



Publication of the activity report and financial information for the first half-year (April – Sept. 2018)

Jacou (France), December 3, 2018, 5.45 pm

Period highlights

In the United States, our partner Teva Pharmaceuticals initiated a Phase III clinical study for an investigational long-acting treatment for schizophrenia. This is the final stage of clinical development before applying for marketing approval. This product formulation (mdc-IRM) is based on our proprietary technology.

Other products in development

- Initiation of non-clinical development activities of a second product in the Central Nervous System (CNS) in partnership with Teva
- Launch of the first clinical trial (Phase II) in the United States of a product that aims to treat orthopaedic postoperative pain, in partnership with AIC

Enhanced financial visibility

- Cash of €11.4 million in available funds and €4.6 million in non-risky financial assets
- EIB loan: €7.5 million received (a further €12.5 million still available)
- Initial Public Offering: €31.4 million (post-closing event)
- Increase in R&D spending: +23% (compared with the first half of 2017)

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 Company's full half-year financial report is available in the Investors section of the MedinCell website (invest.medincell.com), as well as on the AMF (Autorité des Marchés Financiers) website.

First Phase III trial in the United States (mdc-IRM program)

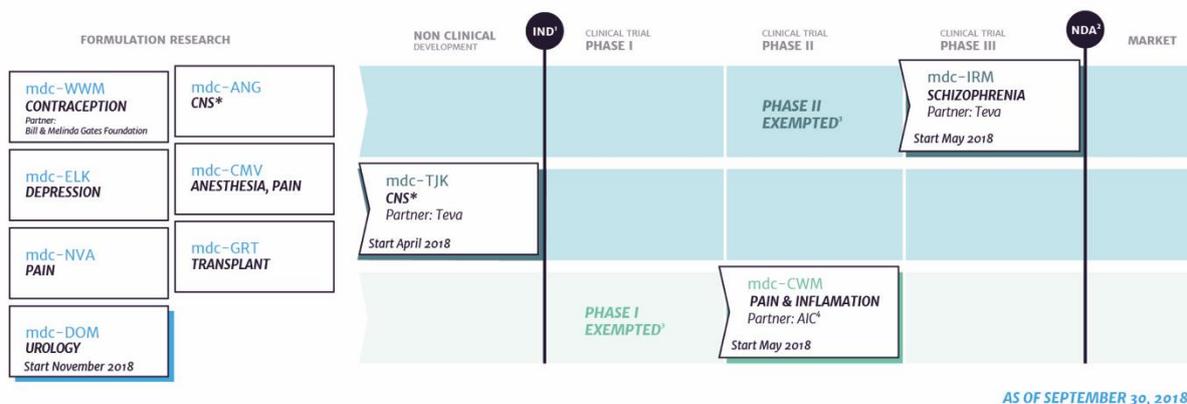
The most advanced program based on our proprietary technology is in a Phase III clinical study. This is the final stage of clinical development before applying for marketing approval. Using risperidone, an already widely-adopted active pharmaceutical ingredient, mdc-IRM is the first product from a new generation of long-acting injectables 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. MedinCell is entitled to milestone payments at specified points along the development and commercialization stages, as well as royalties on future product sales.

mdc-IRM is being investigated on parameters that include ease of use and subcutaneous injection to see if it may address unmet medical needs in the treatment of schizophrenia. In 2017, long-acting injectable antipsychotics represented a market of 4.7 billion dollars in developed markets, growing 21% per year.

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 procedure and did not require a Phase II clinical trial.

The Phase III study started in June 2018 and includes 596 patients in 80 centres. The estimated Primary Completion Date is January 2020.

Status of the product portfolio



*Central Nervous System
1. Investigational New Drug

2. New Drug Application

3. Products based on already approved Active Pharmaceutical Ingredients can benefit from accelerated regulatory pathways such as the 505(b)(2) in the US

4. Arthritis Innovation Corporation (AIC): Company founded by North American physicians & entrepreneurs

The positive results from the first clinical trials having marked a major step in the validation of the BEPO® technology, the Company is now implementing its strategy aimed at expanding its product portfolio in order to accelerate its impact on global health and the value creation.

Programs in development

The following milestones were met during the first half-year of 2018:

- **Initiation of non-clinical development activities of a second product in CNS in partnership with Teva**
This program could enter clinical development in the first half of 2019.
- **Launch, in the United States, of the Phase II clinical trial of the mdc-CWM product for the treatment of postoperative inflammation and pain in orthopaedic surgery, in partnership with Canadian company Arthritis Innovation Corporation (AIC)**
The results of this study are expected in 2019.

Products in the formulation research phase. This initial phase aims to obtain a prototype of the product that justifies progressing the program to a non-clinical development phase when the chances of success are deemed to be positive.

- Launch of the mdc-DOM program (urology)
- Continuation of the six programs already in the formulation research phase in different therapeutic areas: psychiatry, transplants, chronic pain, anaesthesia and women's health (formulation of a 6-month injectable contraceptive in collaboration with the Bill & Melinda Gates Foundation)
Some of these programs could enter a non-clinical development phase during the first half of 2019.

Recruitment of Joël Richard as Head of Technical and Pharmaceutical Operations. Joël is in charge of formulation research and non-clinical development activities as well as defining the specific regulatory strategy for each product. His arrival is in line with the Company's strategy of strengthening its in-house expertise. Joël Richard joins MedinCell with many years of experience acquired in R&D

management positions at Merck Serono, Etypharm and, more recently, Ipsen, where he oversaw the pharmaceutical development activities.

Selected financial information for the first half-year 2018

Enhanced available cash and financial visibility

At September 30, 2018, MedinCell had €11.4 million in available funds and €4.6 million in non-risky financial assets (compared with respectively € 8.8 million € 4.7 million a year ago). The first half of 2018 was marked by the success of the Company's financial strategy aimed at providing it with the necessary resources and financial visibility to accelerate the development of its product portfolio. The Company notably carried out the following financial operations:

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

Signing of a €20 million loan from the European Investment Bank (EIB) to finance the formulation research and development phases of proprietary products of the Company. An initial amount of €7.5 million was received in June 2018. 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 million.

Post-closing event - IPO on the Euronext market in Paris for €31.4 million 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.

Given this available cash, combined with its current and forecast cash burn levels (negative operating cash flow of €6.4 million over the first half of 2018), the Company benefits from a solid financial visibility. Furthermore, it should continue to benefit from revenue from partnerships (service revenue and milestone payments) and from Research Tax Credit.

<i>(€ thousands)</i>	30/09/2018 6 months	30/09/2017 6 months
Net cash flow from activity	(6,371)	(4,740)
Net cash flow from investment operations	(404)	1,933
Net cash flow from financing operations	9,352	3,269
Change in net cash position	2,577	462
Cash and cash equivalents at start of period	8,791	3,824
Cash and cash equivalents at end of period	11,368	4,286

Consolidated cash flow statement

Income statement

A- Income from ordinary activities: €1.8 million

Revenue

In the first half of the 2018 financial year, revenue came from services provided for formulation research activities for partnered products. Paradoxically, the decrease in revenue compared with the first half of the previous financial year reflects the progress made in the projects undertaken in partnership with Teva who directly funds all pre-clinical 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 progress made with mdc-IRM and mdc-TJK programs, which have progressed into Phase III and preclinical development respectively, were booked in the previous semester.

The Company points out that the first revenue associated with 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 certain elements such as services fees, milestone payments, royalties, cost sharing, profit sharing, etc.), its revenue may vary significantly from a year to the next.

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 19% compared with the same period of 2017 and totalled €1 million. The Company expects to receive this sum in the second half of 2019.

B- Operating expenses: €8.4 million

Operating expenses increased by 24% compared with the same period last year. Over half of the additional spending concerned R&D, of which the budget increased by 23% this half-year. In line with the Company's strategy of expanding its product portfolio, these R&D investments thus enabled the Company to:

- Strengthen its scientific teams, whose workforce has risen from 68 to 84 employees over the past twelve months, and notably the team dedicated to assessing and validating the compatibility of the molecules used in products expected to enter the formulation research phase. This initial phase aims to increase the chances of success specific to each program
- Finance MedinCell's partner CRO (Contract Research Organisation) services in order to move forward with the programs currently in the formulation research phase

Sales & Marketing expenses increased by 33% over the same period last year, notably 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.

To support the Company's operations, General & Administrative expenses increased by 20%. It should be noted that a portion of this increase was dedicated to training the teams, necessary to accompany the Company's development strategy. A substantial portion was attributable to the financing operations undertaken over the 6 months, and notably the travel they required.

C- Financial expenses: €3.3 million

The Company's IPO generated exceptional financial expenses of €2.3 million. These expenses include the IFRS adjustment of the fair value of bonds redeemable in shares (non-cash expense) as well as the impact of the partial repayment of the Teva debt due to Teva's participation in the IPO.

<i>(€ thousands)</i>	30/09/2018 6 months	30/09/2017 6 months
Products sales, Royalties	-	-
Income from development services	716	1,808
Licences, Milestones	-	-
Income from polymer sales	66	45
Revenue	783	1,853
Other income from ordinary activities	1,018	855
A Income from ordinary activities	1,801	2,708
Cost of products & services sold	(78)	(33)
Research & Development expenses (b)	(4,797)	(3,895)
Sales & Marketing expenses	(1,171)	(883)
General & Administrative expenses (c)	(2,372)	(1,977)
B Total operating expenses	(8,418)	(6,787)
Core operating profit/loss	(6,617)	(4,080)
Other operating expenses/income	(20)	(29)
Operating profit/loss	(6,637)	(4,109)
Gross financial debt income/expense	(981)	(891)
Other financial income/costs	(2,246)	177
C Financial profit/loss (d)	(3,227)	(714)
Pre-tax profit/loss	(9,864)	(4,823)
Tax income/expense	34	(40)
Net profit/loss	(9,830)	(4,863)
Attributable to MedinCell shareholders	(9,830)	(4,863)
Attributable to non-controlling interests	-	-
EPS (Earnings Per Share), €	(0.68)	(0.34)
Diluted EPS, €	(0.68)	(0.34)

Consolidated income statement

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 millimetres, fully bioresorbable. Based in Montpellier, MedinCell currently employs more than 120 people representing over 25 different nationalities.

Glossary

Clinical development

Clinical development includes three major trial phases undertaken on human cohorts:

- Phase I includes healthy volunteers to assess their tolerance to the treatment.
- Phase II is carried with a limited group of sick patients to assess the treatment's efficacy, the drug's optimal dose and any side effects.

- Phase III is undertaken with a large number of sick patients to compare the treatment's efficacy to that of a placebo or standard of care. If successful, this is the final step before the marketing of the product.

NB: as the products developed by MedinCell use active ingredients that are already widely known and marketed, they can be exempt from certain clinical studies.

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.

Non-clinical development

Launched after the development of the prototype, non-clinical 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 non-clinical development.

CRO (Contract Research Organisation)

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.

IFRS

These are international financial information standards issued by the International Accounting Standards Board and imposed on listed companies or companies who call in investors in order to harmonise the presentation of their financial statements.

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