



GLOBAL IMPACT LONG-ACTING INJECTABLE MEDICINES

SEPTEMBER 2021



INVESTMENT HIGHLIGHTS

FDA ACCEPTANCE OF NDA



Most advanced product (mdc-IRM / schizophrenia): Phase 3 pivotal efficacy study completed

Study met its primary efficacy endpoint

Commercial launch in the US by Teva expected in 2022

GROWING PORTFOLIO



Same technology as mdc-IRM validated in Phase 3

1 product at New Drug Application (NDA) stage

2 products ready for Phase 3 initiation in 2021

5 products in preclinical

HIGH-VALUE NETWORK



Tier 1 partnerships:

Teva Pharmaceuticals

The Bill & Melinda Gates Foundation

Polymer joint-venture with Corbion (Amsterdam: CRBN)

IMPACT COMPANY



Long Acting Injectables (LAIs) have the potential to positively impact both compliance and access to healthcare, two major global health challenges

140 employees from 25 nationalities in Montpellier (France), all shareholders

Solid financial visibility

FDA ACCEPTANCE OF NEW DRUG APPLICATION VALIDATION OF TECHNOLOGY

FDA ACCEPTANCE OF NDA FOR MDC-IRM

Press Release – August 31, 2021

The acceptance is based on Phase 3 data from two pivotal studies: TV46000-CNS-30072 (the RISE Study – The Risperidone Subcutaneous Extended-Release Study) and TV46000-CNS-30078 (the SHINE Study - A Study to Test if TV-46000 is Safe for Maintenance Treatment of Schizophrenia). These studies evaluated the efficacy and longterm safety and tolerability of TV-46000 as a treatment for patients with schizophrenia.

Results will be shared at future scientific conferences and in peer-reviewed publications.

WHAT IT MEANS FOR MEDINCELL

Comprehensive antipsychotic portfolio increasingly taking shape

- Commercial launch in the US by Teva expected in 2022
- 2 further antipsychotics in development

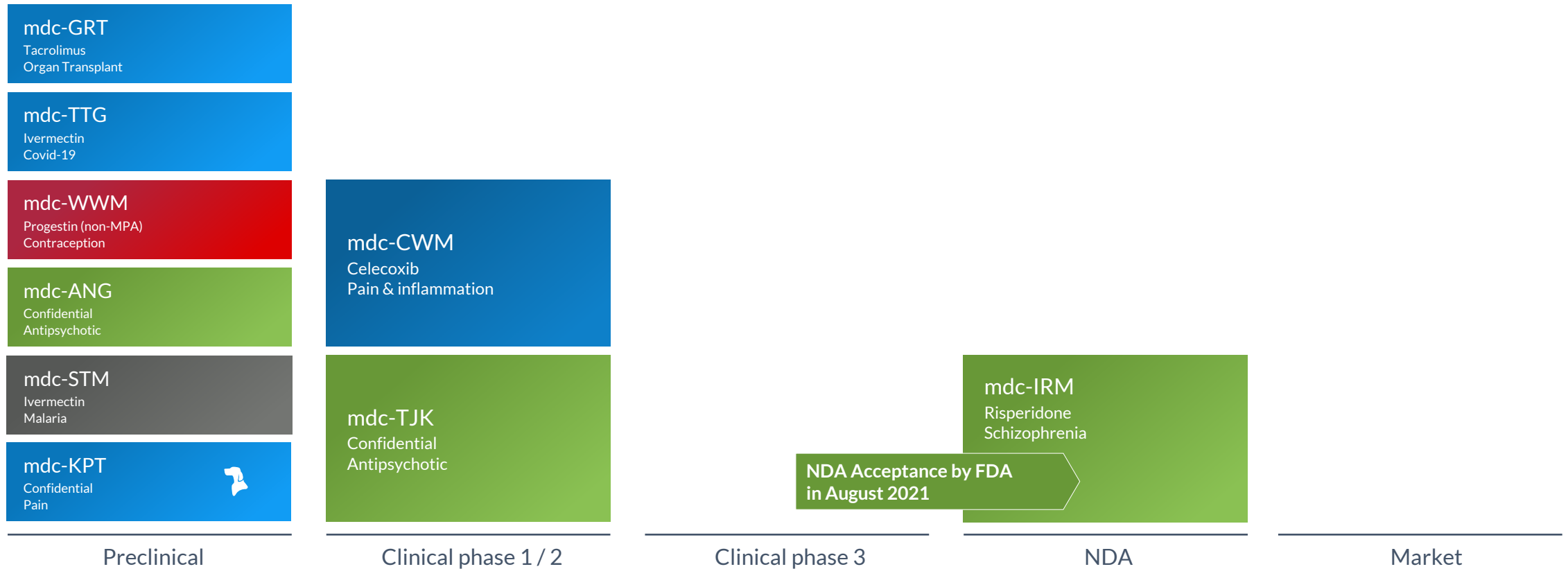
De-risking of the technology benefits to all pipeline assets

- Current portfolio progressing fast
- Additional programs will follow

Acceleration of partnering discussions

Portfolio as of September 1st, 2021

mdc-IRM, the Tip of the Iceberg

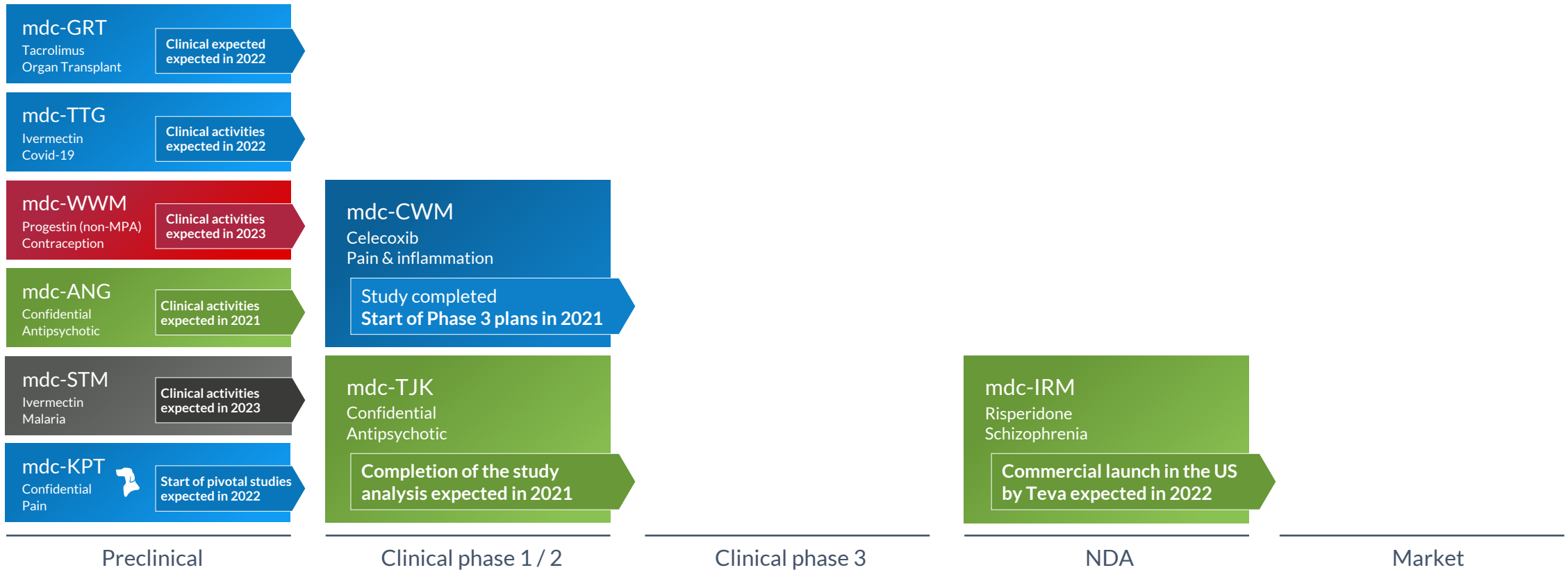


- Internal programs
- In partnership with Teva Pharmaceuticals
- Supported by the Bill & Melinda Gates Foundation
- In partnership with AIC
- Supported by Unitaid
- Animal Health product (different clinical development process)

All products of current portfolio are based on approved APIs and 505(b)2 regulatory pathway

Portfolio as of September 1st, 2021

1 NDA, 2 Phase 3 starts, 2 more products in clinical to come

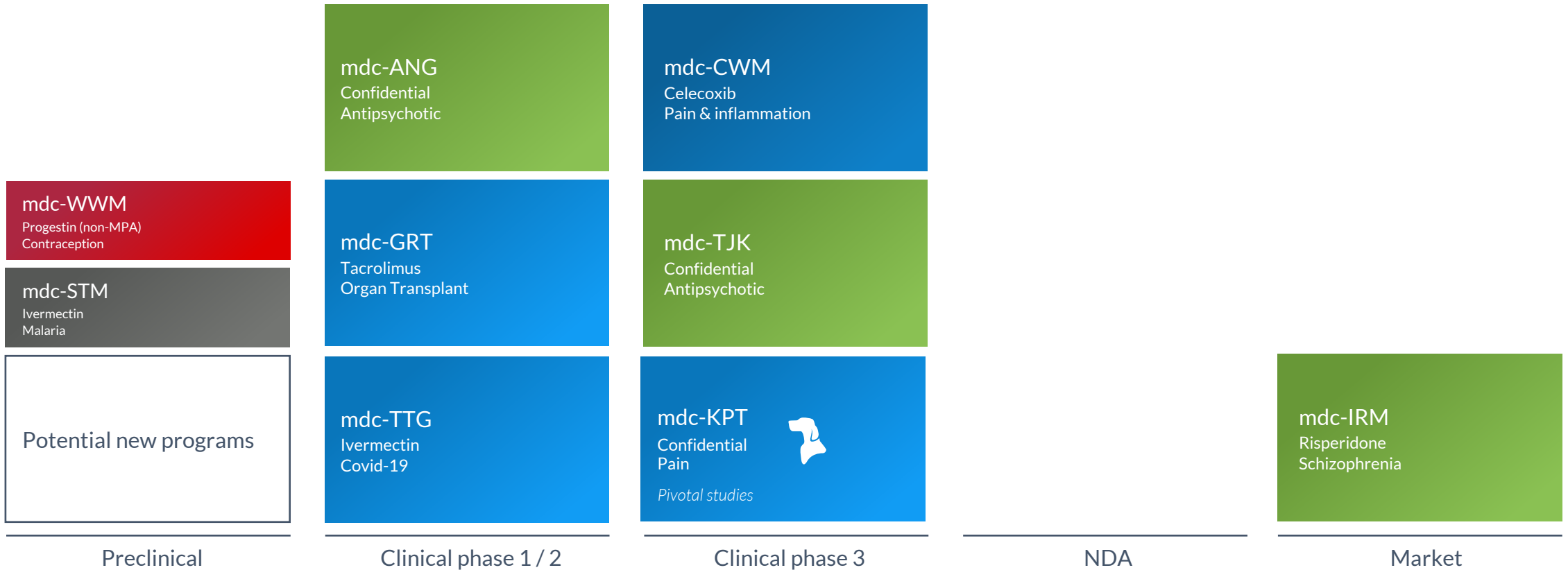


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Portfolio as of September 1st, 2021

1 product on market + 6 programs in clinicals



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BEPO®

Long-Acting Injectable Cutting-Edge Technology

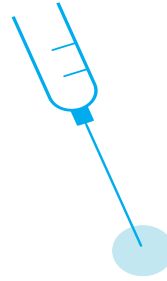
BEPO[®], LAI CUTTING-EDGE TECHNOLOGY



FORMULATION

Customized formulation
for each indication

- > PEG/PLA polymers
- > Hydrophilic solvent
- > Active pharmaceutical Ingredient



SUBCUTANEOUS OR LOCAL INJECTION

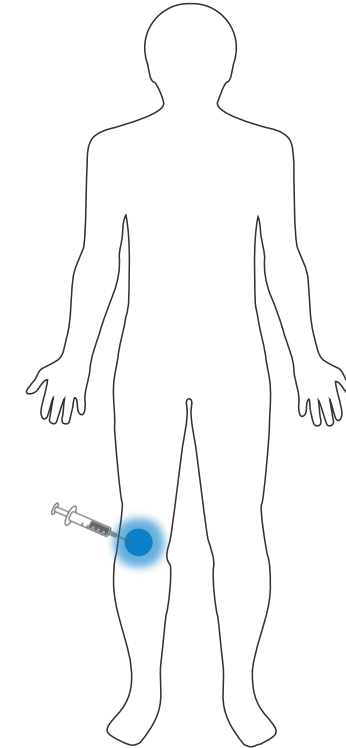
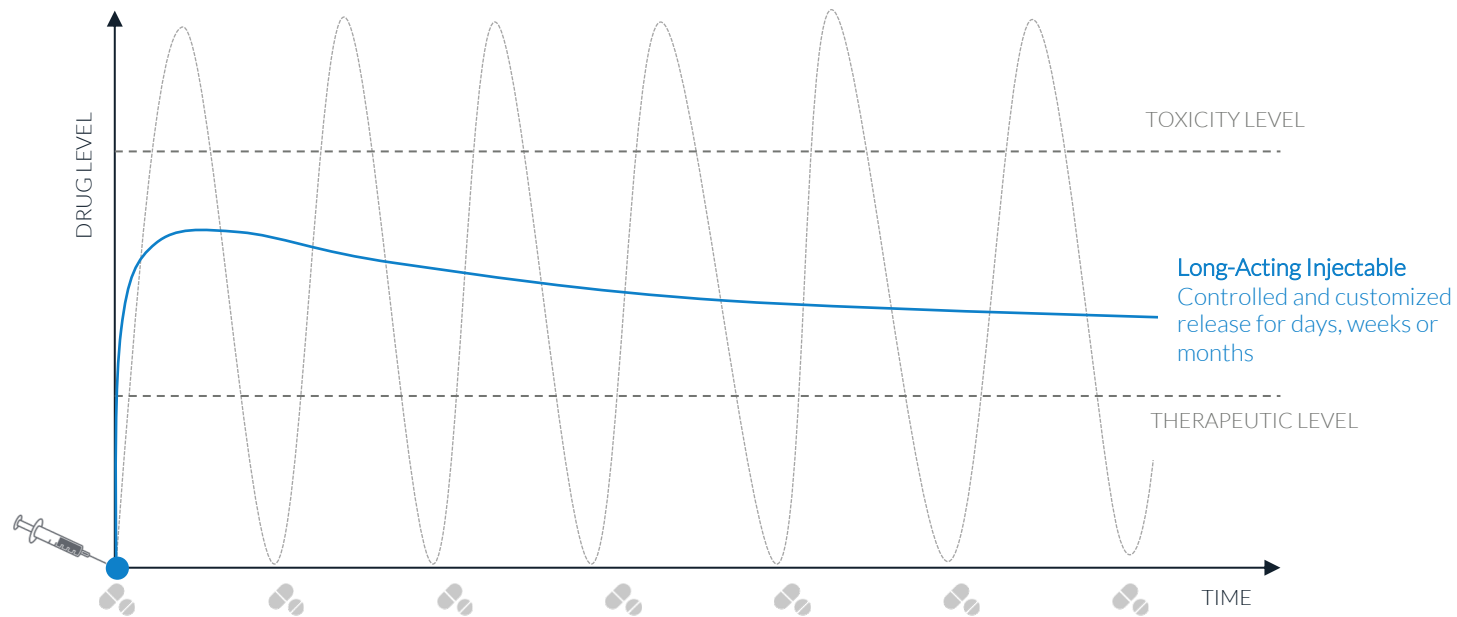
In situ depot precipitates
immediately after subcutaneous
or local injection



CONTROLLED RELEASE

API is released as depot
fully degrades

BEPO[®], LAI CUTTING-EDGE TECHNOLOGY



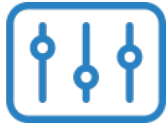
TIME IMPACT

- > Known approved API
- > Same indication

SPACE IMPACT

- > Known approved API
- > New indication

WE'VE BROKEN THE MAIN BARRIERS TO LAIs ADOPTION



SUPERIOR CONTROLLED RELEASE

Polymers customized to each application

Many levers to fine tune release

Better release profile, longer duration, burst control



PATIENT AND CLINICIAN FRIENDLY

Subcutaneous , not intramuscular

No lag time to therapeutic onset

Depot can be removed



GMP READY

No capital investment from partners required for polymers

Low COGS

► increases reach



RAPID FORMULATION DEVELOPMENT

Less than 18 months to complete typical formulation phase



3 ANTIPSYCHOTICS IN DEVELOPMENT WITH TEVA PHARMACEUTICALS

mdc-IRM | mdc-TJK | mdc-ANG

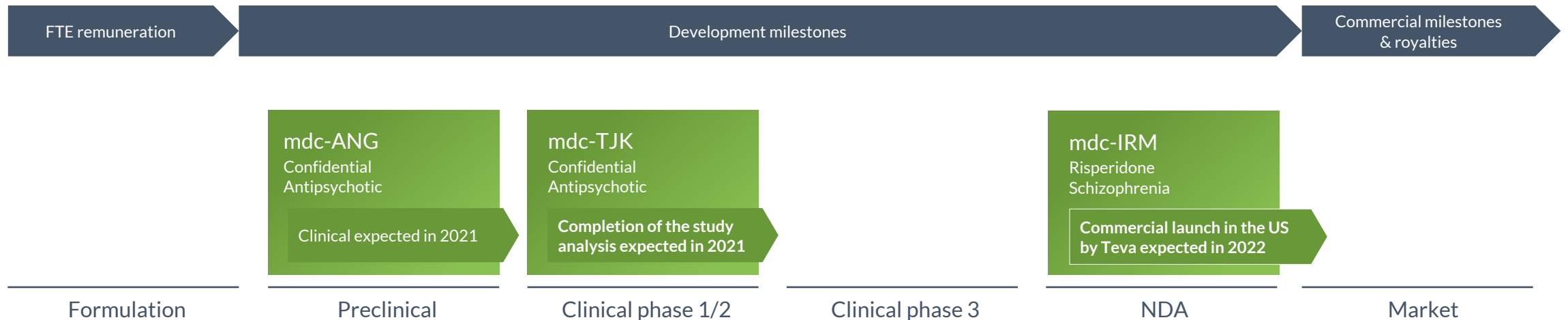
TEVA COLLABORATION

3 antipsychotics in development

ALL OPERATIONAL AND DEVELOPMENT COSTS COVERED BY TEVA PHARMACEUTICALS

POTENTIAL REVENUE FOR MEDINCELL

- Development and commercial milestones of up to \$122m for each product (\$366m total)
- Royalties on sales



mdc-IRM

Extended- Release Subcutaneous Injectable Risperidone for Patients with Schizophrenia

FDA ACCEPTANCE OF NEW DRUG APPLICATION

Press Release – August 31, 2021

The acceptance is based on Phase 3 data from two pivotal studies: TV46000-CNS-30072 (the RISE Study – The Risperidone Subcutaneous Extended-Release Study) and TV46000-CNS-30078 (the SHINE Study - A Study to Test if TV-46000 is Safe for Maintenance Treatment of Schizophrenia). These studies evaluated the efficacy and long-term safety and tolerability of TV-46000 as a treatment for patients with schizophrenia.

Results will be shared at future scientific conferences and in peer-reviewed publications.

Teva will continue to lead the clinical development and regulatory process and be responsible for commercialization of this candidate treatment, with MedinCell eligible for development milestones, royalties on net sales and future commercial milestones.

About the RISE Study

RISE Study met its primary efficacy endpoint of delaying time to relapse.

Patients treated with the investigational subcutaneous risperidone injection either monthly (q1M) (n=183) or once every two months (q2M) (n=179) experienced a statistically significant delay in time to relapse versus placebo (n=181), the study's primary endpoint, with $p < 0.0001$ for each comparison.

No new safety signals have been identified that are inconsistent with the known safety profile of other risperidone formulations. The second of Teva's Phase 3 studies (the SHINE study) evaluating the long-term safety and tolerability of the investigational subcutaneous risperidone injection across 331 patients is ongoing. Interim results align with the safety findings of the RISE study.

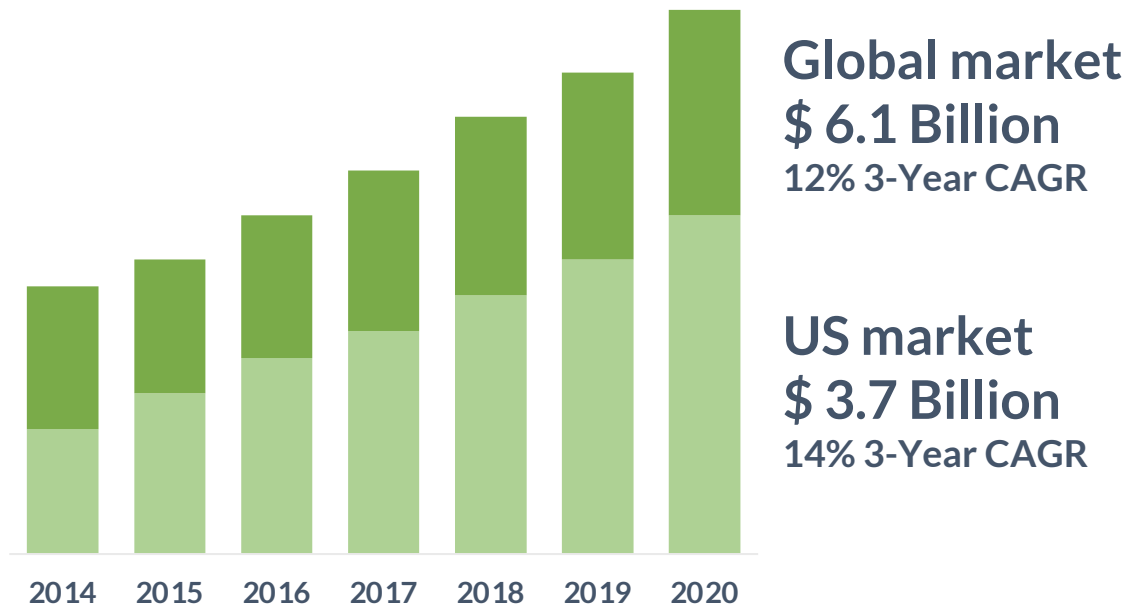
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mdc-IRM

Extended- Release Subcutaneous Injectable Risperidone for Patients with Schizophrenia

Antipsychotic LAIs market

(net sales reported by companies)



US antipsychotics LAIs market

\$3.7 Billion in 2020 with 14% 3-Y CAGR

Yearly treatment cost from
\$ 19K to \$ 25K

(LAIs based on risperidone and its metabolite paliperidone- gross price)

160K+ US patients diagnosed with schizophrenia use LAIs in 2020

Products based on risperidone and its metabolite are among the most frequently used

mdc-IRM

Extended- Release Subcutaneous Injectable Risperidone for Patients with Schizophrenia

ABOUT SCHIZOPHRENIA

Schizophrenia is a chronic, progressive and severely debilitating mental disorder that affects how one thinks, feels and acts.¹ Patients experience an array of symptoms, which may include delusions, hallucinations, disorganized speech or behavior and impaired cognitive ability. Although schizophrenia can occur at any age,² the average age of onset tends to be in the late teens to the early 20s for men, and the late 20s to early 30s for women.⁴ The long-term course of schizophrenia is marked by episodes of partial or full remission broken by relapses that often occur in the context of psychiatric emergency and require hospitalization.² Patients are often unaware of their illness and its consequences, contributing to treatment nonadherence, high discontinuation rates,⁵ and ultimately, significant direct and indirect healthcare costs from subsequent relapses and hospitalizations.^{8,9}

Approximately 1% of the world's population will develop schizophrenia in their lifetime,² and 3.5 million people in the U.S. are currently diagnosed with the condition.³

Approximately 80% of patients experience multiple relapses over the first five years of treatment,⁵ and each relapse carries a biological risk of loss of function, treatment refractoriness, and changes in brain morphology.^{6,7}

74% of patients had discontinued medication within 18 months due to insufficient efficacy, intolerable side effects or for other reasons

Schizophrenia accounts for 20% of all hospital bed-days and over 50% of all psychiatric beds¹⁰

Annual cost: Between \$134 and \$174 billion per year¹¹

\$38 billion for excess direct health care costs

Hospital inpatient treatment, outpatient and emergency department visits, medications

\$9 billion for direct non-health care costs

Law enforcement, incarceration, homeless shelters

\$117 billion for indirect costs

Unemployment, lost productivity, premature mortality

¹ Patel, K. R., Cherian, J., Gohil, K., & Atkinson, D. (2014). Schizophrenia: overview and treatment options. P & T: a peer-reviewed journal for formulary management, 39(9), 638-645 ; ² Biagi, E., Capuzzi, E., Colmegna, F., Mascarini, A., Brambilla, G., Ornaghi, A., Santambrogio, J., & Clerici, M. (2017). Long-Acting Injectable Antipsychotics in Schizophrenia: Literature Review and Practical Perspective, with a Focus on Aripiprazole Once-Monthly. Advances in therapy, 34(5), 1036-1048 ; ³ SARDA, About Schizophrenia. Available at: <https://sardaa.org/resources/about-schizophrenia/>. Accessed December 2020 ; ⁴ NAMI, About Mental Illness: Schizophrenia. Available at: <https://www.nami.org/About-Mental-Illness/Mental-Health-Conditions/Schizophrenia>. Accessed December 2020 ; ⁵ Emsley, R., & Kilian, S. (2018). Efficacy and safety profile of paliperidone palmitate injections in the management of patients with schizophrenia: an evidence-based review. Neuropsychiatric disease and treatment, 14, 205-223 ; ⁶ Emsley, R., Chiliza, B., Asmal, L. et al. (2013) The nature of relapse in schizophrenia. BMC Psychiatry 13, 50 ; ⁷ Andreasen, N. C., et al. (2013). Relapse duration, treatment intensity, and brain tissue loss in schizophrenia: a prospective longitudinal MRI study. The American journal of psychiatry, 170(6), 609-615 ; ⁸ Pennington, M., & McCrone, P. (2017). The Cost of Relapse in Schizophrenia. Pharmacoeconomics, 35(9), 921-936 ; ⁹ Jin, H., & Mosweu, I. (2017). The Societal Cost of Schizophrenia: A Systematic Review. Pharmacoeconomics, 35(1), 25-42 ; ¹⁰ Comprehensive understanding of schizophrenia and its treatment, Maguire GA. Am J Health Syst Pharm. 2002 ; ¹¹ Analysis Group, Otsuka, Lundbeck LLC - 2016



A FUTURE STANDARD OF CARE FOR POST OPERATIVE PAIN MANAGEMENT ?

mdc-CWM

mdc-CWM

Extended- Release Intraarticular Injectable Celecoxib for Post-Operative Pain and Inflammation Treatment

START OF PHASE 3 PLANNED IN 2021

Press Release – Mar 25, 2021 / Jun 16, 2021 / Aug 31, 2021

Our partner AIC is targeting FDA approval to initiate Phase 3 efficacy studies before the end of 2021.

The start of the safety study, aimed at completing the long-term safety database for mdc-CWM, has been moved at the request of the FDA after the preliminary results of the first Phase 3 study are obtained. Our partner indicates that this will have no impact on the overall program schedule.

The regulatory development in pain commonly includes two phase 3 efficacy trials to provide convincing evidence of benefit for regulatory agencies. AIC has the potential to initiate the second phase 3 trial prior to the completion of the first.

The mdc-CWM program development is led and financed by MedinCell's partner, Arthritis Innovation Corporation (AIC), **who closed a \$23 million CAD private equity financing in February 2021 to support clinical and manufacturing activities**

ABOUT mdc-CWM

One-time local delivery for the control of post-operative pain and inflammation through sustained release of Celecoxib in the intraarticular space, with improved safety (better cardio and gastrointestinal-toxicity profiles).

Little to no systemic exposure avoids risk of adverse NSAID issues.

Celecoxib has been approved by the FDA in the pain treatment in 1998. It is often used in the treatment of acute pain, rheumatoid arthritis, ankylosing spondylitis etc.

First indication: Total Knee Replacement (TKR) post-operative pain and inflammation treatment

Collaboration with Arthritis Innovation Corporation (AIC), Company founded by North American physicians & entrepreneurs

Clinical development cost borne by AIC

50-50 profit sharing

Data represents means, Day 0, n=35, Day 7, n=5, 4 for F14, Control; Day 30 & 90, n=5

mdc-CWM

Extended- Release Intraarticular Injectable Celecoxib for Post-Operative Pain and Inflammation Treatment

STRONG MARKET OPPORTUNITY

UNSATISFYING POST-SURGERY PAIN TREATMENT

Significant pain for two weeks and reduced but continued pain for 6-12 weeks post surgery

Contraindication of traditional oral anti-inflammatory products post surgery

Effectiveness of current practices for postoperative pain management remains limited: 57% to 73% of operated patients report moderate to extreme postoperative pain, leading to longer hospitalization stay, revision surgery, disability leave, etc.

Source: Gan TJ, Habib AS, Miller TE, White W, Apfelbaum JL. Incidence, patient satisfaction, and perceptions of post-surgical pain: Results from a US national survey. *Curr Med Res Opin.* 2014;30(1):149-160

OPIOIDS EPIDEMIC ISSUE

15.2% of TKR patients become long-term opioid users

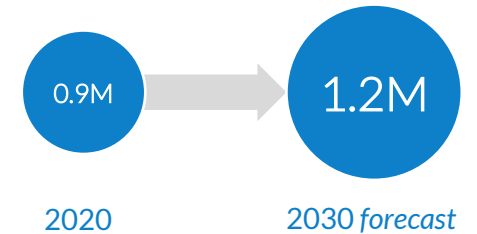
Source: 2018 Choices Matter Survey - Exposing a silent gateway to persistent opioid use

The use of opioids in the treatment of postoperative pain is globally widespread and particularly in the US: c. 90% of operated patients

Negative side effects observed in 96% of operated patients, increasing the duration of hospitalization in 55% of cases

130 people die every day in the US because of opioids overdose according to the CDC

Sources: Gan TJ, Habib AS, Miller TE, White W, Apfelbaum JL. Incidence, patient satisfaction, and perceptions of post-surgical pain: Results from a US national survey. *Curr Med Res Opin.* 2014;30(1):149-160 ; sler ER, Shah M, Gruschus SK, Raju A. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: Opioid-related adverse events and their impact on clinical and economic outcomes. *Pharmacotherapy.* 2013;33



Number of TKR procedures in the US

Source: GlobalData, Orthopedic Devices [Knee Reconstruction] Market, United States, 2009-2023, Absolute Units, 2017



COLLABORATION WITH THE BILL & MELINDA GATES FOUNDATION

mdc-WWM

mdc-WWM

6-Month Subcutaneous Contraceptive

ADDRESSING THE GLOBAL CHALLENGE OF FAMILY PLANNING

An estimated 74 million women fall pregnant unintentionally every year leading to 25 million unsafe abortions and 47,000 maternal deaths (WHO - Oct. 2019)

BEST-IN-CLASS PRODUCT

mdc-WWM could be the first contraceptive to combine the following essential features to make it a best-in-class product worldwide: progestin molecule (non-MPA), 6-month duration, subcutaneous injection, auto injectable, full bio resorption, affordability

Current status: preclinical

Next step: Clinical Phase 1 expected in 2022

\$22.5 M FINANCING BY THE BILL & MELINDA GATES FOUNDATION

December 2017

\$3.5 million financing

to fund the formulation of the product

November 2019

Up to \$19 million additional financing

over four years to fund preclinical activities and phase 1 clinical trial. The grant is structured in advanced installments to cover the costs that will be incurred by the project

mdc-WWM

6-Month Subcutaneous Contraceptive

MEDINCELL OWNS THE COMMERCIAL RIGHTS WORLDWIDE, ESP. IN THE US

CONTRACEPTION A \$5 BILLION US MARKET

(2018)

Long-Acting Reversible Contraceptives

LARC (primarily solid implants and intrauterine devices) – Source: IQVIA

- **28% of the US market**
- **\$1.4 Billion**
- **5-year CAGR at 7.8%**

mdc-WWM product could capture a significant share of the LARC market and expand it by easing the adoption of this type of contraception

GLOBAL ACCESS STRATEGY

In accordance with the Global Access strategy of both partners and to ensure a significant impact on women's lives, the objective is to make the product widely available. Affordable pricing in emerging economies will help eliminate cost as a barrier to increased availability and voluntary access to the product. High demand among women and girls for long-acting contraceptive options illustrate the potential for market growth and measurably improving maternal, newborn and child health. The Gates Foundation also has a non-exclusive license for non-commercial market in low- and middle-income countries.



IMPACT COMPANY

WE CONTRIBUTE TO SOLVING GLOBAL HEALTH CHALLENGES

COMPLIANCE & ACCESS ARE KEY ISSUES IN DEVELOPING WORLD



WHO estimates that one patient in two does not start or does not continue to follow their treatment and that adherence improvement would have a greater impact than any improvement in specific medical treatments.

(World Health Organization: Adherence to Long-Term Therapies, Evidence for Actions - 2003)

LAI can impact both compliance and access issues

AFFORDABILITY AND ACCESSIBILITY SHOULD ALLOW TO TAP PROFITABILITY RESERVOIR IN DEVELOPING COUNTRIES



Much higher volumes will counterbalance pricing

Low COGS technology

PHARMACEUTICAL RESIDUES BECOMING A MAJOR ENVIRONMENTAL CHALLENGE



1/3 of US prescription become waste

Up to 95% less APIs required for a same treatment
(MedinCell estimates on potential positive impact of BEPO)

A 21st CENTURY PHARMA COMPANY MODEL

“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.” “Raison d’être” of MedinCell voted by the General Assembly in September 2019

01

**25 NATIONALITIES
OUT OF 140 EMPLOYEES**

03

**ALL EMPLOYEE AND
MANAGEMENT INCENTIVE ARE
COLLECTIVE AND LINKED TO
MILESTONES**

02

**100% OF MEDINCELL
EMPLOYEES ARE SHAREHOLDERS**

Employee share ownership is promoted through adapted tools that guarantee alignment of the interests of employees and other shareholders. It enables a fair sharing of the value created and a balanced relationship between management and all employees

04

**REDUCED
SALARY SPREAD**

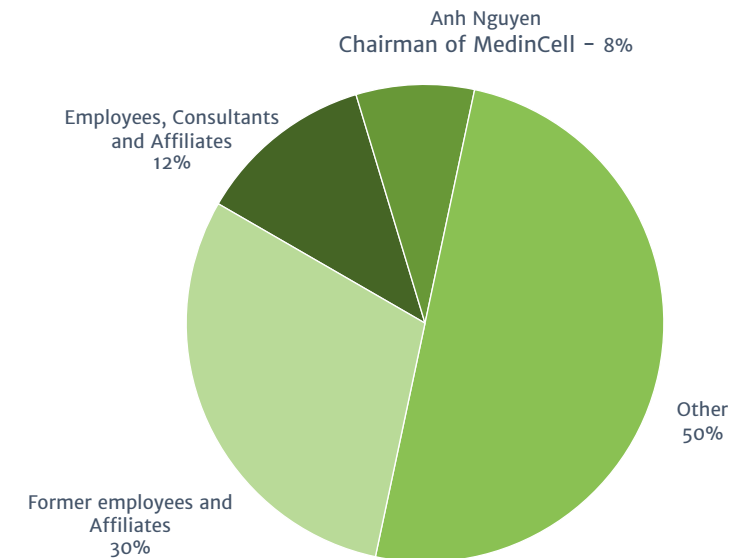
KEY FINANCIALS

AS OF MARCH 31, 2021

€ million	1-Year period March 31, 2021	1-Year period March 31, 2020
Revenue	11.8	6.0
Operating result	(15.6)	(19.3)
Net result	(19.0)	(23.9)
Earning per share (€)	(0.86)	(1.19)
Cash position	47.1*	12.4**

* not including 2.8 M€ in short-term investments and 1.1 M€ in non-current financial assets

** not including 0.4 M€ in short-term investments and 3.3 M€ in non-current financial assets



ISIN: FR0004065605

Market Cap: c. 250 M€
outstanding shares: 24.7 M