MedinCell publishes its financial results for the first semester of 2022-2023 (April - September 2022)

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Revenue: €7.7 million (+89% compared to the first half of the previous year)

Operating expenses: €19.4 million (+27% compared to the first half of the previous year)

Cash consumption from operations: €10 million

Available cash: €11.7 million in cash and cash equivalent + €2.5 million in non-risky current financial assets in September 30, 2022

Post-closing: expected cash inflows of more than €29 million by the end of the first semester 2023 and revision of the investment plan

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Jaime Arango, MedinCell's Chief Financial Officer stated: *"We have a good cash visibility through at least the end of the first quarter of 2024. Our pipeline continues to advance with a first product close to commercialization and two others in Phase 3. Several of our internal programs should reach clinical stage next year and and two new ones have started in major indications. In parallel, our financial strategy and investment plan have evolved in light of the global financial environment."*

Development of the product portfolio based on BEPO technology®

mdc-IRM (schizophrenia): Commercialization as UZEDY™ expected in the first half of 2023 by Teva in the U.S., subject to FDA approval.

- Teva receives a Complete Response Letter (CRL) from the US FDA in April 2022
- Resubmission of the marketing application announced on November 3, 2022 by Teva, which expects a six-month review period.

mdc-TJK (schizophrenia): decision by Teva to move to clinical Phase 3 in the U.S. announced in August 2022.

mdc-CWM / F14 (post-operative pain): launch of a Phase 3 clinical study in the U.S. by MedinCell's partner AIC. The first patient was enrolled on November 18, 2022 *(post-closing)*.

Advancement of preclinical activities for three programs that should be ready for the start of clinical trials in 2023: **mdc-GRT (immunosuppressor/transplantation)**, **mdc-WWM (contraception)** with the support of the Bill & Melinda Gates Foundation, and **mdc-STM (malaria)** with the support of Unitaid.

Substantial milestones planned in 2023 for **mdc-KPT (animal health)** and **mdc-TTG (Covid-19)** could enable to engage partners to pursue their development.

Launch of formulation activities for two new internal products (at this stage, the details of these programs are confidential).

Several collaborations with pharmaceutical partners are currently in technical feasibility studies, a necessary step before the launch of formulation activities.

In addition to these activities, MedinCell continues to work on expanding its internal programs portfolio.

Details of the portfolio of products in regulatory development as of December 6, 2022

HUMAN HEALTH

Program awaiting marketing authorization

mdc-IRM Treatment of schizophrenia Partner: Teva Active ingredient: Risperidone	The US marketing application was filed in June 2021 by Teva and accepted for review by the US Food and Drug Administration (FDA). It is based in particular on the positive results of the Phase 3 study, which showed significant improvements for patients with schizophrenia. These results were unveiled by Teva at Psych Congress 2021 (Oct. 29-Nov. 1st , San Antonio, USA). In April 2022, Teva received a Complete Response Letter (CRL) from the FDA. A CRL is issued by the FDA when the marketing application cannot be approved in its current state. To the extent possible, the FDA proposes corrective actions and makes recommendations for approval. In May 2022, Teva initiated preclinical evaluation for an additional neuroscience indication using the mdc-IRM formulation. Post-Closing: On November 3, 2022, Kåre Schultz, CEO of Teva, announced that his teams had conducted a full quality audit of all clinical data and already re-filed the marketing application with the U.S. FDA. He expects this resubmission to be followed by a six-month review period by the FDA. Our partner is confident of obtaining marketing approval and plans to launch the commercialization of mdc-IRM under the name UZEDY™ in the first half of 2023.

Programs at the clinical stage

mdc-TJK Treatment of schizophrenia Partner: Teva Active ingredient: Olanzapine	In August 2022, Teva informed MedinCell of its decision to initiate a Phase 3 clinical trial for mdc-TJK.
mdc-CWM Postoperative pain and inflammation Partner: Arthristis Innovation Corporation Active ingredient: Celecoxib	Post closing: A Phase 3 clinical trial conducted in the U.S. and funded by AIC began in November 2022. This is a 150-patient, multi-center, randomized, double-blind, safety and efficacy trial that was designed in consultation with U.S. regulatory authorities. The first patient was enrolled in the study on November 18, 2022.

Next potential candidates for clinical development

mdc-GRT Organ transplantation MedinCell Program Active ingredient: Tacrolimus	Regulatory preclinical activities are underway. The Phase 1 clinical trial should be ready to start in 2023.
mdc-TTG Covid-19 MedinCell Program Active ingredient: Ivermectin	Results of the SAIVE Phase 2 clinical trial, which aims to demonstrate the prophylactic efficacy of regular, daily, oral ivermectin, are expected in early 2023. The company does not plan to disclose the results before peer-reviewed scientific publication. In case of favorable results, the company believes that it will be critical to find the right partner to continue the development of a long-acting injectable for the prophylaxis against Covid-19. At this stage, the company has decided not to pursue the development of the program alone.
mdc-WWM Contraception Partner: Bill & Melinda Gates Foundation Active ingredient: Progestin (not MPA)	Regulatory preclinical activities are underway. The Phase 1 clinical trial should to be ready to start in 2023.
mdc-ANG Schizophrenia Partner: Teva Active ingredient: Confidential	The eventual start of clinical activities will depend on the conclusions of the ongoing analysis of preclinical data and the decisions of our partner Teva.
mdc-IRM Neuroscience Partner: Teva Active ingredient: Risperidone	Teva initiated preclinical regulatory activities in May 2022 to seek approval for mdc-IRM in an additional neurology indication.
mdc-STM Malaria Partner: Unitaid Active ingredient: Ivermectin	Following the selection of a candidate formulation in June 2021, preclinical activities have begun with the objective of starting regulatory toxicology studies in 2023.

ANIMAL HEALTH

mdc-KPT Pain MedinCell Program Active ingredient: Confidential	The company believes that during the first half of 2023 it will have all the necessary data to engage the best partner to continue the development of this important asset for animal health.

Selected financial information for the first half of 2022*

Consolidated key data - IFRS (In thousands of €)	30/09/2022 6 months	30/09/2021 6 months
PROFIT AND LOSS ACCOUNT		
Revenues from sales	6 027	1 602
Other income from ordinary activities	1 682	2 477
Current operating income	(11 652)	(11 215)
Operating income	(11 657)	(11 214)
Financial result	(2 090)	(544)
Net income	(13 747)	(11 758)
CASH FLOW		
Net cash linked to operating activities	(9 962)	(11 293)
Net cash linked to investing activities	(230)	463
Net cash linked to financing activities	(2 700)	(1 871)
BALANCE SHEET	**30/09/2022**	**31/03/2022**
Consolidated shareholders' equity	(26 069)	(13 371)
Total non-current liabilities	41 291	19 433
Total current liabilities	17 554	38 241
Total non-current assets	11 651	10 229
Of which financial assets and other non-current assets	*3 227*	*1 519*
Total current assets	21 125	34 074
Of which cash and cash equivalents	*11 727*	*24 617*
FINANCIAL DEBT		
Financial debt, non-current portion	38 224	16 249
Financial debt, current portion	6 863	27 764
GROSS FINANCIAL DEBT	**45 087**	**44 014**
Cash and cash equivalents	11 727	24 617
Capitalization contract **	2 542	2 560
NET FINANCIAL DEBT	**30 818**	**16 837**

** The auditors' report will be finalized and issued in the coming days*

*** The Group has sums tied up in a capitalization contract and euro funds given as security for a bank loan of €7 million, the balance of which to be repaid amounts to €0.1 million at September 30, 2022.*

Financial visibility assured at least until the first quarter of 2024

As of September 30, 2022, MedinCell had €11.7 million of cash and €2.5 million of non-risky current financial assets, compared to €24.6 million of cash and €2.5 million of non-risky financial assets as of March 31, 2022.

Cash flow from operations for the first half of the year reflects the increased investment required to expand and advance the Company's product portfolio.

In November 2022, the Company definitively signed an agreement for an additional €40 million in financing with the European Investment Bank of which around €23 million will be used to repay existing funding.

The estimated cash visibility includes more than €29 million of post-closing cash cashing:

- US$ 4 million from the Bill & Melinda Gates Foundation received in November 2022 as part of the grant awarded in 2019 for the mdc-WWM project
- €7 million net from the first two tranches of the new loan signed with the European Investment Bank, which can be cashed in immediately
- An additional €10 million from the same loan, available upon approval of mdc-IRM, expected in the first half of 2023

- €4.2 million of Research Tax Credit expected in Q1 2023
- Anticipation of a US$ 4 million milestone payment and commercial launch of mdc-IRM in the first half of 2023 following the announcement of the new drug application by Teva on November 3, 2022

The estimated financial visibility does not include revenues that could be derived from:

- Licensing of our internal products
- Licensing of our technologies
- Transfer of licenses after feasibility studies in progress or to come
- New agreements with our existing partners

*Consolidated statement of cash flows**

	(In thousands of €)	30/09/2022 6 months	30/09/2021 6 months
A	NET CASH LINKED TO OPERATING ACTIVITIES	(9 962)	(11 293)
B	NET CASH LINKED TO INVESTING ACTIVITIES	(230)	463
C	NET CASH LINKED TO FINANCING ACTIVITIES	(2 700)	(1 871)
	NET CHANGE IN CASH POSITION	(12 889)	(12 703)
	Cash and cash equivalents - opening balance	24 617	47 095
	Cash and cash equivalents - closing balance	11 727	34 392

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A- Net cash generated from operating activities

Company's cash burn was €10 million during the first six months of the year. Revenue for the period is mainly composed of a € 2.9 million milestone payment from Teva following the decision to start Phase 3 activities for mdc-TJK.

B- Net cash generated from investing activities

The negative flow is mainly due to the company's tangible and intangible investments (€0,4 million) during the period. In the previous year, a positive revaluation of investment securities had created a positive variation in this flow.

C- Net cash generated from financing activities

This negative cash flow of €2.3 million is mainly due to the repayment of the existing debt. On April 1st, 2022 MedinCell received the balance of the conditional advance of €0.6 million from the Occitanie region under a Growth Contract.

Income Statement

Revenue from ordinary activities: €7.7 million

Revenues for the first semester of the 2022-2023 financial year, up 89% compared to the previous period, were generated by (i) the payment of a milestone of € 2.9 million by Teva for the transition to Phase 3 of the mdc-TJK program, and services rendered in connection with (ii) the collaboration with the Bill & Melinda Gates Foundation (development of an injectable female contraceptive active for 6 months), (iii) the collaboration with the international agency Unitaid (project aimed at combating malaria transmission) and (iv) new collaborations.

The company also points out that the first revenues linked to product sales should be royalties from the marketing of the first mdc-IRM product developed with Teva. Until then, due to the product development cycle and depending on the financial parameters set up within the framework of partnerships (which may or may not include certain elements such as invoicing for formulation services, milestone payments, royalties, cost sharing, profit sharing, etc.), its revenues may vary significantly from one period to another.

The company benefits from the Research Tax Credit for its research and development (R&D) activities, which is recorded under "Other income from ordinary activities". It's down 32% from last year due to the progress of the programs, as clinical CRO expenses are not included in the scope of expenses eligible for the Research Tax Credit.

Current operating expenses in line with the development of the Company's portfolio: €19.4 million

Operating expenses increased by 27% compared to the same period of the previous year in line with the resumption of activities and the progress of the various programs.

More than 76% of expenses were for R&D with cost increased by 32% in the first semester. In line with forecasts and the company's strategy of expanding its product portfolio, R&D expenses were mainly dedicated to non-clinical and clinical CRO services, and CMO services to advance programs in formulation research or in preclinical studies to prepare the next steps. Marketing and sales expenses increased by 19% compared to the same period of the previous year, returning to normal levels after two years of restrictions. The Business and Development teams have also been strengthened.

Overheads increased slightly by 11% over the period, mainly due to personnel costs, travel and relocation costs following the lifting of health restrictions, as well as rent and related costs in view of the move to new premises in January 2022.

Net financial income: €(2.1) million

The increase in financial expenses is mainly due to the re-estimation of the variable remuneration of the EIB loan of €1.6 million, as well as the effects of the new amendment signed on June 1, 2022. These expenses were partially offset by foreign exchange gains over the period due to the favorable evolution of the euro/US dollar rate.

Consolidated income statement*

(In thousands of €)	30/09/2022 6 months	30/09/2021 6 months	Var Eur	Var % (%)
Revenue from development services	2 702	1 602	1 100	69%
Milestones	2 902	-	2 902	0%
Royalties	423	-	423	0%
Revenues from sales	**6 027**	**1 602**	**4 425**	**276%**
Research tax credit	1 682	2 483	(801)	(32%)
Other income	-	**(6)**	6	NA
Other income from ordinary activities	**1 682**	**2 477**	**(795)**	**(35%)**
A- Revenue	7 709	4 080	3 629	89%
Cost of goods and services sold	-	-	-	0%
Research and development costs	(14 732)	(11 187)	(3 545)	32%
Marketing and sales costs	(1 308)	(1 106)	(202)	18%
General and administrative costs	(3 321)	(3 003)	(318)	11%
B- Total operating expenses	(19 361)	(15 296)	(4 065)	27%
Current operating income	(11 652)	(11 215)	(437)	4%
Other non-current operating expenses	(62)	(1)	(61)	n.a.
Other non-current operating income	57	2	55	n.a.
Operating income	(11 657)	(11 214)	(443)	4%
Financial interest income	11	56	(45)	-80%
Cost of gross financial debt	(3 479)	(872)	(2 607)	299%
Other financial expenses	(12)	(5)	(7)	140%
Other financial income	1 380	277	1 103	398%
Financial income	(2 090)	(544)	(1 546)	284%
Income from companies accounted for by the equity method	-	-	-	0%
Income before taxes	(13 747)	(11 758)	(1 989)	17%
Tax income/ (expense)	-	-	-	0%
Net income	(13 747)	(11 758)	(1 989)	17%
- Attributable to MedinCell shareholders	(13 747)	(11 758)	(1 989)	
- Attributable to non-controlling interests	-	-		
Earnings per share (in €)	(0,55)	(0,47)		
Diluted earnings per share (in €)	(0,55)	(0,47)		

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Summary of the balance sheet*

(In thousands of €)	30/09/2022	31/03/2022
Total non-current assets	11 651	10 229
Total current assets	21 125	34 074
TOTAL ASSETS	32 776	44 303
Consolidated shareholders' equity	(26 069)	(13 371)
Total non-current liabilities	41 289	19 433
Total current liabilities	17 554	38 241
TOTAL LIABILITIES	**32 776**	**44 303**

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Other highlights of the first half

In August 2022, MedinCell published its annual CSR report which details the different pillars of its ESG policy, its implementation through concrete and clearly defined objectives, and the evolution of the company's non-financial data.

In May 2022, Dr. Richard Malamut, a pharmaceutical development specialist in the United States, joined MedinCell as Medical Director in charge of clinical development and regulatory affairs. He had notably overseen the initial clinical strategy for mdc-IRM at Teva (2013-2016). He was previously Chairman of MedinCell's Medical Board and an observer on the Company's Supervisory Board. Joël Richard resigned from the Executive Board in October 2022 and will definitely leave the company in January 2023.

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 150 people representing over 30 different nationalities.
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