MedinCell announces 2018/19 fiscal year results

Jacou, France, June 4th 2019, 5.45 pm

Achievement of all anticipated milestones for programs in development

Product portfolio progression with a first product in clinical trials* phase 3 and another one in phase 2 in the United States, and two programs in regulatory preclinical* studies

Strong cash position, cash usage in line with expectations

Main clinical progressions of the portfolio *(more details and post-closing events on page 3)*

CNS (Central Nervous System) treatments developed by our partner TEVA, based on our patented technology

- Start of a Phase 3 clinical study in the US
  ***mdc-IRM** / TV46000 - investigational long-acting treatment for schizophrenia*
- Initiation of preclinical regulatory development activities of a second product (mdc-TJK)

Pain Management

- Start of a Phase 2 clinical trial in the US (safety and activity study)
  ***mdc-CWM** - orthopedic postoperative pain and inflammation with AIC*
- Start of preclinical regulatory development for a second product
  ***mdc-CMV** – a single injection that combines surgical anesthesia and 3 days of analgesia – most advanced internal program of MedinCell*
- Progression of the formulation of a third product
  ***mdc-NVA** – chronic pain management*
- These products aim at reducing the use of opioids for pain management

Collaboration with the Bill & Melinda Gates Foundation

- Renewed support from the Foundation for the development of a 6-month contraceptive following the promising results of in vivo studies and payment of the second part of the grant – ***mdc-WWM***

Other products in development

- Promising progression in the formulation of a long acting injectable for patient who received an organ transplant - ***mdc-GRT***
- Launch of the formulation selection for a new product in urology - ***mdc-DOM***

Strengthened financial visibility

- **21.3 M€ in cash and cash equivalents + 0.7 M€ in short-term investments**
- **3.9 M€ in non-current financial assets**
- **12.5 M€ drawable under conditions from the European Investment Bank loan**
- **Cash usage from operating activities in line with expectations: 15.9 M€**

MedinCell = MedinCell SA + affiliates.

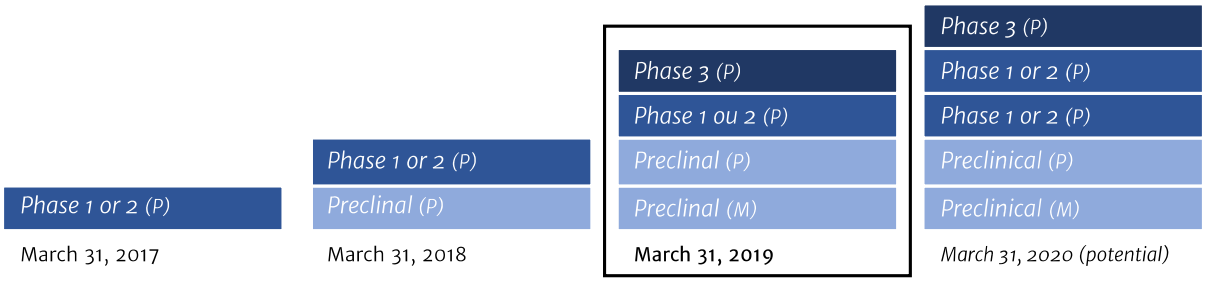
This press release principally covers elements that the Company estimates are essential for assessing its activity, notably the status of its product portfolio and its financial visibility (cash position). The annual and consolidated financial statements of the Company have been approved by the Management Board and reviewed by the Supervisory Board. The reports of the auditors will be issued after the completion of the procedures required for the publication of the annual financial report.

Words with a * are defined in a glossary at the end of the press release.

Strategy and perspectives

MedinCell expects to continue advancing its product portfolio, including advancing existing programs to the next preclinical and clinical phases and starting new programs based on already approved pharmaceutical ingredients. Several major value inflection points are expected, especially the first results of the ongoing clinical phases.

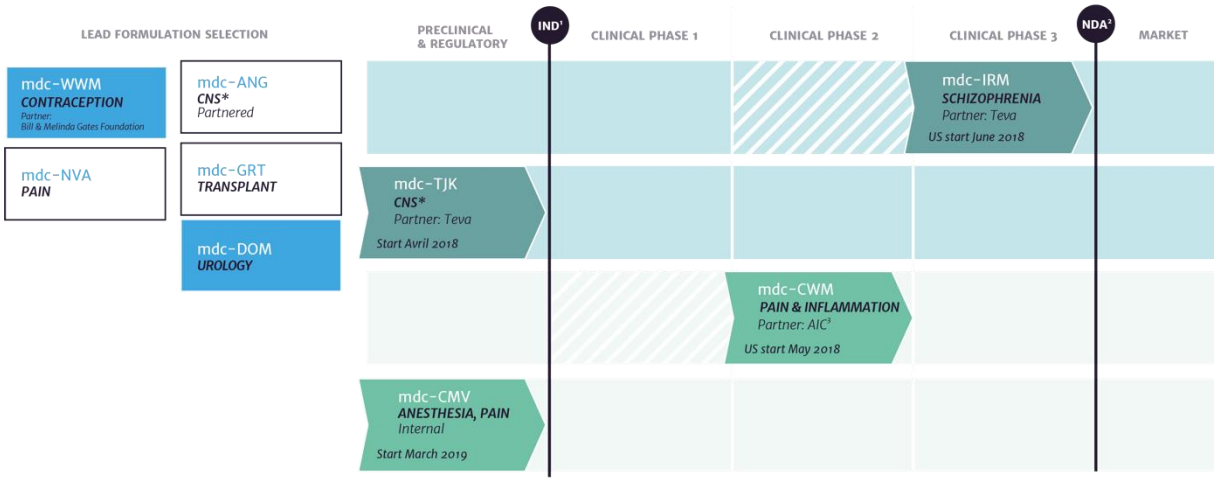
Evolution of the preclinical and clinical portfolio:



Programs in development
(P) : Partnered program – (M) : MedinCell internal program

Product portfolio development during the financial year 2018-19

In line with its strategy and objectives, MedinCell has advanced its product portfolio, with the significant progress of several programs (green arrows below), and the launch of formulation selection for new products (in blue below).



*Central Nervous System
1. Investigational New Drug
2. New Drug Application
3. Arthritis Innovation Corporation (AIC): Company founded by North American physicians & entrepreneurs

March 2019

Anesthesia and postoperative opioid free pain management (mdc-CMV)

> Start of regulatory preclinical development

In vivo studies have demonstrated that mdc-CMV offers surgical anesthesia and a minimum of 3 days of analgesia after a single preoperative injection that could improve and simplify postoperative pain management, reduce the risk of developing chronic pain and avoid the use of opioids

The development of this product is part of a multimodal approach to opioid-free pain management with, in addition to mdc-CMV, two other programs: mdc-CWM currently in Phase 2 clinical trials in the United States and mdc-NVA in formulation selection.

mdc-CMV is the most advanced internal program of MedinCell. It could enter in clinical development in 2020.

February 2019

Treatment of depression (mdc-ELK)

> Stop of formulation research phase

This decision was made in line with the Company's strategy to confirm the feasibility of a program as earlier as possible.

January 2019

6-month injectable contraceptive (mdc-WWM)

> Payment by the Bill & Melinda Gates Foundation of the second part of the grant to fund formulation of the product

This payment of $ 1.5M on a $ 3.5M total grant is based on promising in vivo results that have been obtained during the first 12 months of the project and substantiates the feasibility potential

The program could enter in preclinical regulatory development in 2020.

November 2018

Urology (mdc-DOM)

> Start of formulation selection activities

The launch of this program follows preliminary studies that validated the technical feasibility and the potential of the product.

June 2018

Maintenance treatment of schizophrenia (mdc-IRM)

> Start of a Phase 3 clinical study in the US

Developed by Teva, the most advanced program based on our proprietary technology is in a Phase 3 clinical study. This is the final stage of clinical development before applying for marketing approval. Using risperidone, an already widely-adopted active pharmaceutical ingredient, mdc-IRM is destined for the maintenance treatment of schizophrenia developed in partnership with Teva who conducts and funds the development of mdc-IRM and will market the product if and when approved.

This product illustrates the particularly attractive risk/benefit profile of MedinCell's products using approved molecules with documented efficacy and safety. In the United States, mdc-IRM benefits from the 505(b)(2) simplified regulatory pathway and did not require a Phase 2 clinical trial.

The estimated Primary Completion Date is January 2020 and the study should end in April 2020.

May 2018

Opioid free treatment of postoperative inflammation and pain in orthopaedic surgery mdc-CWM)

> Start of Phase 2 clinical trial in the United States (safety and activity study)

This product is developed with our Canadian partner AIC (Arthritis Innovation Corporation).

In April 2019, AIC capped recruitment at 20 patients (of the allowed 50) for the active phase 2 clinical study. A formal analysis of all available data will be conducted after the 20th patient completes the 3-month follow-up visit in Summer 2019. AIC plans to subsequently meet with FDA to present their findings and to validate the next trial design.

April 2018

Long-acting treatment - Central Nervous System (mdc-TJK)

> Start of regulatory preclinical development

It's the second product in partnership with Teva.

mdc-TJK could be subject to an IND filing and start of clinical activities in the first half of 2019.

Other highlights of the year

Successful financing operations to support the expansion strategy of the portfolio and validation of the MedinCell model by leading financial players.

Issuance of bonds redeemable in shares for a total of 3.2 M€, cashing of the first tranche of 7.5 M€ from the EIB loan (12.5 M€ still available) and success of the IPO with 31.4 M€ capital increase in gross proceed, strengthened the R&D to advance and enrich the product portfolio, including new proprietary technologies.

Partnership strategy

Validation of the expertise of MedinCell teams and the BEPO® technology with the initiation of a first phase 3 clinical study in the United States, and the visibility of a listed company, have help to initiate contacts with potential partners in the second half of the year. Discussions are currently underway with US, European and Asian pharmaceutical companies. They cover new programs based on already approved pharmaceutical ingredients.

Global Health impact

During the past year, MedinCell participated in several international conferences on major global health issues and potential solutions, such as the World Health Assembly in Geneva (May 2018) and the World Health Summit in Berlin (October 2018). This initiative has significantly expanded the Company's network within both official (e.g: WHO) and non-governmental organizations (MedinCell is now a member of the World Health Council). These contacts aim to accurately identify the needs of certain populations who could benefit from long-acting injectable treatments and to consider alternative funding for new programs, like the one with the Bill & Melinda Gates Foundation.

Animal Health, exploration of a market with strong financial potential

The expertise of MedinCell and its technology allow to consider applications in the field of animal health, which offers strong commercial and financial potential. The Company has taken an initiative to move in this direction without impacting its core business in human health and its financial resources.

Development of shareholders and investors relations

Many institutional and individual investors joined the Company's long-standing shareholders following its IPO in October 2018. The company has initiated various communication operations (dedicated website, half-year teleconferences, shareholders' meeting in Paris, open-day in Jacou, investor conferences, non-deal road shows, etc.) for all its shareholders and potential new investors.

At the heart of MedinCell's corporate project, employee ownership makes it possible to align the interests of employees and shareholders. As a continuation of what has been done since its creation, MedinCell has launched in April 2019 a new Free Share plan that is equally awarded to all employees but whose final acquisition will depend directly on the performance of the share price.

MedinCell, laureate #LetsgoFrance 2019 trophy in the category "France, a model of sustainable economy" (PWC)

This award recognizes MedinCell's business model in which all employees are shareholders and placed at the heart of the Company's development. It also values the Company's potential impact on the sustainable economy. This philosophy reinforces the commitment and emancipation of employees and supports operational performance to support the mission. This award is in addition to other ones recently received, including the *prix de l'innovation de la Région Occitanie*, the *prix d'entreprise la plus créative de France des Trophée PME Bougeons-Nous* and the *Pass French Tech*.

Financial information for the financial year 2018/2019

Enhanced available cash and financial visibility

At March 31, 2019, MedinCell had 21.3 M€ in cash and cash equivalents and 0.7 M€ in short-term investments (compared to respectively 8.8 M€ and 0.7 M€ a year ago). The Company also had 3.9 M€ in non-current financial assets. In addition, there are also 12.5 M€ to could be drawn under conditions from the European Investment Bank's loan. During the financial year, MedinCell has completed its financial strategy aiming at providing it with the necessary resources and financial visibility to advance its product portfolio.

	(€ thousands)	2018/2019 12 months	2017/2018 12 months
A	Net cash flow from / (used in) operations	(15 932)	(5 426)
B	Net cash flow from investing activities	(832)	2 242
C	Net cash flow from financing activities	29 240	8 153
	Net Change in cash & cash equivalent position	12 493	4 967
	Cash and cash equivalents – opening balance	8 791	3 824
	Cash and cash equivalents – closing balance	21 284	8 791

Cash flow statement

A- Net cash flow used in operations

During the year, the Company's burned more cash than the previous year, mainly due to lower revenues from milestones and partner services, (revenue of 1.4 M€ against 6.4 M€ the previous year). Over the same period, operating expenses rose from 15.2 M€ to 19.6 M€, mainly due to higher R&D expenses.

The Company points out that the first revenue from product sales are expected to be the royalties generated by the commercialization of the first products developed with Teva. 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 year to year.

B- Net cash flow from investing activities

The (0.8) M€ change is mainly due to the acquisition of machinery and fixed assets for 0.2 M€ and intangible asset acquisitions for 0.5 M€, related to intellectual property and internal development of prototypes designed to improve formulation analyzes.

C- Net cash flow from financing activities

The Company carried out the following financial transactions in order to increase its financial visibility:

- Issuance of bonds redeemable in shares subscribed by CM-CIC Innovation and BNP Paribas Développement for a total of 3.2 M€. These issues add to those carried out during the previous exercise and subscribed by a number of funds managed by Seventure Partners (Natixis - BPCE group) for 4 M€.

- Cashing of the first tranche of 7.5 M€ in June 2018 from the loan of the European Investment Bank (EIB). This loan of 20 M€ aims to finance the formulation research and development phases of proprietary products of the Company. Payment of the two remaining tranches is subject to targets. Some of these having already been met, the Company can, at any time, request the payment by the EIB of the second tranche of 7.5 M€.

- IPO on the Euronext market in Paris for 31.4 M€ of gross proceeds, after exercise of the over-allotment option. This operation was notably carried out with the support of the Company's financial investors (CM-CIC Innovation, Seventure Partners, BNP Paribas Développement), Teva and French and international funds specialised in healthcare or socially responsible investments. As a reminder, as agreed in our financial agreements, Teva's participation cannot exceed 5% of the share capital. The net proceeds of the IPO were 28.6 M€ of which 6.0 M€ were used for Teva's deb partial repayment, as announced at the time of the transaction.

Taking into account the available cash, to be compared with current and foreseeable levels of cash consumption (negative operating cash flow of 15.9 M€ over the year), the Company benefits from strong financial visibility. It should also continue to benefit from existing partnership revenues such as service revenues and milestone payments and the Research Tax Credit.

Income statement

A- Income from ordinary activities: 4.0 M€

Revenue

Revenue of the fiscal year came from services provided for formulation research activities for partnered products. Paradoxically, the decrease in revenue compared with the previous year reflects the progress made in the projects undertaken in partnership with Teva who directly funds all preclinical and clinical development activities once the formulation stage has been completed, thus reducing the remuneration to MedinCell.

This decrease was partially offset by revenue from the collaboration with the Bill & Melinda Gates Foundation related to the development of a 6-month injectable contraceptive.

Furthermore, there was no milestone revenue from the partnerships recognized during the period. Milestones related to mdc-IRM and mdc-TJK programs, which have progressed into Phase 3 and preclinical development respectively, were booked in the previous year.

Other income from ordinary activities

The Company benefits from Research Tax Credit with respect to its Research and Development (R&D) activities. Reflecting the increase in investments, this Research Tax Credit rose by 40% compared with last year and totaled 2.6 M€. The Company expects to receive this sum in the second half of 2019.

B- Recurring operating expenses under control and in line with Company's expectations: 19.6 M€

Recurring operating expenses increased by 29% compared with the previous year. Over half of the additional spending concerned R&D, of which the budget increased by 35% this year and totaled 11.9 M€. In line with the Company's strategy of expanding its product portfolio, these R&D investments thus enabled the Company to:

- Finance MedinCell's partner CRO (Contract Research Organisation) services in order to move forward with the programs currently in the formulation research phase like mdc-CMV, in anesthesia and postoperative opioid free pain management and mdc-GRT in Organ transplant.
- Strengthen its scientific teams, whose workforce has risen from 77 to 90 employees, and notably the team dedicated to assessing and validating the compatibility of the molecules used in products expected to enter the Totaling 2.7 M€, Sales & Marketing expenses increased by 42% compared to last year, especially with a significant strengthening of the Strategic Marketing and Market Access team whose role is to identify the future controlled-release treatments that will be developed by the Company and to assess their commercial potential and maximize the chances partnerships.

To support the Company's operations, General & Administrative expenses increased by 15%. It should be noted that a portion of this increase was dedicated to training the teams, necessary to accompany the Company's development strategy. Another significant part was dedicated to financing operations and partnership development.

C- Financial expenses: (4.2) M€

The Company's IPO generated other financial expenses of 2.2 M€. These expenses include the fair value of bonds redeemable in shares (non-cash expense) as well as the impact of the partial repayment primium of the Teva debt due its participation in the IPO.

D- Financial debt: 27.0 M€

At March 31, 2019, the gross financial debt amounted to 27.0 M€ and the net financial debt to 1.1 M€ vs. 31.0 M€ and 17.5 M€ the year before. It should be noted that 71% of the current debt is repayable beyond April 1st, 2023 when MedinCell should receive income from the sale of the first products based on its proprietary technology.

Consolidated income statement

	(€ thousands)	31/03/2019 12 months	31/03/20108 12 months	Evolution	
	Product sales, Royalties	-	-	-	-
	Income from development services	1 375	3 134	(1 759)	(56%)
	Licences, Milestones	-	3 019	(3 019)	Na
	Income from polymer sales	68	285	(217)	(76%)
	Revenue	**1 443**	**6 439**	**(4 995)**	**(78%)**
	Other income from continuing operations	2 605	1 862	743	40%
A	**A Income from ordinary activities**	**4 047**	**8 301**	**(4 254)**	**(51%)**
	Cost of goods & services sold	(79)	(218)	139	(64%)
	Research & Development costs	(11 900)	(8 846)	(3 054)	35%
	Sales & Marketing costs	(2 676)	(1 888)	(788)	42%
	General & Administrative costs	(4 899)	(4 246)	(653)	15%
B	**Total operating expenses**	**(19 554)**	**(15 198)**	**(4 356)**	**29%**
	Recurring operating income / (expense)	**(15 507)**	**(6 897)**	**(8 610)**	**125%**
	Other operating expenses/income	(9)	(481)	472	(98%)
	Operating income / (expense)	**(15 516)**	**(7 378)**	**(8 138)**	**110%**
	Gross financial debt income / (expense)	(2 036)	(1 792)	(244)	14%
	Other financial income / (expense)	(2 157)	(45)	(2112)	Na
C	**Financial income / (expense)**	**(4 193)**	**(1 837)**	**(2 356)**	**128%**
	Income / (Loss) before tax	**(19 710)**	**(9 215)**	**(10 495)**	**114%**
	Tax income / (expense)	28	(360)	388	(107,8%)
	Net income / (loss)	(19 682)	(9 575)	(10 107)	105,6%
	Attributable to owners of MedinCell	(19 687)	(9 571)	(10 116)	105,7%
	Attributable to non-controlling interests	5	(4)	9	na
	Earnings / (loss) per share, €	*(1,14)*	*(0,66)*	*(0,48)*	72,7%
	Diluted earnings / (loss) per share, €	*(1,14)*	*(0,66)*	*(0,48)*	72,7%

Balance sheet summary

(€ thousands)	31/03/2019	31/03/2018
Total non-current assets	11 962	11 714
Total current assets	26 020	13 639
Total assets	37 982	25 353
Consolidated shareholder's equity	6 243	(11 750)
Total non-current liabilities	23 968	28 969
Total current liabilities	7 771	8 133
Total liabilities	37 982	25 353

About MedinCell

MedinCell is a 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.

Glossary

Clinical development
Clinical development includes all the trials conducted on human panels. It is divided into stages (Phases 1, 2 and 3) to test and validate the treatment tolerance and its effectiveness.
Note: the products developed by MedinCell using active already-approved and known pharmaceutical ingredient, they can in some cases benefit from a lightened clinical development.

Formulation research
Formulation research is the first stage for all programs. It enables a prototype of the product to be obtained that complies with the targeted specifications, notably the duration of action and the dose of active ingredient to be regularly released. For each product, a new combination of polymers is created, thus making each formulation unique and exclusive.

Preclinical regulatory development
Launched after the development of the prototype, preclinical development includes a series of studies and operations aimed at confirming the product's viability, testing its safety and establishing the scientific bases and regulatory strategy necessary for all applications for clinical trial approval.

CMC (Chemistry Manufacturing Control) regulatory strategy
It is used to put together the dossier for applying for clinical trial approval that includes all the necessary elements proving that the product can be safely administered to patients and that the company is capable of manufacturing this product on a pilot scale

Application for clinical trial approval
Launching trials on humans is subject to prior approval from the bodies responsible for health, such as the FDA (Food & Drug Administration) in the United States and EMA (European Medicines Agency) in Europe. Applications for clinical trial approval are based on a dossier comprising the work undertaken during preclinical development.

CRO (Contract Research Organization)
A CRO is a company that provides services in the field of biomedical research for the pharmaceutical or biotechnology industries. CROs may intervene during any stage of the Research & Development process, from pre-clinical studies to marketing and pharmacovigilance, including conducting clinical trials and assistance in research work.

Redeemable Bond in Shares
Redeemable Bond in Shares is an obligation, that is to say a part of a loan issued by a company, having the particularity of being repayable in action.

Current and non-current assets
Current assets (inventories, advance payments on orders, etc.) are assets that a company uses, replaces, or converts into cash in a typical operating cycle, usually less than 12 months.
A non-current asset is an asset used sustainably for operating purposes by a company that has a life of more than one year. It mainly corresponds to property, plant and equipment such as land, buildings or intangible assets such as patents.

Opioids
Psychotropic substance that can be synthetic or natural. In pharmacy, opioids are prescription pain relievers to relieve chronic or acute pain.

Opioids crisis
The opioid crisis refers to the rapid increase in the use of opioids, with or without a prescription since the mid-2010s. In the United States, opioid overdoses are responsible for 140 deaths per day according to the CDC, the main US federal health agency.

Contacts

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

NewCap
Louis-Victor Delouvrier / Alexia Faure
Investors relation
medincell@newcap.eu
+33 (0)1 44 71 94 94

NewCap
Nicolas Merigeau
Medias relation
medincell@newcap.eu
+33 (0)1 44 71 94 94

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