

# MedinCell publishes its financial results and activity report for the first half of 2021-2022 (April - September 2021)

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Revenue: €4.1 million (+30% compared with the first half of the previous year)

Operating expenses: €15.3 million (+36%)

Cash consumption from operations: €11.3 million

Available cash: €34.4 million in cash + €3.0 million in non-risky financial assets (€2.9 million current + €0.1 million non-current)

Post-closing (November 2021)

€3.1 million received in Research Tax Credit + €3.0 million loan received from Bpifrance +  $1.0 \in M$ , partially collected, as a grant within the framework of the French Recovery Plan (Plan France Relance)

# mdc-IRM (schizophrenia): marketing planned from 2022 by Teva in the United States, subject to FDA approval

- FDA acceptance of New Drug Application for mdc-IRM for treatment of patients with schizophrenia in August 2021
- Phase 3 data for mdc-IRM, presented by Teva Pharmaceuticals at Psych Congress (October 30-November 1, 2021), shows significant improvements for patients with schizophrenia: prolonged time to impending relapse, decreased risk of relapse and increased chance of clinical stability

Portfolio of products based on BEPO® technology in regulatory development as of December 1, 2021



#### Key events of the period

Press releases available on invest.medincell.com

April 2021 mdc-TTG (Covid-19): clinical trial validates the safety of ivermectin in daily oral form to simulate continuous

release of the active ingredient by a long-acting injection

June 2021 mdc-STM (malaria): following the selection of the drug candidate announced in June 2021, the long-acting

injectable product has entered the regulatory development phase

August 2021 mdc-IRM (schizophrenia): Teva and MedinCell announce FDA acceptance of New Drug Application

#### Post-closing

November 2021

mdc-IRM (schizophrenia) - Phase 3 data presented by Teva Pharmaceuticals at Psych Congress (October 30-November 1, 2021) shows significant improvements for patients with schizophrenia: prolonged time to impending relapse, decreased risk of relapse and increased chance of clinical stability.

Developed in collaboration with Teva Pharmaceuticals, mdc-IRM, a risperidone extended-release injectable suspension for the treatment of patients with schizophrenia (Teva codename: TV-46000), is the most advanced investigational product based on MedinCell's BEPO® technology. Ongoing New Drug Application review by FDA could lead to commercialization as early as 2022 in the U.S. by Teva, provided marketing authorization. MedinCell is eligible for development and commercial milestones (\$122 million), and royalties on net sales.

December 2021

MedinCell obtains €4 million in financing:

- €3 million loan from Bpifrance for the development of a long-acting ivermectin-based drug designed to protect against Covid19 and its variants for several weeks (mdc-TTG program).
- €1 million grant from the French Ministry of Industry's call for project "Resilience", which is part of the France Recovery Plan, for its new laboratory at the Jacou site, France.

At the Company's request, Teva and AIC have provided updated information on the programs for which they finance and manage regulatory changes:

- mdc-TJK (schizophrenia): our partner Teva informs that the ongoing analysis of the results of the first
  in-human study is expected in 2022 and that it will drive decisions on next development steps.
- mdc-ANG (schizophrenia): our partner Teva informs that ongoing preclinical work could eventually lead to the start of clinical activities in 2022.
- mdc-CWM (post-operative pain and inflammation): our partner AIC informs that discussions continue
  with the FDA to optimize the Phase 3 development plan and it is ready to start Phase 3 in the first
  half of 2022.

# Details of the portfolio of products in regulatory development based on BEPO® technology

As of December 8, 2021, MedinCell's product portfolio consists of:

- 1 product candidate awaiting marketing approval in the United States for marketing as early as 2022 provided marketing authorization from FDA,
- 2 product candidates in clinical development and 6 product candidates in preclinical regulatory development,
- 6 are being developed in partnership with or with the financial support of health foundations or agencies, the others are internal programs funded directly by MedinCell,
- Among these programs (at preclinical and clinical stage), 8 are in human health and 1 in animal health.

Several other programs, developed alone, in partnership with pharmaceutical companies or with the support of foundations or international agencies, are currently at the evaluation or formulation stage, which is a prerequisite to the selection of a product candidate.

# Program awaiting marketing approval

#### mdc-IRM

Treatment of schizophrenia Partner: Teva Pharmaceuticals The marketing application is currently under review by the FDA. Commercial launch in the United States could occur in 2022.

## Clinical stage programs

#### mdc-TJK

Treatment of schizophrenia Partner: Teva Pharmaceuticals Our partner Teva informs that the ongoing analysis of the results of the first in-human study is expected in 2022 and that it will drive decisions on next development steps

#### mdc-CWM

Post-operative pain and inflammation

Partner: AIC

Our partner AIC informs that discussions continue with the FDA to optimize the Phase 3 development plan and it is ready to start Phase 3 in the first half of 2022.

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

#### mdc-ANG

Treatment of schizophrenia

Partner: Teva Pharmaceuticals

Our partner Teva informs that ongoing preclinical work could eventually lead to the start of clinical activities in 2022.

#### mdc-GRT

Organ Transplantation MedinCell program The program is in regulatory preclinical development with clinical trial scheduled to start in 2023.

### mdc-TTG

Covid-19 and variants MedinCell program MedinCell is preparing the launch of a Phase 2 clinical study in several European countries to confirm the prophylactic efficacy of ivermectin in regular, daily, oral form (to simulate the continuous release of the active ingredient by a long-acting injectable). The findings of this study and the global context of the pandemic will drive future developments of the long-acting injectable.

#### mdc-WWM

Contraception

The program is in regulatory preclinical development with clinical trials expected to start in 2023.

Partner: Bill & Melinda Gates Foundation

# mdc-KPT (animal health)

Pain

MedinCell program

The program is in regulatory development with the initiation of pivotal studies planned for the second half of 2022.

#### mdc-STM

Malaria

Partner: Unitaid

A candidate formulation has been selected based on in vivo studies. The program is in regulatory preclinical development with clinical trials expected to start in 2023.

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#### Selected financial information for the half-year 2021

#### Financial visibility maintained

MedinCell still benefits from a solid financial visibility.

The operating cash flow for the first half of the year reflects the increase of investment required to expand and advance the Company's product portfolio.

As of September 30, 2021, MedinCell had €34.4 million in cash and €3.0 million in non-risky financial assets, compared to €47.1 million in cash and €3.9 million in non-risky financial assets as of March 31, 2021.

No new loans were obtained during the first half of the year. Post-closing, the Company received €3.0 million from Bpifrance in the form of a loan and secured €1.0 million grant, partially collected, within the framework of the French Recovery Plan (Plan France Relance).

(€ thou	usands)	30/09/2021	30/09/2020
		6 months	6 months
Α	Net cash generated from operating activities	(11,293)	(6,658)
В	Net cash generated from investing activities	463	(432)
С	Net cash generated from financing activities	(1,871)	22,165
	Net change in cash position	(12,703)	15,075
	Cash and cash equivalents – opening balance	47,095	12,377
	Cash and cash equivalents – closing balance	34,392	27,451

#### A- Net cash provided by operating activities

During the first six months, the Company's operating cash burn increased compared to the same period of the previous year. Firstly, the reimbursement of the €3.1 million Research Tax Credit for 2020 was received in November, whereas the previous year, €3.2 million was received in May 2020. Secondly, the Company had implemented austerity measures at the beginning of the pandemic in March 2020 given the economic uncertainties of that period.

# B- Net cash flow from investing activities

#### C- Net cash flow from financing activities

Cash flow during the first half of the year was negative, as it mainly comprises repayment of financial debts, interests and leases during the period. It should be noted that, in the first half of the previous fiscal year, the Company obtained €11.9 million in State Guaranteed Loans and carried out a capital increase of €15.6 million gross.

# Income statement

# Income from ordinary activities: €4.1 million

Revenues for the first half of the 2021-2022 fiscal year increased 30% compared to the previous period and were mainly generated by services for product formulation activities developed with partners. These first-half revenues resulted from (i) collaborations with the Bill & Melinda Gates Foundation: development of an injectable female contraceptive active for 6 months; and (ii) the collaboration with the international agency Unitaid on a project that aims to fight malaria transmission.

The Company also points out that the first revenues linked to product sales should be royalties from the marketing of the first product developed with Teva Phamaceuticals. 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 the next.

# Other revenue from ordinary activities

The Company benefits from Research Tax Credit for its research and development (R&D) activities, which is recorded under "Other income from ordinary activities". This one has increased significantly compared to last year, by 29%, due to the increased need of CRO (Contract Research Organization) and CMO (Contract Manufacturer Organization) services. Following the prioritization of the

Company's activities in favor of strategic projects on the first wave of the pandemic in 2020, and the implementation of partial activity between April and June 2020, the amounts of the Research Tax Credit were highly impacted.

## Current operating expenses in line with the Company's strategy: €15.3 million

Operating expenses increased by 36% compared to the same period of the previous year, as progress was made in the various programs.

More than 73% of the expenses are related to R&D, whose costs increased by 44% this semester. In the first half of the previous year, the Company had implemented savings measures, delayed expenses and had certain teams in partial activity.

In line with the forecasts and the strategy of expanding the Company's product portfolio, R&D expenses included mainly CRO and CMO services to advance the programs that are in formulation research or in preclinical studies in order to prepare their next steps.

Sales and Marketing expenses increased by 46% compared to the same period of the previous year. In the first half of the previous year, the health crisis prevented any travel and led to a reduction in the activities of the strategic marketing, market access and business development team, resulting in a reduction or a delay of expenses. This year, activities, with the exception of travel, which remains limited, have returned to a normal level.

G&A expenses increased slightly over the period, mainly due to personnel costs and the impact of Restricted Stock Units (AGA) plans.

#### Net financial result: €(0.5) million

Net financial expenses amounted to €0.5 million, compared to €2.6 million in the first half of the previous year, and mainly consisted of interest charges on the bond and the EIB loan. During the first six months ending September 30, 2020, the characteristics of the variable remuneration were modified in the June 2020 amendment related to the conditions of the third and final €5.0 million tranche of the EIB loan. This implied a new estimate of the cost of debt linked to the variable remuneration of the EIB loan of €1.3 million was recorded.

#### Consolidated income statement

(€ thousands)	30/09/2021 6 months	30/09/2020 6 months	Chan	ge
Product sales, royalties	-	-	-	-
Income from development services	1,603	1,226	377	31%
Licenses, Milestones	-	-	-	-
Income from polymers sales	-	-	-	-
Revenues from sales	1,603	1,226	377	31%
Other income	2,477	1,920	557	29%
Revenue	4,080	3,146	934	30%
Cost of goods & services sold	-	-	-	-
Research and Development costs	(11,187)	(7,759)	(3,428)	44%
Sales and Marketing costs	(1,106)	(758)	(348)	46%
General and Administrative costs	(3,003)	(2,760)	(243)	9%
Total operating expenses	(15,296)	(11,277)	(4,019)	36%
Recurring operating income	(11,215)	(8,131)	(3,084)	38%
Other non-current operating costs	(1)	(20)	19	-95%
Other non-current operating income	2	-	2	-
Operating income	(11,214)	(8,151)	(3,063)	38%
Financial interest income	56	10	46	460%
Cost of gross financial debt	(872)	(2,456)	1,584	-64%
Other financial expenses	(5)	(508)	503	-99%
Other financial income	277	351	(74)	-21%
Financial income (loss)	(544)	(2,603)	2,059	-79%
Income from companies accounted for by the equity method	-	-	-	0%
Income before taxes	(11,758)	(10,754)	(1,004)	9%

Tax Income / (expense)	-	-	-	0%
Net income	(11,758)	(10,754)	(1,004)	9%
Attributable to MedinCell shareholders	(11,758)	(10,754)	(1,004)	
Attributable to non-controlling interests	-			
Earnings per share (EPS), €	(0.47)	(0.51)		
Diluted EPS, €	(0.47)	(0.51)		

#### **Balance sheet summary**

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As of September 30, 2021, the Company's assets included €37.4 million in cash, cash equivalents and non-risky investments and a gross debt of €41.5 million at September 30, 2021, versus €42.3 million at March 31 2021. 90% of this is non-current debt and primarily consists of a European Investment Bank loan of €22.5 million and State-Guaranteed Loans (PGE) of €13.8 million. Net Debt was thus €4.1 million, versus €(8.8) million at March 31st, 2021.

(€ thousands)	30/09/2021	31/03/2021
Total non-current assets	12,005	7,281
Total current assets	42,794	56,325
Total assets	54,799	63,606
Consolidated shareholders' equity	(1,628)	8,916
Total non-current liabilities	41,342	41,089
Total current liabilities	15,084	13,600
Total liabilities	54,799	63,606

### About MedinCell

MedinCell is a clinical stage pharmaceutical company 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. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.

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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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