



MedinCell announces fiscal year consolidated results April 2020 – March 2021

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Income from ordinary activities: €11.8 million (+96% compared to the previous year)

Operating expenses: €27.1 million (+8%)

Cash consumption from operations: €12.1 million

Available cash: €47.1 million + €3.9 million of non-risky financial assets

Estimated financial visibility until summer 2023

Key developments of the product portfolio over the period April 2020–March 2021

- Following the announcement of positive results for the Phase 3 trial of mdc-IRM / TV46000 (schizophrenia) in January 2021, Teva Pharmaceuticals, which is leading and funding the program, is preparing for the U.S. regulatory filing, which is expected in mid-2021.
- Expected by the end of 2021, the findings of the ongoing analysis of the results of the *first-in-human* study of mdc-TJK, the second program in partnership with Teva Pharmaceuticals, will drive future developments.
- End of the Phase 2 clinical trial of mdc-CWM (post-operative pain and inflammation), developed with AIC. Our partner plans to launch new safety and efficacy clinical studies (Phase 3) in 2021.
- Selection of candidate formulations and entry into regulatory development of four new products: mdc-WWM (contraception), mdc-GRT (organ transplant), mdc-KPT (pain/animal health) and mdc-TTG (prophylaxis against Covid-19 and its variants).
- Post-closing: the company announced on June 15, 2021 the selection of a candidate formulation for the mdc-STM (malaria) program supported by the international health agency Unitaid, paving the way for the launch of pre-clinical activities.

Portfolio of products based on BEPO® technology in regulatory development as of June 16, 2021



Key facts of the year

Press releases available on invest.medicell.com

April 2020	Announcement of the launch of the Covid-19 research project Launch of regulatory development of mdc-WWM program
May 2020	€10.9 million non-dilutive financing in the form of a French state-guaranteed loan (out of a total of €13.7 million received during the year)
June 2020	€15.6 million capital increase through a private placement with qualified French and international investors
September 2020	Start of a first clinical trial in the Covid-19 program
November 2020	End of primary data collection for the Phase 3 trial of the mdc-IRM program
December 2020	Appointment of Elisabeth Kogan to the Supervisory Board Covid-19: First positive results for clinical study to validate the safety of ivermectin in continuous oral administration
January 2021	Announcement of positive results for the Phase 3 trial for the approval of mdc-IRM in the United States
February 2021	Announcement of the entry into regulatory development of 3 products: mdc-TTG (Covid-19), mdc-GRT (transplantation) and mdc-KPT (pain/animal health) Capital increase of €30 million through a private placement with qualified French and international investors
March 2021	MedinCell publishes an in-depth study on the safety of ivermectin as part of its Covid-19 program (mdc-TTG) Announcement of the upcoming development plan of the mdc-CWM program in partnership with AIC. Safety and efficacy studies are planned to be launched in 2021
Post-closing	
April 2021	MedinCell-led clinical trial confirms safety of ivermectin in continuous oral administration
June 2021	Announcement of the selection of a candidate formulation for the mdc-STM program

Details of the portfolio of products based on the BEPO® technology

As of June 16, 2021, the portfolio is composed of 3 products in clinical development, 6 product candidates in regulatory preclinical phase and several other projects in formulation phase. Among the product candidates or in formulation, 6 are developed in the framework of industrial partnerships or with the financial support of foundations or health agencies, the others being directly funded by MedinCell. 1 program is dedicated to animal health, all the others to human health.

CLINICAL STAGE PROGRAMS

mdc-IRM <i>Treatment of schizophrenia</i> Partner: Teva Pharmaceuticals	Following the announcement of positive results for the Phase 3 trial, Teva Pharmaceuticals is preparing for the U.S. regulatory filing, which is expected in mid-2021
mdc-TJK <i>Antipsychotic</i> Partner: Teva Pharmaceuticals	Expected by the end of 2021, the findings of the ongoing analysis of the results of the <i>first-in-human</i> study will drive future developments
mdc-CWM <i>Post-operative pain and inflammation</i> Partner: AIC	The next late-stage clinical trials are planned as follows: > The first of two Phase 3 efficacy studies in the second half of 2021; > A safety study to complete the long-term safety database of mdc-CWM during the summer of 2021.

NEXT POTENTIAL CANDIDATES FOR CLINICAL DEVELOPMENT

mdc-ANG Antipsychotic Partner: Teva Pharmaceuticals	Ongoing preclinical work could lead to the start of clinical activities before the end of 2021
mdc-GRT Organ transplantation MedinCell program	A candidate formulation has been selected based on <i>in vivo</i> studies. The program is in regulatory preclinical development with clinical trials expected to start in 2022
mdc-TTG Covid-19 and variants MedinCell program	A first candidate formulation has been selected on the basis of <i>in vivo</i> studies. The program is in regulatory preclinical development with clinical trials scheduled to start in 2022
mdc-WWM Contraception Partner: Bill & Melinda Gates Foundation	A candidate formulation has been selected based on <i>in vivo</i> studies. The program is in regulatory preclinical development with clinical trials expected to start in 2023
mdc-KPT (animal health) Pain MedinCell program	A candidate formulation has been selected on the basis of <i>in vivo</i> studies. The program is in regulatory development with pivotal studies expected to start before the end of 2021
mdc-STM Malaria Partner: Unitaid	In June 2020, a candidate formulation was selected on the basis of <i>in vivo</i> studies paving the way for the launch of preclinical activities (post-closing)
mdc-CMV Anesthesia and post-operative pain MedinCell program	The Company had placed the program on stand-by to conduct additional investigations. Following these investigations, the program was definitively stopped (post-closing)

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

Launched in September 2019 with the support of the Bill & Melinda Gates Foundation, the evaluation of the feasibility of an HIV prevention treatment based on a molecule at the experimental stage combined with the BEPO[®] technology did not lead to favorable results and the program did not enter formulation.

The other programs at the evaluation or formulation stage are now confidential for strategic reasons.

Selected financial information for fiscal year 2020-2021

Significant reinforcement of financial resources providing visibility until at least the summer of 2023

As of March 31, 2021, MedinCell had €47.1 million in cash and cash equivalents and €3.9 million in, current and non-current, non-risky financial assets (compared to €12.4 million and €3.6 million respectively a year ago).

The strengthening of financial visibility is due to:

- The strong growth in income from activities, which amounted to €11.8 million over the year, an increase of 96% compared to the previous year,
- The financing strategy, aimed at securing the Company in the face of uncertainties related to the Covid-19 crisis:
 - Renegotiation of the EIB loan and receipt of the last tranche: €5.0 million
 - French State Guaranteed Loans (PGE): €13.7 million
 - Private placements with qualified French and international investors: €42.0 million (net)

These financial resources, together with expected revenues from existing and future partnerships, provide MedinCell with the necessary means to continue the development of its product portfolio.

Consolidated cash flow statement

(en milliers d'€)		2020/2021 12 mois	2019/2020 12 mois
A	Net cash flow from / (used in) operations	(12 136)	(12 539)
B	Net cash flow from investing activities	(1 062)	72
C	Net cash flow from financing activities	47 917	3 563
	Net Change in cash & cash equivalent position	34 719	(8 907)
	Cash and cash equivalents – opening balance	12 377	21 284
	Cash and cash equivalents – closing balance	47 095	12 377

A- Net cash provided by operating activities

During the year, the Company's cash consumption from operations was slightly lower than the previous year, despite the increase in expenses, due to the increase in revenues from milestones and partner services. Over the same period, current operating expenses increased from €25.2 million to €27.1 million, mainly due to higher R&D expenses. In addition, the Company has limited or postponed certain activities as of March 2020 to deal with the Covid-19 crisis and has implemented partial activity for part of the teams between April and June 2020.

The Company recalls that the first revenues linked to product sales should be royalties from the commercialization of products developed with Teva. Until then, 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.), its revenues may vary significantly from one year to the next.

B- Net cash flow from investing activities

The increase of €1.1 million is mainly due to investments made by the Company for the acquisition of machinery and fixed assets, for improvements at the Jacou site amounting to €0.6 million, and for the acquisition of intangible assets related to intellectual property amounting to €0.2 million.

C- Net cash flow from financing activities

During the year, the Company has notably:

- Received the final €5.0 million tranche of the European Investment Bank (EIB) loan,
- Received €13.7 million in State Guaranteed Loans (PGE),
- Conducted two private placements with qualified French and international investors for net proceeds of €42.0 million

These financing operations were intended to secure the Company in the context of the health crisis and to finance the formulation research and development phases of the Company's own products.

During the year, the company partially repaid the TEVA bond loan for €8.2 million.

Income statement

A- Income from ordinary activities: €11.8 million

Income from ordinary activities for the period amounted to €11.8 million, an increase of 96% compared to the previous year, and is mainly composed as follows

- Revenues of €8.2 million, an increase of +187% compared to the previous year, including (i) formulation activities invoiced to industrial partners or subsidized by the Gates Foundation and Unitaid; (ii) milestones received when products in partnership with Teva Pharmaceuticals pass certain development milestones; (iii) intellectual property royalties charged to the joint venture with CM Biomaterials B.V.
- The remainder of the revenue corresponds to the Research Tax Credit, amounting to €3.6 million. The increase of 14% compared to the previous year reflects the intensification of research and development activities.

B- Current operating expenses under control and in line with the Company's expectations: €27.1 million

Current operating expenses increased by 8% compared to the previous year. This growth is concentrated exclusively in R&D activities, which represent 72% of operating expenses, reaching €19.6 million (compared to 68%, or €17.2 million, for the previous year). Measures for adapting the activity to the health crisis led to a decrease in marketing and sales expenses (-24%) and to a near-stagnation of general and administrative expenses (+3%).

In line with the growth of the Company's product portfolio, investments in R&D made it possible to:

- Fund the CRO and CMO services required to advance the programs undergoing formulation research towards preclinical development, notably mdc-WWM in contraception, mdc-GRT in organ transplantation and the two new programs mdc-TTG against Covid-19 and mdc-STM against malaria;
- Strengthening the scientific teams, which increased from 101 to 109 people during the year, particularly those dedicated to preclinical and clinical regulatory activities, preclinical batch manufacturing and analytical activities.

Marketing and selling expenses amounted to €1.8 million as of March 31, 2021, a decrease of 24% compared to the previous year. Personnel costs included in marketing and sales expenses decreased during the year due to the use of partial activity and because some positions remained vacant for part of the year. The significant reduction in external expenses was due to the cancellation of participation in scientific symposium and conferences as a result of health precautions related to the Covid-19 crisis, as well as travel expenses, the non-renewal of certain consulting contracts and the limited use of market access services.

To support operations, general expenses remained relatively stable with a small variation of +3%. This change is linked to personnel costs which, despite the use of part-time work, have increased, in particular due to the recruitment of two Directors and exceptional consultancy costs. On the other hand, the use of part-time work and the massive recourse to home working have resulted in a reduction in travel expenses over the year and the postponement or even cancellation of training expenses.

C- Financial income: €(3,4) million

The financial result decreased by 61% compared to the previous year. The net financial loss thus amounts to €3.4 million compared to €2.1 million. The increase in financial expenses is due to interest expenses on the Teva Pharmaceuticals bond and the EIB loan, which amounted to €0.8 million and €2.5 million respectively at March 31, 2021, compared to €1.1 million and €0.8 million at March 31, 2020.

The increase in interest expense on the EIB loan is due in particular, for €1.3 million, to the revaluation of future cash flows linked to variable remuneration, the contractual characteristics of which were modified by an amendment in June 2020.

D- Financial debt: €42.3 million

As of March 31, 2021, gross financial debt amounted to €42.3 million and net financial debt to €(8.8) million, compared respectively with €32.7 million and €16.7 million a year earlier. It should be noted that 49% of this debt is repayable after April 1, 2024, the date on which MedinCell should receive royalty revenues from the sale of the first products based on its proprietary technology.

Consolidated income statement

(€ thousands)	31/03/2021	31/03/2020	Evolution	
	12 mois	12 mois		
Product sales, Royalties	-	-	-	-
Income from development services	3 660	1 520	2 140	141%
Licences, Milestones	4 073	1 332	2741	206%
Income from polymer sales	453	-	453	na
Revenue	8 186	2 852	5 334	187%
Other income from continuing operations	3 589	3 148	441	14%
Income from ordinary activities	11 775	6 000	5 775	96%
Research & Development costs	(19 568)	(17 214)	(2 354)	14%
Sales & Marketing costs	(1 799)	(2 362)	563	(24%)
General & Administrative costs	(5 776)	(5 599)	(177)	3%
Total operating expenses	(27 143)	(25 175)	(1 968)	8%
Current operating income	(15 368)	(19 175)	3 807	(20%)
Other operating expenses/income	(239)	(150)	(89)	59%
Operating income	(15 607)	(19 324)	3 717	(19%)
Cost of gross financial debt	(3 583)	(2 113)	(1 470)	70%
Other financial income / (expense)	170	(5)	175	
Financial income	(3 413)	(2 118)	(1 295)	61%
Income	(19 020)	(21 442)	2 422	(11%)
Tax income / (expense)	-	(2 473)	2 473	-100%
Net income	(19 020)	(23 915)	4 895	(20%)
Attributable to owners of MedinCell	(19 020)	(23 915)	4 895	(20%)
Attributable to non-controlling interests	-	-	-	-
	3 660	1 520	2 140	141%

Balance sheet summary

(€ thousands)	31/03/2021	31/03/2020
Total non-current assets	7 281	9 573
Total current assets	56 325	17 734
Total assets	63 606	27 307
Consolidated shareholder's equity	8 916	(15 958)
Total non-current liabilities	41 089	36 663
Total current liabilities	13 600	6 602
Total liabilities	63 606	27 307

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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