

# MedinCell announces its full year financial results

April 2022 - March 2023

Euronext: MEDCL • Montpellier • France • June 26, 2023 • 5:45 pm (CEST)

# 2022-23 Highlights

- Launch of UZEDY™, first commercial product based on BEPO® technology in May 2023 (post-closing)
- Successful financing strategy: European Investment Bank Ioan (November 2022) and fundraising (May 2023, post-closing)
- Products for schizophrenia and post-operative pain based on BEPO, entered Phase 3 clinical trials, and the rest of the pipeline has progressed with three new programs expected to enter Phase 1 clinical trials in 2024

# Consolidated FY 2023 financials

- Income from ordinary activities: € 13.7 million, +64% vs previous year
- Operating expenses: € 37.7 million, +17% vs previous year, 74% of the expenses are devoted to R&D
- Cash consumption from operating activities: € 21.2 million, -1% vs previous year

Note: audit procedures on the Company's 2022 consolidated financial statements by the Company's statutory auditors are in progress.

Cash situation increasing significantly post year-end, with a total of  $\in$  40.8 million, including cash received post-closing and additional cash inflow anticipated in 2023-24, not including potential new partner service or licensing revenue:

- € 6.5 million in cash and cash equivalents as of March 31, 2023
- € 30.8 million cash received since year-end
  - € 4.0 million of 2021 Research Tax Credit partially pre-financed in April 2023
  - € 3.6 million (\$ 4 million) milestone payment from Teva following UZEDY approval by U.S. FDA on April 28, 2023
  - € 23.2 million net from capital raise on May 12, 2023
- € 10 million withdrawable from EIB financing, as the last condition, approval of UZEDY, is now met

Jaime Arango, CFO of MedinCell, commented: "The U.S. FDA approval of our first product is a major step for MedinCell. We can now expect royalties and commercial milestones, they could cover our operational expenses as soon as 2025. In addition, the recent capital raise provides us cash visibility beyond mdc-TJK and mdc-CWM Phase 3 key results."

# Development of the product portfolio based on BEPO technology

#### mdc-IRM (schizophrenia)

- Complete Response Letter (CRL) from the U.S. FDA received by MedinCell's partner, Teva, in April 2022
- Resubmission of the marketing application announced on November 3, 2022, by Teva
- U.S. FDA approval achieved on April 28, 2023
- Commercial launch under the brand name UZEDY by Teva in the U.S. in May 2023
- First commercial product based on MedinCell's long-acting injectable technology, BEPO

# mdc-TJK (schizophrenia)

- Decision by MedinCell's partner, Teva, to move to clinical Phase 3 in the U.S. announced in August 2022
- Phase 3 clinical study initiated in the U.S. in January 2023
- If approved, mdc-TJK would be the first long-long-acting injectable olanzapine with a favorable safety profile offering a valued treatment option as a complement of UZEDY for severe schizophrenia patients

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

- Initiation of a first Phase 3 clinical trial being conducted and funded by MedinCell's partner, Arthritis Innovation Corporation (AIC), in November 2022 It is a 150-patient, multi-center, randomized, double-blind, safety and efficacy trial designed by AIC post consultation with the U.S. FDA
- Recruitment ongoing as anticipated and is expected to be completed in Q3 2023
- mdc-CWM is designed to provide pain relief for patients over an extended period post-surgery

#### Early-stage pipeline progression

- Progress of preclinical activities for three programs in preparation to enter Phase 1 clinical trials in 2024: mdc-GRT (immunosuppressor/organ transplant), mdc-WWM (contraception) with the support of the Bill & Melinda Gates Foundation, and mdc-STM (malaria) with the support of Unitaid
- Launch of formulation activities for two new internal products (kept confidential at this stage)
- Several collaborations with pharmaceutical partners are at technical feasibility stage, the first step of formulation activities
- In addition, MedinCell continues to work on expanding its internal programs portfolio

# FORMULATION CMC & PRECLINICAL PHASE 1/2 PHASE 3 APPROVED mdc-IRM UZEDY Schizophrenia mdc-TJK Schizont teva Estimated primary completion date\* in H2 2024 Recruitment completed expected in H2 2023\*\* IND\*\* planned in H2 2023 CTA\*\* planned in H1 2024 Financial support from the Bill & Melinda Gates Foundation for Global Access Financed by Unitaid, Global Heath Additional indication for mdc-IRM O No further investment planned, stra \*Source: clinicaltrials gov, as of June 26, 2023 - The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure. Lead formulation selection planned in H1 2024 \*\*At least one additional study will be needed. Regulatory process in pain management typically comprises several efficacy and safety trials. \*\*\*An IND in the US (Investigational New Drug) or a CTA in Europe (Clinical Trial Application) is a request for authorization to administer an investigational drug to humans with the objective to collect clinical data (e.g., safety, PK, efficacy, ...)

# MedinCell's portfolio as of June 26, 2023

"Prime" ISS ESG rating received as a recognition of the embedment of Corporate Social Responsibility across the Company



- Institutional Shareholder Services (ISS) awarded MedinCell a "Prime" Environmental, Social, and Governance (ESG) rating in January 2023
- Rating places MedinCell among the top 10% in the Pharmaceuticals & Biotechnology sector
- ISS, one of the world's leading ratings agencies for sustainable investments, provides a highly relevant, material assessment of ESG performance to investors

# Selected financial information for the year 2022-2023

Key consolidated data - IFRS (In thousands of €)	31/03/2023 12 months	31/03/2022 12 months
PROFIT AND LOSS ACCOUNT		
Revenue	9 889	4 090
Other income from ordinary activities	3 766	4 247
Current operating profit	(24 025)	(23 812)
Operating profit	(24 046)	(23 814)
Financial result	(5 452)	(992)
Net result	(29 498)	(24 806)
CASHFLOW		
Net cashflow from operating activities	(21 029)	(21 362)
Net cashflow from investing activities	1 298	(316)
Net cashflow from financing activities	1 577	(800)
BALANCE SHEET		
Equity of the consolidated group	(39 781)	(13 371)
Total non-current liabilities	17 662	19 433
Total current liabilities	51 458	38 241
Total non-current assets	9 772	10 229
Of which financial assets and other non-current assets	1 460	1 519
Total current assets	19 568	34 074
Of which cash and cash equivalents	6 4 6 7	24 617
FINANCIAL DEBT		
Financial debt, non-current portion	14 762	16 249
Financial debt, current portion	37 245	27 764
GROSS FINANCIAL DEBT	52 008	44 014
Cash and cash equivalents	6 467	24 617
Capitalization contract *	-	2 560
NET FINANCIAL DEBT	45 541	16 837

\* The Group had funds immobilized in a capitalization contract and euro funds given as collateral for a bank loan of  $\in$ 7.0m, the balance of which was repaid in 2022/2023.

#### Cash position significantly strengthened

On March 31, 2023, MedinCell had  $\in$  6.5 million of cash and cash equivalents (compared to  $\in$  24.6 million of cash and cash equivalents and  $\in$  2.6 million of current and non-current non-risky financial assets a year ago).

Financial strategy of the Company was adjusted following FDA's Complete Response Letter received by Teva on April 19, 2022, which resulted in commercialization of MedinCell's first product approximately one year later than expected.

In November 2022, the Company signed a loan agreement for  $\notin$  40 million with the European Investment Bank (EIB). The two first tranches of the credit facility for a total amount of  $\notin$  30 million have been drawn in Q4 2022 and Q1 2023, of which around  $\notin$  23.3 million have been used to repay the existing EIB loan from 2018 as specified in the agreement. Disbursement of the last  $\notin$  10 million was conditioned to approval by U.S. FDA of UZEDY that occurred on April 28, 2023. This last tranche is available immediately. In addition to the new EIB loan, the Company successfully completed a  $\notin$  23.2 million net capital raise in May 2023 through an offering to French and international investors via a Private Placement and to retail investors in France.

Considering these financing operations and anticipated revenues from existing collaboration, MedinCell has the resources to continue its portfolio development.

As of March 31, 2023, one of the EIB loan covenants had not been met, giving EIB the right to ask for partial or total early repayment of the existing loan. On June 12, 2023, the Company obtained a waiver from EIB. The Company points out that, with its current base cash forecast, that does not include potential new partner service or licensing revenue, the covenant may not be met again as of March 31, 2024. This is a significant uncertainty on the going concern. To avoid this, the Company continues having discussions with the EIB. With a positive outcome, the cash visibility of the company's current base cash forecast is estimated until at least Q4 2025.

#### Consolidated cashflow statement

	(In thousands of €)	31/03/2023 12 months	31/03/2022 12 months
А	Net cashflow from operating activities	(21 029)	(21 362)
В	Net cashflow from investing activities	1 298	(316)
С	Net cashflow from financing activities	1 577	(800)
	Impact of non-monetary items and foreign exchange rate changes	-	-
	Change in net cash position	<b>(18 149</b> )	(22 478)
	Cash and cash equivalents - opening balance	24 617	47 095
	Cash and cash equivalents - closing balance	6 467	24 617

#### A- Net cashflow used in operating activities

During the year, the Company's cash consumption was similar to the previous year at € 21 million. Over the same period, operating expenses increased from € 32.2 million to € 37.7 million, mainly due to the increase in Research & Development activities.

The Company points out that the first revenues directly linked to product sales should be royalties from the commercialization of products developed with Teva, mainly UZEDY. In the meantime, due to the product development cycle and depending on the financial parameters set up in the context of partnerships (which may or may not include certain elements such as invoicing for formulation services, milestone payments, royalties, cost sharing, profit sharing, etc.), revenues may vary significantly from one year to the next.

# B- Net cashflow from investing activities

The increase of  $\notin$  1.6 million compared to previous year corresponds to the end of the capitalization contract in Q1 2023 ( $\notin$ 2.6 million) partially offset by the acquisition of machinery and fixed instruments, improvements at the Jacou site for  $\notin$  0.6 million, and the acquisition of intangible assets for  $\notin$  0.5 million related to intellectual property.

# C- Net cashflow from financing activities

The net cashflow from financing activities is driven by the new contract with the EIB signed in November 2022, of which  $\notin$  30 million have been withdrawn as of March 31, 2023. This cash has been partly used to early repay the 2018 EIB loan in January 2023 of  $\notin$  23.3 million.

# Profit and loss account

#### Income from ordinary activities: € 13.7 million

For the year ended March 31, 2023, revenues correspond to:

Development services of  $\notin$  5.8 million, mainly related to activities for mdc-WWM and mdc-STM products financed by international health foundations and agencies, compared to  $\notin$ 4.0 million in the previous year.

- The development of a long-acting injectable malaria product supported by the Unitaid health agency generated revenue of € 2.2 million compared to € 1.3 million in the prior year.
- The development of a long-acting contraceptive product supported by the Bill & Melinda Gates Foundation generated revenue of € 2.0 million compared to € 2.4 million in the prior year
- Reflecting the intensification of Business Development, R&D activities related to new partnered programs(proof of feasibility) generated € 1.6 million revenue compared to €0.3 million in the prior year.

In addition, the Company received a milestone payment from Teva of € 2.9 million after their decision in August 2022 to start Phase 3 clinical activities for mdc-TJK, the second schizophrenia product candidate.

The Company also received a  $\in$  1.2 million royalty payment from the joint venture, CM Biomaterials, dedicated to the sale of polymers to the Company's partners, significantly higher than the  $\in$  0.1 million the year before.

The Research Tax Credit recognized during the period amounted to € 3.7 million (€ 4.2 million in the prior year).

#### Current operating expenses aligned with the Company's plan: € 37.7 million

Current operating expenses increased by 17% compared to the previous year. This increase was mainly driven by R&D activities, which accounted for 74% of operating expenses, reaching  $\notin$  27.9 million, compared to  $\notin$  23.6 million in the previous year. This

increase is driven by the advancement of the current portfolio and increased cash requirements in the preclinical stages and the clinical study conducted during the year.

Resuming to normal activities after the pandemic crisis led to a 14% increase in marketing and business development costs, as travel is no longer as restrictive as it was in the recent past. Also, G&A expenses increased by 14%, driven by additional consulting fees and salaries and benefits increase.

#### Financial result: € (5.5) million

The financial result is mainly impacted by the new EIB financing signed in May and November 2022, partially offset by forex gains of € 1.2 million.

#### About MedinCell

MedinCell is an innovative pharmaceutical company developing a portfolio of long-acting injectable products in various therapeutic areas - from development to commercialization - by combining its proprietary BEPO technology (licensed to Teva under the name SteadyTeq<sup>™</sup>) with active ingredients already known and marketed. Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved compliance and to a significant reduction in the quantity of medication required. MedinCell's proprietary BEPO technology makes it possible to control the delivery of a drug at a therapeutic dose for several days, weeks or months, from the subcutaneous or local injection of a simple, fully bioresorbable deposit just a few millimeters in size. The first treatment based on BEPO technology for the treatment of schizophrenia was approved by the FDA in April 2023 and is now commercialized in the United States by Teva under the name UZEDY<sup>™</sup>.

MedinCell collaborates with leading pharmaceutical companies and foundations to improve global health through new therapeutic options. Based in Montpellier, MedinCell currently employs over 140 people representing more than 25 different nationalities. <a href="http://www.medincell.com">www.medincell.com</a>

UZEDY<sup>™</sup> and SteadyTeq<sup>™</sup> 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", "will", "may", "anticipate", "estimate", "estimate", "estimate", "estimate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "estimate", "anticipate", "estimate", "estimate", "estimate", "anticipate", "estimate", "estimate", "estimate", "estimate", "estimate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "anticipate", "estimate", "estimate", "estimate", "estimate", "estimate", "anticipate", "estimate", "estimate, "estimate", "estimate, "estimate", "estimate, "estimate,

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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