on 6 November 2024 (after market close), Medincell's partner Teva raised by 25% the sales forecast for UZEDY® in 2024 that it had announced in January 2024. These are now estimated at $100 million, compared with $80 million previously. TEVA also announced that in the first 9 months of 2024, sales reached $75 million, including $35 million in the third quarter.

In July 2024, Teva announced that it was exploring a new indication for UZEDY® for the treatment of bipolar I disorder in adults.

During the first half of the year, Teva delivered several presentations on UZEDY® at scientific conferences:

- New data supporting the switch from Invega Sustenna® (monthly intramuscular injection of paliperidone palmitate) to UZEDY® for the treatment of schizophrenia presented at Psych Congress Elevate 2024 (May 30-June 2, 2024, Las Vegas, United States)
- New data supporting the transition from Perseris® to UZEDY® for the treatment of schizophrenia presented at ENCP 2024 (21-24 September 2024, Milan, Italy). In July 2024, the manufacturer of Perseris® announced that it would no longer be marketed.
- Overview of UZEDY® treatment regimens in real-life situations since its approval for the treatment of schizophrenia in adults by the FDA in April 2023 presented at Psych Congress 2024 (29 October-2 November 2024, Boston, United States).

Programs in phase 3 clinical trials

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 bringing this product to first-in-class status. mdc-TJK offers a complementary treatment solution to UZEDY® for patients with more severe forms of schizophrenia.

- **Announcement of positive efficacy results from the SOLARIS phase 3 trial (9 May 2024)**

mdc-TJK met the primary endpoint in all dose groups. The mean change in the Positive and Negative Symptom Scale (PANSS) total score from baseline to week eight was -9.71 points, -11.27 points, and -9.71 points compared to placebo for the high, medium, and low dose groups, respectively. These differences from placebo were clinically remarkable and statistically significant with adjusted values of P<0.001 for each comparison. Several key secondary endpoints also showed statistically significant improvements after homogenization: the ICG-S (Clinical Global Impressions - schizophrenia) and the PSP (Personal and Social Performance Scale) total score.

Additional efficacy, safety and tolerability data were presented in September at the ECPN congress in Milan and in November at Psych Congress 2024. In particular, the data presented showed that, in the phase 3 SOLARIS study, mdc-TJK significantly improved social interactions and quality of life at week 8 for the three doses assessed compared with placebo in a hospital population.

- **Announcement of no PDSS after 100% of targeted injections for submission (6 November 2024 - after market close)**

Post-injection delirium/sedation syndrome (PDSS) is a rare but significant complication associated with current long-acting injectable formulations of olanzapine. PDSS occurs when some of the injected drug accidentally enters the bloodstream too quickly, causing sudden sedation, confusion, and potentially serious side effects, such as breathing problems. For healthcare professionals and patients, PDSS remains a barrier to the widespread use of olanzapine LAI. The need for close monitoring after injection limits the convenience and flexibility of this treatment option. Medincell's olanzapine LAI has been designed to eliminate this risk of PDSS and has been shown in the SOLARIS clinical trial to potentially offer a safer and more accessible treatment option.

mdc-CWM / F14 (celecoxib - post-operative pain)

F14 is an innovative sustained-release non-steroidal anti-inflammatory drug (NSAID) designed for targeted intra-articular administration. Medincell's partner, Arthritis Innovation Corporation (AIC), conducted a phase 3 trial to evaluate

the efficacy and safety of F14 in the management of pain and inflammation following knee replacement surgery. The study compared the results between patients receiving standard multimodal analgesic therapy (MMA) alone and those treated with MMA combined with a single intra-articular dose of F14 administered during the operation.

- **Results of phase 3 clinical trial, May 2024**

  The study failed to meet its primary endpoint, the 14-day time-weighted AUC of pain intensity, when comparing treatment with multimodal analgesia (MMA) alone with MMA plus a single dose of F14, administered into the knee at the time of total knee arthroplasty. The control MMA received by each patient was defined by the protocol as a standard periarticular infiltration with bupivacaine, oral acetaminophen (paracetamol) and a complementary opioid drug.

  However, a quantitative improvement in favor of F14 was observed for the primary endpoint. The secondary endpoints of time-weighted AUC of pain intensity at 3 and 7 days also showed a quantitative improvement in favor of F14. The safety profile of F14 was consistent with the previous phase 2 study, with no new safety signals identified and no SAEs reported as being related to F14 treatment.

  The study also assessed multiple effects related to inflammation (not just pain) following total knee arthroplasty. Patients treated with F14 showed substantial improvements in knee range of motion, in effusion in the treated knee (i.e. swelling) and in the Timed-Up-and-Go (TUG) test.

- **Favorable results from analysis of a sub-group of patients, representing 70% of study participants (November 2024)**

  The sub-group analyzed included 108 patients (out of 151 for the study as a whole) who had not already undergone knee replacement surgery on the other knee. This analysis shows the following advantages:

  - 70% reduction in the number of opioid users at 3 months post-surgery,
  - 28% reduction in the total quantity of opioids consumed during the first 3 months post-surgery,
  - Lower daily knee pain over the endpoints of 3 and 7 days, 2 and 6 weeks, and 3 months post-surgery,
  - Range of motion (ROM) milestone (100 degrees) achieved significantly faster,
  - Significant improvements across multiple, independent assessments of pain, inflammation and function.

  This subgroup of patients will be the primary focus of future clinical development, planned for 2025, provided FDA agreement.

Programs in formulation and at pre-clinical stage

- Progress in preclinical activities for two programs with a view to starting clinical trials in 2025: mdc-WWM (contraception) and mdc-STM (malaria).
- Start of preclinical and CMC activities prior to the entry into clinical development of the first drug candidate developed with AbbVie.
- Several collaborations with pharmaceutical partners are currently at the formulation stage.
- Medincell continues to work on expanding its portfolio of in-house programs.

Selected financial information for the first half of the 2024-2025 fiscal year

Consolidated key figures - IFRS (In thousands of €)

PROFIT AND LOSS ACCOUNT	09.30.2024 6 months	09.30.2023 6 months
Revenues	8 620	6 985
Other income	815	1 195
Current operating result	(7 598)	(8 957)
Operating result	(7 529)	(8 981)
Financial result	(6 910)	823
Net result	(14 568)	(8 158)

Operating and other income up 15%: €9.4m

Revenue for the first half of the 2024-2025 financial year were 23% higher than in the same period last year, driven by the following components:

- €2.8 million in royalties invoiced by Medincell, calculated based on net sales of UZEDY® achieved by Teva in the United States during the period

- Services for the formulation of products developed with partners. These revenues mainly result from the new collaboration agreement signed in April 2024 with the pharmaceutical group AbbVie, the collaboration with the Bill & Melinda Gates Foundation on the development of an active injectable female contraceptive (mdc-WWM), and the collaboration with the international agency Unitaid on a project to combat the transmission of malaria (mdc-STM)
- Recognition of the initial portion, on a percentage-of-completion, for the $35 million payment received from AbbVie and allocated to the first program of the partnership: €3.7 million
- Royalties on intellectual property invoiced to the CM Biomaterials joint venture amounting to €0.4m

As part of its research and development (R&D) activities, the Company benefits from the Research Tax Credit recorded under 'Other income'. It decreased of 39% compared to the previous year, due to the revaluation of the provision for risks relating to the CIR (tax credit for research).

Stable operating expenses: €17.0 million

More than 60% of expenditure relates to R&D. These costs fell by 8%, the first half of the previous financial year having been impacted by the purchase of raw materials for the mdc-CWM project.

Marketing and sales costs increased by 20% and overheads by 11% over the period, mainly due to higher staff costs and slightly higher fees and consultancy costs.

Financial result: €(6.9) million

Net financial expense was €6.9 million, compared with net financial income of €0.8 million in the first half of the previous year. The difference is mainly due to the rise in the Company's share price, which automatically increased the fair value of the warrants issued to the European Investment Bank. The impact of the change in the fair value of the financial liabilities corresponding to these warrants therefore went from an income of €3.0 million at 30 September 2023 to an expense of €(4.3) million one year later. The change in fair value between March 31, 2024, and September 30, 2024, is mainly due to the rise in the Company's share price during the six months ending September 30, 2024.

The financial result was also impacted by financial exchange losses totaling €1.0 million, due to the unfavorable movement in the EUR/USD exchange rate, that affected cash held in USD.

The deterioration in the financial result had an automatic impact on net result, with the loss increasing by €6.4 million over the period, from €8.2 million to €14.6 million, despite a €1.4 million improvement in operating profit, thanks to a 15% increase in operating income and other income.

BALANCE SHEET	**09.30.2024**	**03.31.2024**
Equity of the consolidated group	(54 030)	(40 824)
Total non-current liabilities	80 236	61 304
Total current liabilities	32 657	16 466
Total non-current assets	11 111	9 690
Of which financial assets and other non-current assets	*3 305*	*1 792*
Total current assets	47 752	27 258
Of which cash and cash equivalents	*31 636*	*19 460*

FINANCIAL DEBT	**09.30.2024**	**03.31.2024**
Financial debt, non-current portion	49 878	50 541
Financial debt, current portion	6 886	5 518
Non-current derivative liabilities	9 589	5 745
Current derivative liabilities	-	-
GROSS FINANCIAL DEBT	**66 353**	**61 804**
Cash and cash equivalents	31 636	19 460
Financial investments	7 217	-
NET FINANCIAL DEBT	**27 500**	**42 344**

Consolidated cash flow statements

(In thousands of euros)		09.30.2024 6 months	09.30.2023 6 months
A	Net cashflow from operating activities	21 559	(11 759)
B	Net cashflow from investing activities	(6 993)	(190)
C	Net cashflow from financing activities	(2 398)	32 260
	Change in net cash and cash equivalents	12 176	20 312
	Opening cash and cash equivalents	19 460	6 467
	Cash and cash equivalents at end of period	31 636	26 779
	Financial investments at end of period	7 217	-

As of 30 September 2024, Medincell had cash and cash equivalents of €31.6 million and term deposits of €7.2 million, compared with cash and cash equivalents of €26.8 million and €19.5 million on September 30, 2023, and March 31, 2024, respectively.

Considering the liquidity available to Medincell and the assumptions structuring activity over the next 12 months, detailed further in the annex to the semi-annual consolidated financial statements, management estimates it has sufficient resources to fund at least the next 12 months of operations. Additionally, regarding the EIB contract, two additional covenants will come into effect as of April 1, 2025. Based on their definition, the Company might not comply with them after March 31, 2025, and has already initiated advanced discussions with the EIB. Based on these discussions, the Company is confident in its ability to obtain a waiver from the EIB to avoid a potential early partial or full repayment of the loan that the EIB might request.

The change in net cash flow from operating activities is explained by the receipt of the initial payment from AbbVie, the receipt of UZEDY® royalties and the payment from Unitaid in the first half of the 2024-2025 financial year, and by operating expenses broadly comparable to those of the previous financial year.

Net cash used in investing activities was mainly due to the €7.2 million change in financial investments over the period. These financial investments consist exclusively of highly liquid term deposits with no risk of capital loss. They can be easily mobilized if necessary and generate additional financial income.

Net cash used in financing activities in the first half ended September 30, 2024, was mainly due to the repayment of financial debts and rental liabilities (total cash outflow of €2.4 million), whereas the first half of the previous financial year included cash received in connection with the capital increase carried out in May 2023 (€23.3 million net of costs) and the drawdown of the final €10 million tranche of the BEI loan.

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.

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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