

2 April 2019

ASX Code: MXC

MXC's 2019 Pharma Product Commercialisation Strategy Delivering Strong Pipeline of GMP Medicinal Cannabis Products

MGC Pharmaceuticals Ltd (ASX: MXC) (OTC: MGCLF) ("MGC Pharma" or "the Company"), a pure bio-pharma company focused on developing and commercialising a portfolio of cost-effective phytocannabinoid based medicines, is pleased to provide a positive update on its pharmaceutical operations and seed-to-pharmacy business plan.

- Established commercialisation strategy of focusing exclusively on two core divisions, Seed-to-Pharmacy Manufacturing and Research & Development, with the objective of becoming a leading supplier of cannabinoid based pharmaceutical products for medical markets in Europe, UK, and Australasia
- R&D division to deliver the production of cost-effective and affordable medicines in collaboration with leading internationally renowned research institutions and ensuring that MGC Pharma remains at the forefront of the sector
- Seed-to-pharmacy manufacturing focused on bringing affordable phytocannabinoid-based medicines to the global markets via cannabis cultivation, extraction, isolation and compounding through to a finished medicinal product
- Strong existing pipeline of phytocannabinoid based medicines targeting conditions such as epilepsy, Alzheimer's, cancer and irritable bowel disease that all at present have no effective treatment. Products are poised for release into the European and Australian markets upon completion of testing and clinical trials, currently underway
- 2019 priority already commenced with patient recruitment into the CogniCann™ clinical trial and the progression and expansion of all RMIT projects following recent approval from the Office of Drug Control in Australia

Roby Zomer, Co-founder and Managing Director, MGC Pharmaceuticals commented

"MGC Pharma has delivered a very productive first quarter with key operational milestones being achieved for the commercialisation of its bio-pharma business. The recent sale of MGC Derma to CannaGlobal has enabled us to position ourselves as a pure pharmaceutical company as we direct our research and focus into our two core divisions.

"Receiving the necessary approvals from the Office of Drug Control in Australia to possess and handle phytocannabinoids for research purposes is integral to the work being undertaken by our R&D division as they continue the rapid development of treatments focusing on the neurological, oncological, dermatological and gastroenterological sectors.

“Having secured an EU licence to produce non-sterile schedule two medicines, which includes all cannabinoids and the consolidation of our European activities in Malta, we are in a strong position to grow and develop our Seed-to-Pharmacy manufacturing division and make excellent progress in 2019.”

Research and Development (R&D) Division

The R&D division’s primary function is to ensure MGC Pharma remains at the forefront of pharmaceutical innovation within the cannabis for medicinal use sector. The R&D division is spearheaded by a team of highly experienced medical practitioners working alongside scientific departments and genetics teams from world leading universities. Importantly, a number of ground-breaking achievements have already been made including the establishment of several pioneering research programs and the development of new proprietary genetic strain MXC-10, containing industry high levels of THC.

Current research and development activities underway to create a pipeline of pharmaceutical and nutraceutical products include; the development of *CannaHub*, in collaboration with the Royal Melbourne Institute of Technology (RMIT) and the Hebrew University of Jerusalem (HUJ); the CogniCann™ clinical trial taking place with the University of Notre Dame in Western Australia; the CannEpi™ clinical trial taking place with the University of Ljubljana, Slovenia; the C4E education platform in collaboration with Epilepsy Action Australia and; MGC Pharma’s genetics development and registration activities with the University of Ljubljana’s biotechnical faculty in Slovenia.

The R&D division is currently focused on three sectors:

1. Neurological disorders

Based on the experience of three of our leading doctors Prof. Uri Kramer, Prof David Neubauer and Dr. Jonathan Grunfeld, MGC Pharma established its first clinical arm with Investigational Medicinal Product (IMP) CannEpi™ to treat Drug Resistant Epilepsy (refractory epilepsy). It has subsequently developed a second product CogniCann™, to improve the quality of life in mild cases of dementia and Alzheimer’s. Further products will be produced as part of a continuous development to target additional neurological indications.

2. Oncology and treatment side effects

Under the guidance of the Group’s CSO Dr. Jonathan Grunfeld, and utilising his vast experience in treatment of cancer patients in Israel, and the support equipment and sciences of RMIT and HUJ, MGC Pharma’s second clinical arm has been established to focus on oncological treatments. Tetrinol™, is the first drug in development for use in the treatment of cancer side effects such as cachexia and acute nausea. Additionally, MGC Pharma is developing medicine for the treatment of Melanoma and Prostate cancer which are part of a pre-clinical research with CannaHub (RMIT and HUJ) and a brain cancer research project with the National Institute of Biology (NIB) Slovenia.

3. Inflammatory and Autoimmune

Utilising data collected over time with CannaHub, MGC Pharma’s third clinical arm aims to treat one of the most rapidly emerging problems in the western but also in the eastern side of the world, which is the chronic Inflammation and Inflammation of the immune system. The Company’s first Anti-Inflammatory products are InCann™, a BiActive microspheres capsule used to treat Inflammatory bowel disease (IBD) Crohn’s disease and colitis, and TopiCann™, an Anti-inflammatory topical cream to treat Eczema and inflamed skin.

Neurological disorders

CannEpi™ - Treatment of Drug Resistant Epilepsy (UNLJ)	Phase IIB Slovenia
CogniCann™ - improving quality of life in dementia and Alzheimer (UNDA)	Phase IIB Australia

Oncological & Cancer Side Effects

Tetrinol™ Treatment of Anorexia Cachexia in Cancer Patients	Preclinical in progress
MXOT02GB01 Treatment of Glioblastoma (NIB)	
MXOT02ME01 Treatment of Melanoma Cancer (RMIT/CannaHUB)	
MXOT02PC01 Treatment of Prostate Cancer (RMIT/CannaHUB)	

Autoimmune Disease - Inflammatory

InCann™ a Treat Inflammatory bowel disease (IBD) (RMIT/CannaHUB)	Preclinical in progress
TopiCann™ Topical Treatment of Eczema and inflamed skin (RMIT/CannaHUB)	Preclinical results: Reduction 70% in 4 w.
MXAI01AB01 Anti Bacterial topical cream (RMIT/CannaHUB)	Preclinical in progress

ODC Approval Received

Royal Melbourne Institute of Technology (RMIT) has received approval from the Office of Drug Control (“ODC”) to possess and handle phytocannabinoids for research purposes. This is a significant milestone achieved for the advancement of all projects currently underway.

Following receipt of this approval, the core research activities at RMIT are:

1. Cancer

The use of nanotechnology in the development of drug delivery systems for the treatment of cancer using existing knowledge from HUJ. Current projects are focussed on researching treatments to inhibit the development of angiogenesis and inflammation in the progression of cancer, antiangiogenic and anti-cancer efficacy of CB2 agonists and Cannabinoid-induced targeted facilitated entry of cytotoxic compounds selectively into tumour cells.

2. Nanotechnology based drug delivery

Both RMIT and HUJ have divisions focussed on nanotechnology-based drug delivery for treatments of various disorders, such as Controlled Release Gastro-Retentive Swelling Dosage Forms for Optimising Therapy of Cannabinoids, targeting of cannabinoids to inflamed tissue: Elucidating the mechanism of immunomodulation and Targeting of nanoparticles containing cannabinoids to peripheral neuronal cells or the extracellular matrix.

3. Combined treatment: traditional medicine and cannabinoid therapy

A current project is underway at RMIT, focussed on researching the benefits and possibility of developing a new treatment that combines medicinal cannabis using traditional medical principles. The objective is to look at multiple compounds and assess how each can be enhanced and developed to create new innovative medicines.

Clinical Trials Progress on Track

Recruitment for the Phase IIB CogniCann™ clinical trial has commenced. The trial remains on track and is scheduled to last 16 weeks focussing on the effects of CogniCann™ on 50 patients aged 65 and over with mild dementia and Alzheimer's.

Seed-to-Pharmacy Manufacturing Division

The Seed-to-Pharmacy division capitalises on the intellectual property generated by the R&D division. Its operations encompass supply chain management and end-to-end cannabis production including cultivation, extraction, isolation and compounding the finished medicinal product. Furthermore, it is focussed on bringing a series of phytocannabinoid based medicines to market that are specifically designed to treat a range of neurological, inflammatory and physiological disorders.

Strategic overview

In order to commercialise its research findings, MGC Pharma has centralised its European operations and retained several operational branches in other strategic territories. Furthermore, the Company has been awarded an EU licence to produce non-sterile schedule two medicines, which includes all cannabinoids and noting this includes THC in particular. MGC Pharma is one of only a few companies to be awarded this licence and it enables the production of compound phytocannabinoid-based medicines.

This licence was issued to the Company's Slovenian facility that contains a CO² super-critical extraction and separation unit that isolates cannabinoids into purified compounds. These purified compounds can then be used as an Active Pharmaceutical Ingredient (API) and be compounded into end product medicines such as Investigational Medicinal Products (IMP).

Additionally, MGC Pharma's operational strategy is to implement a fully integrated supply chain in order to provide cost effective medicines.

2019 to deliver strong progress in Malta – upgraded commercial facility approval

In support of its seed-to-pharmacy strategy, the Company will construct a facility in Malta on the land it was awarded by Malta Enterprise, which is expected to commence very shortly. The original approved 4,000m² site footprint has been increased to 6,000m² as a result of strong relationships established with the government agencies, and will be used for 5,000m² EU GMP certified production and a 5,000m² fully equipped cultivation site, all on the same plot in a multi-story facility. The land will be leased on a long-term basis at preferable cost to the Company with an option to acquire; this is testament to the support for the Company from Malta Enterprise and Malta Industrial Parks.

Aside from an ideal climate of extended sunlight hours and optimal temperatures, Malta also provides the most effective business "climate" due to its low corporate tax, which makes it suitable to be the "market-release" site for MGC Pharma's products to all Europe and MENA countries, as it is part of the European Union.

Malta is also home to one of the largest sea-ports in the Mediterranean and has direct access to Italy, providing the ideal central location for operations and logistics within Europe. As a result, MGC Pharma’s Maltese facility site will become its primary operation site, fully integrating its supply chain and providing easy access to European the global markets.

In preparation for the commencement of construction, the Company has successfully finished its geological survey on the land and has submitted the architectural plans to the relevant authorities for approval. MGC Pharma’s is now waiting for the Acquisition of Immovable Property, by Non-Residents (AIP) in order to sign the final agreement with Maltese Industrial Parks. On execution of these final agreements, the first stage construction activities will then commence.

The Company will update the market on developments in due course.

Strong commercial relationships for growth

As a bio-pharma company, MGC Pharma’s core focus is on the development and manufacturing of cutting edge phytocannabinoid based medicines and to support this, MGC Pharma has partnered with global pharmaceutical companies to generate global exposure within the sector.



MXC’s Distribution footprint

MGC’s distribution network covers Europe, the United Kingdom, MENA countries, Australia and New Zealand, providing it access to patients for its medicinal cannabis products. Maintaining strong relationships with leading pharmaceutical distributors globally also provides MGC Pharma; with the ability to leverage these relationships and expand its operations, distribution and footprint globally.

Due to changes in TGA regulation pertaining to the promotion of IMPs and other non-registered medicinal products, the Company is no longer permitted to provide an update of the current status of any of its IMPs in market. All commercial successes will be reflected as cash inflows from ordinary operations in future Appendix 4C, Half Year and Full Year reporting submissions.

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About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC) is an EU based BioPharma company with many years of technical clinical and commercial experience in the medical cannabis industry. The Company’s founders were key figures in the global medical cannabis industry and the core business strategy is to develop and supply high quality Cannabinoids based pharmaceuticals products for the growing demand in the medical markets in Europe, North America and Australasia.

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