

MedinCell announces fiscal year consolidated results *April 2019 – March 2020*

Euronext: MEDCL • Montpellier – France • June 4, 2020 – 5:45 pm CEST

Strong consolidated financial position as at March 31, 2020 and strengthened since year-end

- 12.4 M€ in cash and cash equivalents
- 3.6 M€ of risk-free financial assets (0.4 M€ current + 3.3 M€ non-current)
- 10.9 M€ of additional non-dilutive financing (PGE) – *Post-closing*
- 3.1 M€ of CIR collected in May 2020 – *Post closing*
- 5.0 M€ to be received from the EIB under conditions

Consolidated financial results:

- Income from ordinary activities: 6.0 M€ (+4,8% compared to the previous year)
- Cash consumption linked to the activity: 12.5 M€ (in line with expectations)

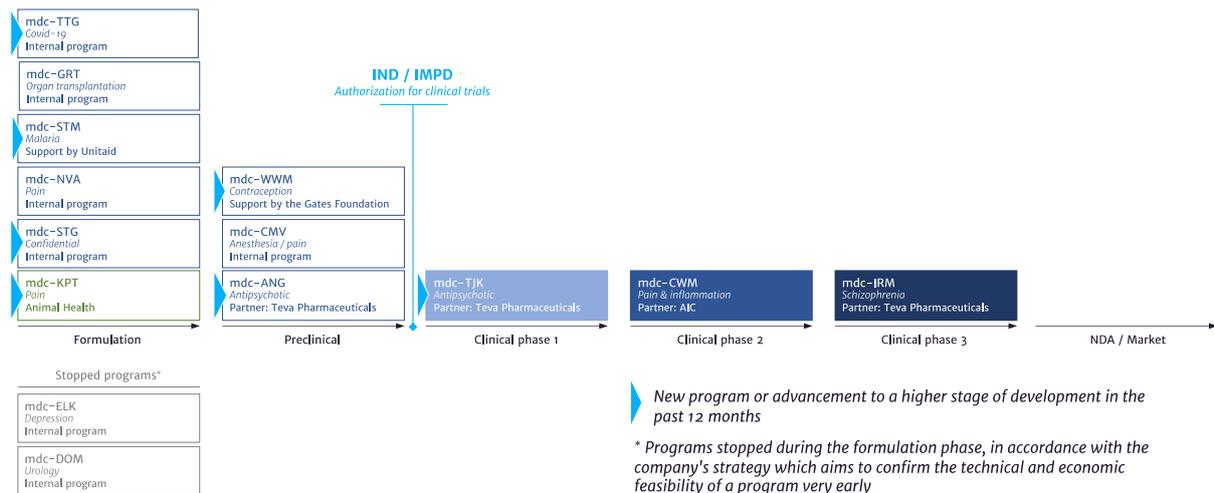
Evolution of the product portfolio in line with expectations

- **Progress in clinical development:** Phase 3 of mdc-IRM (*antipsychotic*), led and funded by Teva Pharmaceuticals and mdc-CWM (*post-operative pain and inflammation*), funded by AIC
- **A third product in clinical development:** start of Phase 1 of the mdc-TJK (*antipsychotic*) product led and financed by Teva Pharmaceuticals
- **Two new products in regulatory preclinical studies:** mdc-ANG (*antipsychotic*) and mdc-WWM (*contraception*), the latter benefiting from a new four-year 19 M\$ grant from the Bill & Melinda Gates Foundation
- **Three programs close to formulation selection that paves the way for preclinical development:** mdc-GRT (*organ transplantation*), mdc-NVA (*pain*) and mdc-KPT (*animal health*)
- **New program launches:**
 - > mdc-STM: formulation of a 3-month active injectable of Ivermectin to neutralize the vector of malaria transmission, the program received a 6.4 M\$ grant over three years from Unitaid
 - > mdc-STG: new internal program in formulation
 - > Feasibility study of an injectable long-acting HIV prevention treatment (PrEP) funded by the Gates Foundation

Significant post-closing events related to the product portfolio:

- Recruitment completed for the mdc-IRM Phase 3 clinical study, interim analysis expected before the end of 2020
- Completion of the mdc-CWM Phase 2 clinical study, Phase 3 is scheduled to begin by the end of 2020
- Launch of a research program for Covid-19 prevention (prophylaxis)

Product portfolio based on BEPO® technology as of 2020, June 1st



Key events of the year

July 2019 – Launch of preclinical development of a third long-acting injectable antipsychotic, mdc-ANG, funded and led by Teva Pharmaceuticals.

August 2019 – Launch of animal health activities with an attractive risk profile and significant financial potential. Products can be tested in the target species during the lead formulation selection, with shorter development times and lower costs compared to human health.

September 2019 – New grant from the Bill & Melinda Gates Foundation to develop a best-in-class long-acting injectable product for HIV PrEP.

September 2019 – The MedinCell General Meeting votes to include the “*Raison d’être*” of the Company in its articles of association: “*Our mission is to contribute to the improvement and protection of the health of populations across the world. The fair sharing of the value created with all our employees is the foundation of our business model. The sustainability of MedinCell is an essential condition for achieving our objectives*”.

November 2019 – Additional \$19 M grant from the Bill & Melinda Gates Foundation over 4 years to fund preclinical activities and a phase 1 clinical trial for the programme mdc-WWM.

December 2019 – Announcement of the launch of the TEVA-funded and TEVA-led U.S. Phase 1 study of the mdc-TJK antipsychotic program.

January 2020 – US Pharma Development Veteran Dr. Richard Malamut Joins the Medical Advisory Board of MedinCell.

March 2020 – 6.4 M\$ grant over three years with global health agency Unitaid, to fund the formulation and preclinical activities of a 3-month acting injectable ivermectin – a drug used to treat many types of parasitic infections – to neutralize the transmission vector of Malaria.

Post-Closing: Launch of a research program for Covid-19 prevention (prophylaxis)

MedinCell announced on April 6, 2020, its Covid-19 project (mdc-TTG) that aims at developing a long-acting injectable Ivermectin formulation for several months to protect people who are not infected with Covid-19 in order to break the virus chain of transmission. Such a tool could play a decisive role in the management of Covid-19 pandemic, by enabling many people around the world, especially those most exposed and at risk, to protect themselves.

In addition to curative treatments and vaccines, MedinCell would open a third path based on Ivermectin.

In the event that no vaccine is found or if it is several years away, such treatment could reduce the impact of confinement with serious social and economic consequences.

The third path to fight Covid-19: Ivermectin

Ivermectin has shown its efficacy in a large number of diseases for more than 30 years. Several tens of millions of human beings have been treated with very few side effects. Ivermectin has also demonstrated its effectiveness in vitro or in vivo in the past on viruses such as dengue fever, West Nile, rabies, HIV, etc.

A first study published in March 2020 showed in vitro efficacy against Covid-19.¹

An observational study from the University of Utah and Brigham & Women's Hospital at Harvard Medical School has shown the potential benefits of Ivermectin in reducing inpatient and intensive care mortality.²

Numerous studies using Ivermectin are underway around the world. Their results could also support our project.

The research on the prophylactic effect of Ivermectin is also based on the recent work on the potential prophylactic effect of nicotine against Covid-19, described in the publication by Dr. Zahir Amoura (La Pitié Salpêtrière) and Jean-Pierre Changeux (Institut Pasteur)³, one of the leading French neuroscientists, who collaborate on our project. Indeed, Ivermectin is one of the most powerful modulators of the "nicotinic" acetylcholine receptor known, as had shown Jean Pierre Changeux and his team⁴, and also has the advantage of not having addictive properties such as nicotine.

MedinCell published last January data showing that Ivermectin can be formulated with BEPO® technology as a long-acting for varying doses and durations of up to several months⁵.

The third path to fight Covid-19: long-acting injection

As in HIV, oral prophylaxis only protects when patients strictly adhere to their treatment. A long-acting injectable becomes necessary to ensure permanent protection.

The third path to fight Covid-19: strategy

The program is advancing on three fronts in parallel to optimize deadlines, in collaboration with renowned scientists and institutes:

- In vitro validation of the protective effect of Ivermectin on Covid-19 cell strains. Results expected for 2020
- Phase 1/2 clinical studies in preparation with oral Ivermectin for potential initiation in the coming weeks with objectives to validate safety and activity in regular dosage for prophylaxis. These studies could be carried out on different populations, especially those most at risk, in areas where the outbreak is active. Results expected by the end of 2020 depending on the evolution of the pandemic.
- In vitro and in vivo development and validation of 1-month and 3-month formulations of Ivermectin. The first candidate formulations could be ready in early 2021 for regulatory development.

The objective is to be able to carry out a phase 3 in 2021 in the event of a rebound of the epidemic.

The third path to fight Covid-19: financing

MedinCell is working on the different funding tools that have been created to support research programs related to Covid-19.

Details of the product portfolio

As of March 31, 2020, the portfolio consisted of 3 products in clinical development and 8 product candidates in the formulation or preclinical phase. Among its products and product candidates, 6 are developed through industrial partnerships or with the financial support of foundations or health agencies, 5 are directly funded by MedinCell. 10 products or candidate products are intended for human health, 1 for animal health.

¹ The FDA-approved Drug Ivermectin inhibits the replication of SARS-CoV-2 in vitro – Leon Caly, Julian D. Druce, Mike G. Catton, David A. Jans, Kylie M. Wagstaff – Antiviral Research, 3 April 2020

² Usefulness of Ivermectin in COVID-19 Illness – Amit N. Patel MD, MS ; Sapan S. Desai MD PhD MBA ; David W. Grainger PhD ; Mandeep R. Mehra, MD, MSc – 19 avril 2020

³ Changeux JP, Amoura Z, Rey F, Miyara MA nicotinic hypothesis for Covid-19 with preventive and therapeutic implications *Compte Rendus Biologies* 343 1-7 May 2020

⁴ Krause R, Buisson B, Bertrand S, Corringier PJ, Galzi JL, Changeux JP, Bertrand D, Ivermectin: a positive allosteric effector of the alpha7 neuronal nicotinic acetylcholine receptor, *Mol Pharmacol* 53 283-294 1998; Changeux JP, The nicotinic acetylcholine receptor: a typical 'allosteric machine'. *Phil. Trans. R. Soc. B* 373: 20170174 2018

⁵ BEPO® : Bioresorbable diblock mPEG-PDLLA and triblock PDLLA-PEG-PDLLA based in situ forming depots with flexible drug delivery kinetics modulation – Christophe Roberge, Jean-Manuel Cros, Juliette Serindoux, Marie-Émérentienne Cagnon, Rémi Samuel, Tjasa Vrlinic, Pierre Berto, Anthony Rech, Joël Richard, Adolfo Lopez-Noriega – *Journal of Controlled Release*, Volume 319, 10 March 2020, Pages 416-427

PROGRAMS AT CLINICAL STAGE

Subcutaneous injection

mdc-IRM <i>Treatment of schizophrenia</i> <i>Partner: Teva Pharmaceuticals</i>	Recruitment completed for the on-going Phase 3 clinical study (post-closing). Interim analysis expected before the end of 2020 upon patient relapse events.
mdc-TJK <i>Antipsychotic</i> <i>Partner: Teva Pharmaceuticals</i>	The first-in-human study for the investigational long-acting injectable antipsychotic mdc-TJK has started in Q4, 2019. The results of this study, expected during 2021, will inform future development.

Intraarticular injection

mdc-CWM <i>Post-operative pain and inflammation</i> <i>Partner: AIC</i>	The Phase 2 clinical study in the United States has been completed (announced in April 2020 - post-closing). AIC, which plans to launch a Phase 3 clinical trial directly before the end of 2020, plans to meet with the FDA in the summer of 2020 to confirm its clinical strategy. <i>The results of the Phase 2 study will not be released for the time being for strategic and competitive reasons.</i>
--	--

NEXT POTENTIAL CANDIDATES FOR CLINICAL DEVELOPMENT

Subcutaneous injection

mdc-ANG <i>Antipsychotic</i> <i>Partner: Teva Pharmaceuticals</i>	Status as of March 31, 2020: Preclinical Preclinical work continues to progress and will inform a decision on further development expected in the second half of 2020.
mdc-GRT <i>Organ transplant</i> <i>MedinCell program</i>	Status as of March 31, 2020: Formulation Full results of ongoing studies should make it possible to select the candidate formulation in 2020.
mdc-WWM <i>Contraception</i> <i>Partner: Bill & Melinda Gates Foundation</i>	Status as of March 31, 2020: Formulation selection / Preclinical Following the selection of the candidate formulation, the program moved into regulatory preclinical development.
mdc-STM <i>Malaria</i> <i>Partner: Unitaid</i>	Current status: Formulation
mdc-STG <i>Indication: confidential</i> <i>MedinCell program</i>	Current status: Formulation
mdc-KPT (animal health) <i>Pain</i> <i>MedinCell program</i>	Current status: Formulation Full results of ongoing studies should make it possible to select the candidate formulation in 2020.

Perineural injection

The two products are the first in MedinCell's portfolio with perineural administration

mdc-CMV <i>Pain</i> <i>MedinCell program</i>	Current status: Preclinical The results of the first preclinical studies do not make it possible to envisage going into the clinic now. Further investigations are underway to determine the strategy.
mdc-NVA <i>Pain</i> <i>MedinCell program</i>	Current status: Formulation Full results of ongoing studies should make it possible to select the candidate formulation in 2020.

Financial information for the financial year 2019/2020

Strong and enhanced financial visibility since the end of the financial year, at least until the end of 2021 in most scenarios

At March 31, 2020, MedinCell had 12.4 M€ in cash and cash equivalents and 0.4 M€ in short-term investments (compared to respectively 21.3 M€ and 0.8 M€ a year ago). The Company also had 3.3 M€ in non-current and risk-free financial assets.

In addition to these resources as of March 31, 2020, MedinCell secured in May 2020 a State Guaranteed Loan (PGE) of 10.9 M€ from Banque Populaire du Sud and BNP Paribas. In May, the Company also received the 2019 research tax credit for an amount of 3.1 M€. Furthermore, the Company may also receive, under certain conditions, the final tranche of 5.0 M€ of the European Investment Bank's (EIB) loan.

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

Cash flow statement

(€ thousands)	2019/2020 12 months	2018/2019 12 months
A Net cash flow from / (used in) operations	(12 539)	(15 932)
B Net cash flow from investing activities	72	(832)
C Net cash flow from financing activities	3 563	29 240
Net Change in cash & cash equivalent position	(8 907)	12 493
Cash and cash equivalents – opening balance	21 284	8 791
Cash and cash equivalents – closing balance	12 377	21 284

A- Net cash flow used in operations

During the year, the Company reduced its cash burn from operations compared to the previous year due to increased milestone and partner services revenues as well as the payment of an initial \$4.75 M in grants from the Bill & Melinda Gates Foundation. Over the same period, operating expenses increased from 19.6 M€ to 25.2 M€, primarily due to increased R&D expenses. In addition, the Company has limited or postponed certain activities from March 2020 to deal with the Covid-19 crisis. The impact of these budget reviews remains limited for the 2019-2020 financial year but could be more significant for the following financial year depending on the extent and duration of the Covid-19 crisis.

The Company points out that the first revenue from product sales are expected to be royalties from the marketing of products developed with Teva Pharmaceuticals. Until then, due to the product development cycle and depending on the financial terms of partnerships (which may or may not include elements such as services fees, milestone payments, royalties, cost sharing, profit sharing, etc.), its revenue may vary significantly from one year to year.

B- Net cash flow from investing activities

The net flow linked to investment operations of 72 K€ is due to i) 0.9 M€ due to the release of financial assets given as collateral, offset by ii) the Company's investments that correspond to the acquisition of machinery and fixed assets for 0.6 M€ and intangible assets for 0.3 M€, related to intellectual property.

C- Net cash flow from financing activities

In July 2019, the Company cashed the second tranche of the EIB loan for an amount of 7.5 M€. This loan, for a total amount of 20 M€, of which 15 M€ has already been received, aims to finance the formulation research and development phases proprietary products of the Company. The payment of the final tranche is subject to certain targets. During the period, the Company also reimbursed a loan of \$1.0 M to a former industrial partner.

Taking into account (i) the available cash, (ii) the expense reductions implemented in the context of the Covid-19 crisis, and (iii) the additional financing put in place since the closing of the fiscal year, the Company benefits from a solid financial visibility. In addition, MedinCell should continue to benefit from revenues from existing or future partnerships, such as revenues from services and milestone payments and the Research Tax Credit.

Income Statement

A- Income from ordinary activities: 6.0 M€

Income from ordinary activities for the period came to 6.0 M€, an increase of 48% compared with the previous financial year, and is divided as follows:

- Revenues of 2.9 M€, up 98% compared with the previous year, including (i) formulation activities invoiced to industrial partners or subsidized by the Gates Foundation and (ii) milestones received from products in partnership with Teva Pharmaceuticals at key development stages.
- The remainder of income from ordinary activities corresponds to the Research Tax Credit (CIR) of 3.1 M€. The increase of 21% compared with the previous year reflects the intensification of research and development activities. This CIR was received by the Company in May 2020 (post-closing).

B- Recurring operating expenses under control and in line with Company's expectations: 25.2 M€

Recurring operating expenses increased by 29% compared with the previous year.

95% of the additional spending were related to R&D, of which the budget increased by 45% this year and totaled 17.2 M€. Other support expenses increased by a limited extent by 5%. In line with the Company's strategy of expanding its product portfolio, these R&D investments thus enabled the Company to:

- Finance CRO and CMO services for ongoing formulation research and preclinical development programs, notably mdc-CMV (anesthesia and postoperative pain) and mdc-NVA (pain management) and mdc-GRT (organ transplantation).
- Strengthen its scientific teams, whose workforce has risen from 90 to 101 employees, and notably the team dedicated to the analysis, evaluation and initial validation of the compatibility of new molecules with BEPO[®] technology. The Company has also strengthened its expertise necessary for more advanced development of products at the end of the formulation and preclinical stages.

Despite the strengthening of the *Business Development* team in charge of the development and management of partnerships, marketing and selling expenses decreased by 12% to 2.4 M€.

To support the Company's operations, General and Administrative expenses increased by 14%. The increase is due in part to the training of the teams required to support the Company's development as well as the intensification of investor relations and communication activities. They also include the implementation of stock option and Free Share programs aimed at developing employee ownership and thus continuing to share with employees the value created while protecting the interests of all shareholders.

C- Financial expenses: (2.1) M€

The financial result improved by 49% compared with the previous year. As a reminder, at the time of the IPO in October 2018, financial expenses of 2.2 M€ were amounted. These expenses included the fair value of bonds redeemable in shares (non-cash expense) as well as the partial repayment premium on Teva Pharmaceuticals' debt due to its participation in the IPO.

D- Financial debt: 32.7 M€

At March 31, 2020, the gross financial debt amounted to 32.7 M€ and the net financial debt to 16.7 M€ vs. 27.0 M€ and 1.1 M€ the year before. It should be noted that 84% of the current debt is repayable beyond April 1st, 2023. At this time MedinCell should already receive royalty revenues from the sale of the first products based on its proprietary technology.

Consolidated income statement

(€ thousands)	31/03/2020	31/03/2019	Evolution	
	12 months	12 months		
Product sales, Royalties	-	-	-	-
Income from development services	1 520	1 375	145	11%
Licences, Milestones	1 332	-	-	na
Income from polymer sales	-	68	(68)	(100%)
Revenue	2 852	1 442	1 410	98%
Other income from continuing operations	3 148	2 605	543	21%
Income from ordinary activities	6 000	4 047	1 953	48%
Cost of goods & services sold	-	(79)	79	(100%)
Research & Development costs	(17 214)	(11 900)	(5 314)	45%
Sales & Marketing costs	(2 362)	(2 676)	314	(12%)
General & Administrative costs	(5 599)	(4 899)	(700)	14%
Total operating expenses	(25 175)	(19 554)	(5 621)	29%
Recurring operating income / (expense)	(19 175)	(15 507)	(3 668)	24%
Other operating expenses/income	(150)	(9)	(141)	na
Operating income / (expense)	(19 324)	(15 516)	(3 808)	25%
Gross financial debt income / (expense)	(2 049)	(2 036)	(13)	1%
Other financial income / (expense)	(69)	(2 157)	2 088	(97%)
Financial income / (expense)	(2 118)	(4 193)	2 075	(49%)
Income / (Loss) before tax	(21 442)	(19 710)	(1 732)	9%
Tax income / (expense)	(2 473)	28	(2 501)	na
Net income / (loss)	(23 915)	(19 682)	(4 233)	22%
Attributable to owners of MedinCell	(23 915)	(19 687)	(4 228)	21%
Attributable to non-controlling interests	-	5	(5)	(100%)

Balance sheet summary

(€ thousands)	31/03/2020	31/03/2019
Total non-current assets	9 573	11 962
Total current assets	17 734	26 020
Total assets	27 307	37 982
Consolidated shareholder's equity	(15 958)	6 243
Total non-current liabilities	36 663	23 968
Total current liabilities	6 602	7 771
Total liabilities	27 307	37 982

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 130 people representing over 25 different nationalities.

Contacts

MedinCell

David Heuzé
Communication leader
david.heuze@medincell.com
+33 (0)6 83 25 21 86

NewCap

Louis-Victor Delouvrier
Relations investisseurs
medincell@newcap.eu
+33 (0)1 44 71 98 53

NewCap

Nicolas Merigeau
Relations médias
medincell@newcap.eu
+33 (0)1 44 71 94 98

This press release may contain forward-looking statements, especially on the Company's progress of its clinical trials. 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 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", "foresee", "aim", "intend", "may", "anticipate", "estimate", "plan", "project", "will", "may", "probably", "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 (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, as well as in the documents and reports to be published subsequently by the Company. In addition, these forward-looking statements speak only as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. 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.

This press release is for information purposes only. The information contained herein does not constitute an offer to sell or a solicitation of an offer to buy or subscribe for the Company's shares in any jurisdiction, in particular in France. Similarly, this press release does not constitute investment advice and should not be treated as such. It is not related to the investment objectives, financial situation or specific needs of any recipient. It should not deprive the recipients of the opportunity to exercise their own judgment. All opinions expressed in this document are subject to change without notice. The distribution of this press release may be subject to legal restrictions in certain jurisdictions. Persons who come to know about this press release are required to inquire about and comply with these restrictions.