

# MedinCell announces its full year financial results

April 2021 - March 2022

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Income from ordinary activities: €8.3 million

Operating expenses: €32.2 million, of which 73% is devoted to Research & Development

Cash consumption from operations: €21.4 million

Available cash on March 31, 2022: €24.6 million in cash + €2.6 million in non-risky financial assets

Estimated financial visibility until Q3 2023

> Ongoing negotiations to significantly extend this visibility through non-dilutive transactions

Outlook for 2022-23: while maintaining the momentum of its R&D activities, the Company anticipates a significant decrease in cash consumption

The year ending on March 31, 2022 was mainly marked by the filing of the New Drug Application (NDA) in the US for the first product based on MedinCell's technology. Commercialization is expected in H1 2023.





The operations carried out during the year by our partners should also lead to a decision regarding the start of the Phase 3 study for mdc-TJK. Additionally, we anticipate the initiation by our partner in H2 2022 of a 150 patients efficacy and safety study of mdc-CWM based upon discussion and agreement with the FDA.

The activities carried out directly by MedinCell's teams included:

- Support to our partners (Teva Pharmaceuticals, AiC, Gates Foundation, Unitaid) in the development of their programs,
- the start of regulatory toxicology studies for mdc-GRT (organ transplantation) and mdc-WWM (contraception) and the preparation of those for mdc-STM (malaria); the preparation of pivotal studies for mdc-KPT (animal health, pain); the start of oral Phase 2 for mdc-TTG (Covid-19),
- the exploration and start of new collaborations,
- the extension of the BEPO® technology versatility.

The Company maintained a high level of ESG performance during the financial year, and started new initiatives aimed at ensuring the positive impact of its activity (the 2022 ESG report will be published shortly).

## Portfolio of products based on BEPO® technology in regulatory development as of June 14, 2022

	HUMAN HEALTH	Preclinical	Clinical Phase 1 - 2	Clinical Phase 3	Regulatory review / Market
Regulatory and clinical activities conducted and funded by partners	Partnership with 	Schizophrenia franchise (3 products)	mdc-ANG	mdc-TJK - Olanzapine	mdc-IRM - Risperidone
		Neuroscience	mdc-IRM - Risperidone New indication		
	Partnership with 	Post operative pain		mdc-CWM - Celecoxib	
Regulatory and clinical activities conducted by MedinCell and funded by partners	Supported by 	Contraception	mdc-WWM - Progestin		
	Supported by 	Malaria	mdc-STM - Ivermectin		
Regulatory and clinical activities conducted and funded by MedinCell		Organ transplant	mdc-GRT - Tacrolimus		
		Covid-19 prophylaxis	mdc-TTG - Ivermectin		
	ANIMAL HEALTH	Regulatory	Pivotal studies	Regulatory review / Market	
		Pain	mdc-KPT - Meloxicam		

## Details of the products portfolio in regulatory development as of June 14, 2022

### HUMAN HEALTH

#### Program awaiting marketing approval

<b>mdc-IRM</b> Treatment of schizophrenia Partner: Teva Pharmaceuticals API: Risperidone	<p>The New Drug Application in the US was filed in June 2021 and accepted for review by the US Food and Drug Administration (FDA). It is based on positive results from the Phase 3 study, which showed significant improvements in patients with schizophrenia. These results were unveiled by Teva at Psych Congress 2021 (Oct. 29 – Nov. 1<sup>st</sup>, San Antonio, USA)</p> <p>Post-closing: Following receipt of a Complete Response Letter from the FDA in April 2022, Teva, which is funding and leading the development of the product, plans to resubmit the New Drug Application in H2 2022. Our partner then anticipates a six-month FDA review period following re-submission.</p> <p>In May 2022, Teva have started pre-clinical evaluation for an additional indication in the field of neuroscience using the mdc-IRM formulation.</p>
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#### Programs at the clinical stage

<b>mdc-TJK</b> Treatment of schizophrenia Partner: Teva Pharmaceuticals API: Olanzapine	Following analysis of the results of the clinical Phase 1 study, Teva is assessing next steps with FDA to clarify the approach to Phase 3.
<b>mdc-CWM</b> Post-operative pain and inflammation Partner: AiC API: Celecoxib	<p>The regulatory process led by our partner AiC is expected to enable the start of 150 patients safety and efficacy study in H2 2022 based upon discussion and agreement with the US FDA.</p> <p>Efficacy results of this study are expected in 2023 and will drive next development steps. Depending on results, at least one additional study will be needed for registration.</p>

#### Next potential candidates for IND/IMPD (clinical trial authorizations)

<b>mdc-GRT</b> Organ transplantation MedinCell Program API: Tacrolimus	<p>Regulatory toxicological studies are underway.</p> <p>The start of clinical trials is planned for the first half of 2023.</p>
<b>mdc-TTG</b> Covid-19 MedinCell Program API: Ivermectin	<p>MedinCell launched the SAIVE clinical trial in March 2022 to demonstrate the prophylactic efficacy of ivermectin in regular, daily, oral form (to simulate the continuous release of the active ingredient by a long-acting injectable). This is a multi-center, randomized, double-blind, placebo-controlled study of 400 participants with an independent monitoring and data analysis committee. The results of this study and the overall context of the pandemic will guide future developments of the long-acting injectable and the search for partners.</p> <p>The Company also announced during the year that a 3-Month active formulation is ready to enter regulatory development.</p>
<b>mdc-WWM</b> Contraception Partner: Bill & Melinda Gates Foundation API: Progestin (non-MPA)	<p>Regulatory toxicological studies are underway.</p> <p>Clinical trials are scheduled to start in the second half of 2023.</p>
<b>mdc-ANG</b> Schizophrenia Partner: Teva Pharmaceuticals API: Confidential	Ongoing analysis of preclinical data will determine the possibility to begin clinical development.
<b>mdc-IRM</b> Neuroscience Partner: Teva Pharmaceuticals API: Risperidone	In May 2022, Teva have started pre-clinical evaluation for an additional indication in the field of neuroscience using the mdc-IRM formulation.
<b>mdc-STM</b> Malaria Partner: Unitaid API: Ivermectin	Following the selection of a candidate formulation in June 2021, preclinical activities have begun with the aim of starting regulatory toxicology studies in the first half of 2023.

### ANIMAL HEALTH

<b>mdc-KPT</b> Pain MedinCell Program API: Confidential	The program is in regulatory development with the launch of pivotal studies planned for 2023.
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## Selected financial information for the year 2021-2022

Key consolidated data - IFRS (In thousands of €)	31/03/2022 12 months	31/03/2021 12 months
<b>PROFIT AND LOSS ACCOUNT</b>		
Revenue	4 091	8 186
Other income from ordinary activities	4 247	3 589
Current operating income	(23 812)	(15 338)
Operating income	(23 814)	(15 576)
Financial result	(992)	(3 410)
Net result	(24 806)	(18 986)
<b>CASHFLOW</b>		
Net cashflow from operating activities	(21 362)	(12 134)
<i>Of which cashflow from operations</i>	(18 995)	(12 758)
<i>Of which change in working capital</i>	(2 367)	624
Net cashflow from investing activities	(316)	(1 062)
Net cashflow from financing activities	(800)	47 917
<b>BALANCE SHEET</b>		
Equity of the consolidated group	(13 371)	9 127
Total non-current liabilities	19 433	40 878
Total current liabilities	38 241	13 600
Total non-current assets	10 229	7 281
<i>Of which financial assets and other non-current assets</i>	1 519	1 929
Total current assets	34 074	56 325
<i>Of which cash and cash equivalents</i>	24 617	47 095
<b>FINANCIAL DEBT</b>		
Financial debt, non-current portion	16 249	39 071
Financial debt, current portion	27 764	3 179
<b>GROSS FINANCIAL DEBT</b>	<b>44 014</b>	<b>42 250</b>
Cash and cash equivalents	24 617	47 095
Capitalisation contract *	2 560	3 930
<b>NET FINANCIAL DEBT</b>	<b>16 837</b>	<b>(8 775)</b>

\* The Group has funds immobilized in a capitalization contract and euro funds given as collateral for a bank loan of €7.0m, the balance of which to be repaid amounted to €0.9m at the end of the year.

## Financial visibility until Q3 2023 and financial strategy

On March 31, 2022, MedinCell had €24.6 million of cash and cash equivalents and €2.6 million of current and non-current non-risky financial assets (compared to €47.1 million and €3.9 million respectively a year ago).

During the year, the Company started initiatives aimed at extending its financial visibility until it receives significant revenues in the form of royalties from the commercialization of a first product in the United States by its partner Teva Pharmaceuticals. The planned operations concern primarily a partial debt restructuring and access to additional non-dilutive financing from the Company's financial partners.

With regards to debt restructuring, a step has already been taken *post-closing* with the modification of the terms of the loan contracted with the European Investment Bank (EIB), approved by both parties on June 1<sup>st</sup>, 2022. It includes postponing of the repayment of the first tranche by six months, from June 2023 to December 2023; postponing by one year of the application of the covenants, from 2022 to 2023; the inclusion of Teva Pharmaceuticals' revenues in the calculation of the variable remuneration; and the absence of penalties for possible early repayments. The analysis of the quantitative and qualitative impact of this amendment is underway. Related financial expenses will be integrated in the financial results of the 1<sup>st</sup> semester of the current fiscal year.

This first step paved the way for further discussions with the EIB.

## Consolidated cashflow statement

(In thousands of €)		31/03/2022 12 months	31/03/2021 12 months (1)
A	Net cashflow from operating activities	(21 362)	(12 134)
B	Net cashflow from investing activities	(316)	(1 062)
C	Net cashflow from financing activities	(800)	47 917
Impact of non-monetary items and foreign exchange rate changes		-	-
<b>Change in net cash position</b>		<b>(22 478)</b>	<b>34 718</b>
Cash and cash equivalents - opening balance		47 095	12 377
Cash and cash equivalents - closing balance		24 617	47 095

### A- Net cashflow provided by operating activities

During the year, the Company's cash burn was higher than in the previous year, due to the absence of milestone revenues and the increase in operating expenses, as expected. Over the same period, operating expenses increased from €27.1 million to €32.2 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 and in particular the mdc-IRM product. 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 €0.7 million corresponds to the acquisition of machinery and fixed instruments, improvements at the Jacou site for €1.6 million, and the acquisition of intangible assets for €0.4 million related to intellectual property. This is partly offset by the variation in financial investments for €1.3 million.

### C- Net cashflow from financing activities

During the previous financial year, the Company received the final €5.0 million tranche of the EIB loan, as well as €13.7 million in the form of a State Guaranteed Loans and carried out successfully two private placements with qualified French and international investors for net proceeds of €42 million.

During the 2021-2022 financial year, the Company continued to repay €2.3 million of debt, subscribed to a €3.3 million loan from BPI and paid out €1.1 million in financial interest.

## Profit and loss account

### Income from ordinary activities: €8.3m

For the year ended March 31, 2022, revenues correspond to:

Development services of €4.1 million, mainly related to activities for mdc-WWM and mdc-STM products financed by international health foundations and agencies, compared to €3.7 million in the previous year.

- The development of a long-acting injectable malaria product supported by the Unitaid health agency generated revenue of €1.3 million compared to €0.8 million in the prior year.
- The development of a long-acting contraceptive product supported by the Bill & Melinda Gates Foundation generated revenue of €2.4 million, similar to previous year.

The company also received a €0.1 million royalty payment from the joint venture, CM Biomaterials, dedicated to the sale of polymers to the Company's partners.

In the year ended March 31, 2022, the Company did not recognize any milestone from any Teva partnered programs, whereas in the previous year, revenue of this nature amounted to €4.1 million.

### Current operating expenses under control and aligned with the Company's expectations: €32.2m

Current operating expenses increased by 19% compared to the previous year. This increase was mainly driven by R&D activities, which accounted for 73% of operating expenses, reaching €23.6 million, compared to 72% or €19.6 million in the previous year. Resuming to normal activities after the pandemic crisis led to a 9% increase in marketing and sales costs and a 3% increase in general and administrative costs.

As in previous years, the allocation of a large proportion of resources to research and development activities was aimed at advancing internal projects.

The increase in these R&D costs has allowed the Company's internal programs to progress through the formulation stages for some and through the regulatory stages for others, including programs in partnership with the Bill & Melinda Gates Foundation and Unitaid. The increase in R&D personnel costs is related to the staff increase to support these developments.

#### Financial result: €(1) million

The financial result shows a net loss reduced by 71% compared to the previous year. The net financial loss was €1.0 million compared with €3.4 million. The financial result is mainly composed of interest charges on the bond loan for €0.1 million and on the EIB loan for €1.3 million on March 31, 2022, compared with €0.8 million and €2.5 million respectively on March 31, 2021.

The decrease in the cost of financial debt on the EIB loan comes for €1.3 million from the re-estimation of future cashflows linked to variable remuneration following the changes contracted by an amendment in June 2020.

#### Consolidated income statement

(In thousands of €)	31/03/2022 12 months	31/03/2021 12 months	Evolution in value	Evolution in %
Revenues	4 091	8 186	(4 095)	-50%
Other income from ordinary activities	4 247	3 589	658	18%
<b>Income from ordinary activities</b>	<b>8 338</b>	<b>11 775</b>	<b>(3 437)</b>	<b>-29%</b>
Research and development costs	(23 607)	(19 546)	(4 061)	21%
Marketing and sales costs	(2 272)	(1 797)	(475)	26%
General and administrative costs	(6 271)	(5 770)	(501)	9%
<b>Total Operating Expenses</b>	<b>(32 150)</b>	<b>(27 113)</b>	<b>(5 037)</b>	<b>19%</b>
<b>Current operating profit</b>	<b>(23 812)</b>	<b>(15 338)</b>	<b>(8 474)</b>	<b>55%</b>
Other non-current operating expenses / income	(2)	(239)	237	-99%
<b>Operating profit</b>	<b>(23 814)</b>	<b>(15 576)</b>	<b>(8 238)</b>	<b>53%</b>
Financial interest income	90	40	50	125%
Cost of gross financial debt	(1 844)	(3 583)	1 739	-49%
Other financial income/expenses	762	133	629	473%
<b>Financial result</b>	<b>(992)</b>	<b>(3 410)</b>	<b>2 418</b>	<b>-71%</b>
<b>Profit before tax</b>	<b>(24 806)</b>	<b>(18 986)</b>	<b>(5 820)</b>	<b>31%</b>
<b>Net income</b>	<b>(24 806)</b>	<b>(18 986)</b>	<b>(5 820)</b>	<b>31%</b>
- Attributable to MedinCell shareholders	(24 806)	(18 986)	(5 820)	31%
- Attributable to non-controlling interests	-	-	-	-

## Summary of the balance sheet

(In thousands of €)	31/03/2022	31/03/2021
Total non-current assets	10 229	7 281
Total current assets	34 074	56 325
<b>Total assets</b>	<b>44 303</b>	<b>63 606</b>
Equity of the consolidated group	(13 371)	9 127
Total non-current liabilities	19 433	40 878
Total current liabilities	38 241	13 600
<b>Total liabilities and equity</b>	<b>44 303</b>	<b>63 606</b>

(The final decision of IFRS-IC in April 2021 to change the method of attributing post-employment benefits to periods of service results in a decrease in the pension liability for an amount of €198k at April 1<sup>st</sup> 2020 impacting the presentation of the accounts at 31 March 2021).

As of March 31, 2022, as the amendment to the EIB contract had not yet been signed, this debt is recognized as current. After the amendment was signed on May 31, 2022, non-current and current liabilities are expected to be €42.4 million and €15.2 million respectively.

## About MedinCell

MedinCell is a pharmaceutical company at premarketing stage that develops a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO® technology 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, i.e. compliance with medical prescriptions, and to a significant reduction in the quantity of medication required as part of a one-off or chronic treatment. The BEPO® technology makes it possible to control and guarantee the regular delivery of a drug at the optimal therapeutic dose for several days, weeks or months starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable. MedinCell collaborate with tier one pharmaceuticals companies and foundations to improve Global Health through new therapeutic options. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.

[www.medincell.com](http://www.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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