# mgc pharma

Leading The Way in Phytocannabinoid Derived Medicines with a Seed to Medicine Strategy

Company Presentation January 2020

PRESCRIPTION ONLY MEDICIN

Mac pharma March 100

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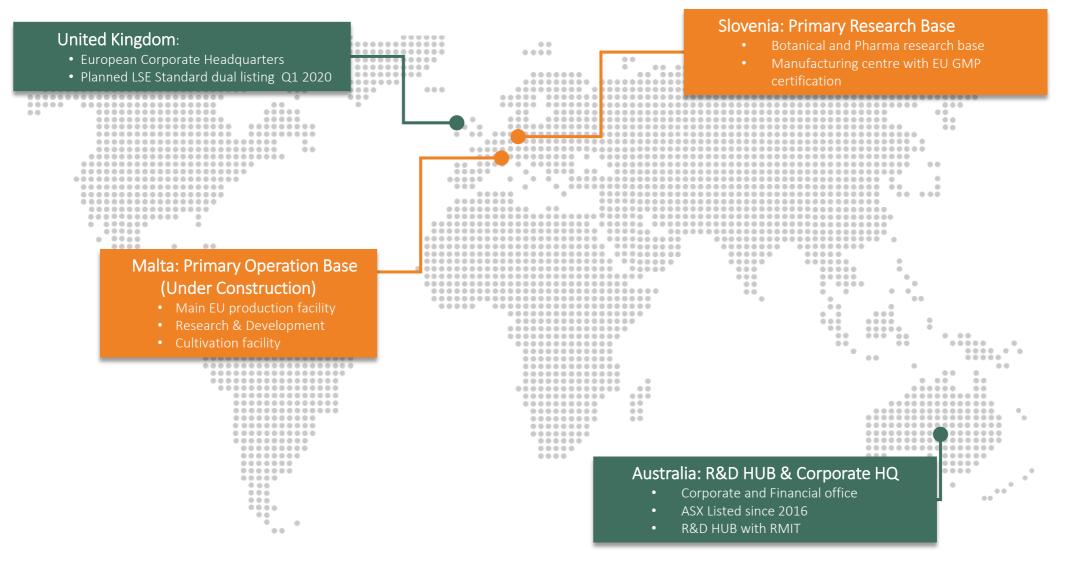
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### Investment Highlights

MGC Pharma is a European based bio-pharma company supplying GMP Phytocannabinoid derived products to patients through the Company distribution channels, with products registered in UK, Ireland, Australia and Brazil

- ✓ EU-GMP certified manufacturing facility in Europe, manufacturing phytocannabinoid derived products
- Two Investigational Medicinal Products (IMP's) targeting medical conditions: Refectory epilepsy, dementia and Alzheimer's disease
- ✓ Additional targeted products in development pipeline with wide IP developments
- ✓ Rapid growing patient base
- ✓ Global distribution via extensive network of commercial partners
- ✓ Highly qualified management team, supported by leading scientific experts
- ✓ Construction has been authorised with site planning completed in Malta for a multi-story building
  - ✓ 10,480m<sup>2</sup> combined manufacturing facility including GMP certified processing and production
  - ✓ 5,240m<sup>2</sup> greenhouse on the roof for cultivation

### **Global Presence**

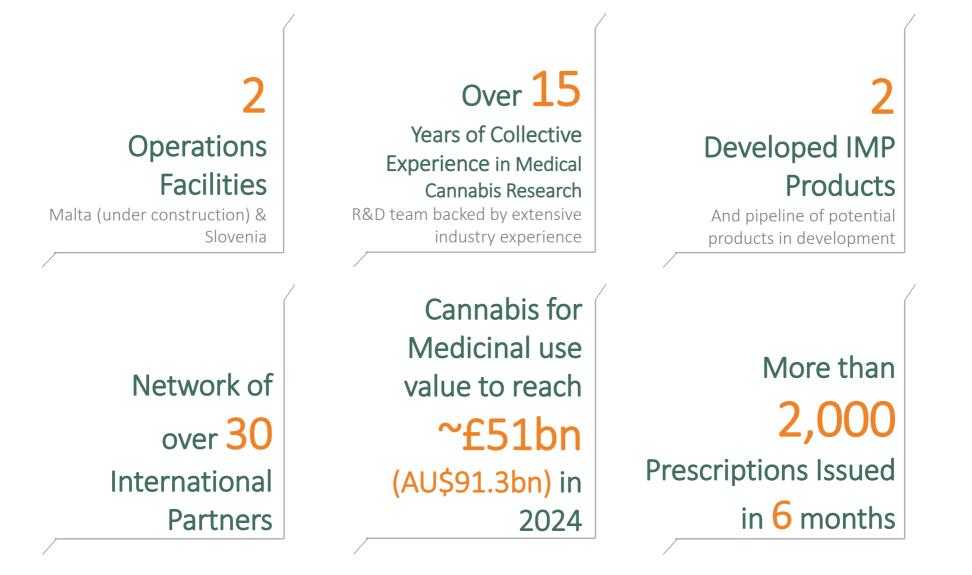


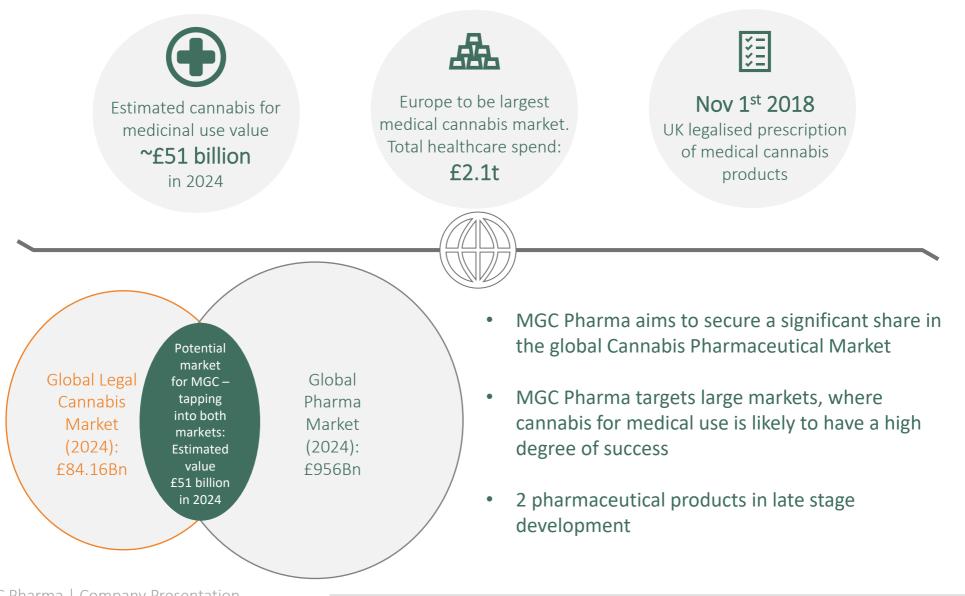
MARKET

APPENDIX

# In Numbers

Established EU-GMP licence, operational in the cannabis for medicinal purposes space





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Source: <u>Prohibition Partners Reports</u> the European Cannabis Report 4th Edition, the Global Cannabis Report November 2019, Evaluate Pharma World Preview 2019, Outlook to 2024

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### **Board of Directors**

Highly qualified team with over 15 years of relevant experience





Roby Zomer Managing Director, CEO & Co. Founder

Following 10 years of experience in the BioTech and AgroTech sectors alongside running large scale projects, Mr. Zomer joined MGC Pharmaceuticals as Executive Director & CTO. bringing his extensive business scientific contacts. and engineering skillset to bear on ensuring MGC's position as a leader in research and development, as well as ensuring top performance from our global operations.

Brett Mitchell Executive Chairman With over 20 years of experience in the founding, financing and management of

financing and management of both private and publicly listed companies, Mr. Mitchell is responsible for the corporate strategy, capital markets and financial management of the company, and is integrally involved in assisting in building a new industry from the ground up in Australia. The founder of MGC Pharma, previously CEO of a Israeli licensed Medical Cannabis company, with over 10 years of experience in the global medical cannabis industry and over 15 years of experience in executive roles. Founded MGC Pharma to expand into the International markets and to raise the quality and viability of medicinal phytocannabinoid products.

**Nativ Segev** 

Strategy & Founder

**Director, Head of Business** 

Dr. Parker has over 30 years of corporate finance, directorship, corporate advisory and investment banking experience focused on the pharmaceutical and biotechnology sectors in the UK, Europe and North America. Dr. Parker is regarded as a leading corporate expert and strategic thinker. He has a reputation for rapid and clear analysis and the ability to translate this analysis into an implemented solution.

**Dr. Stephen Parker** 

**Remuneration Committees** 

**Risk.** Nomination and

Director & Chairman of Audit,

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Dr. Ross Walker Director & Head of Medical Advisory Board

Dr. Walker is a well-known figure in Australian health. as former host of a weekly radio programme and a prominent cardiologist who specialises in echocardiography and preventative cardiology. Dr. Walker has published several lectures books. and both nationally and internationally. His in the medical contacts establishment and beyond allow him to facilitate relationships for MGC and draw positive public attention to the brand.

MARKET

OVERVIEW

APPENDIX

# **Clinical Advisory Team**

Leading experts in the medical cannabis space with unparalleled expertise



**Dr Jonathan Grunfeld** Head of Oncology and Palliative product development

Certified in Israel, with clinical experience at the MD Anderson Cancer Center. Dr. Grunfeld has spent the last twenty years focusing on Neuro-Oncology, with a focus since 2010 on Cannabis as a treatment for oncological palliative care. Involved in the licensing of care including direct clinical monitoring of circa 5,000 medical cannabis patients in Israel, giving him a unique insight into questions of dosing, patient groups and developing treatment methodology.



**Professor Emeritus** Uri Kramer Head of Neurology product development

Kramer has a Prof busv paediatric epilepsy clinic with many patients being treated with cannabis. Prof Kramer has run full scale epilepsy trials with cannabis and brings a wealth of experience in various fields (Paediatric Neurology & Child Development). Additionally, Prof Kramer is a former president of the Israeli League Against Epilepsy.

As Head of Department of Child. Adolescent and Developmental Neurology at University Children's Hospital, Ljubljana, Prof Neubauer is widely published and respected, and has dealt with children and adolescents in Neurological contexts for more than thirty years.

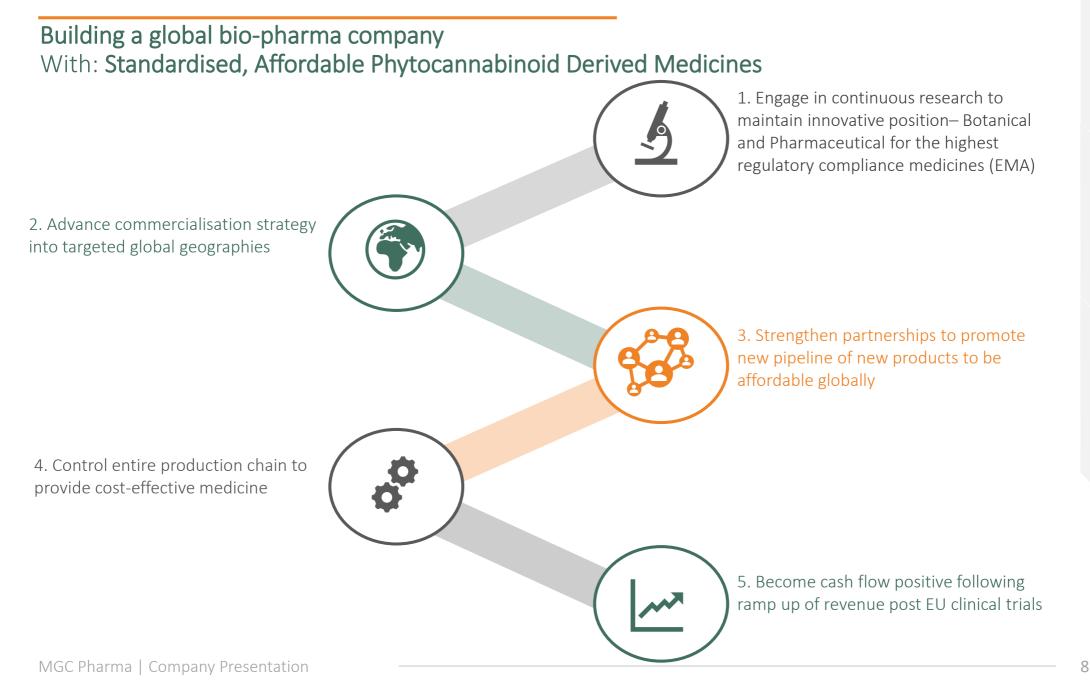
**Professor David** 

Neubauer



Dr Nadya Lisovoder Head of Clinical Research (CRO) and Regulatory

### Mission



APPENDIX

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# Company Snapshot

MGC Pharma is at the forefront of Global Phytocannabinoid derived medicines

### QUALIFIED MANUFACTURING

- EU-GMP certification granted at Slovenian facility for production of phytocannabinoid based Investigational Medicinal Products (Europe)
- Production capabilities at the Malta facility, once operational, is to support over 5,000 patient per month at full capacity<sup>1</sup>
- SME approval by the European Medicines Agency (EMA) for scientific advice and incentives

### EARLY PATIENT ACCESS SCHEME

- MGC products are being accessed through Early Patient Access Schemes in Brazil, UK and Australia
- Strategic Alliance with Australia's leading epilepsy association, Epilepsy Action Australia
- Collaboration on developing C4E campaign to increase awareness and access to medication



### RESEARCH EXCELLENCE

- Landmark collaboration agreement signed between MGC, RMIT and the Hebrew University to establish CannaHub
- Establishing the International Library of Cannabinoids focusing on research on melanoma and prostate cancer
- Developing the CannEpil® App



# IP within Seed to Medicine strategy

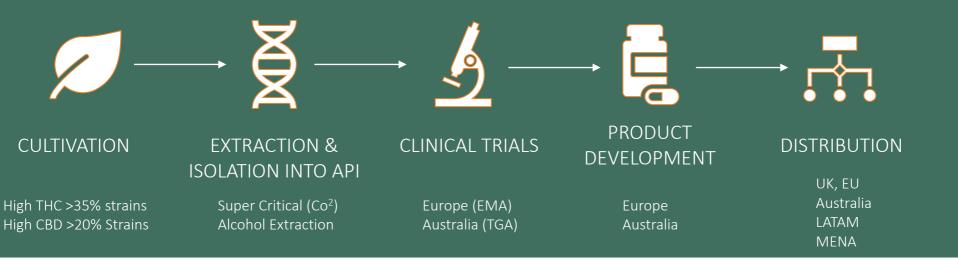
Creation and commercialisation of Phytocannabinoid derived products through a model utilising R&D capability with vertical IP development

#### Global Research and Development

- Multi-National base (AUS, EU), with European R&D HQ in Slovenia
- Cultivation R&D in Slovenia
- EU-GMP certified research facility, from provided API to compounded product

#### From R&D to Commercialisation in New Centralised EU Hub

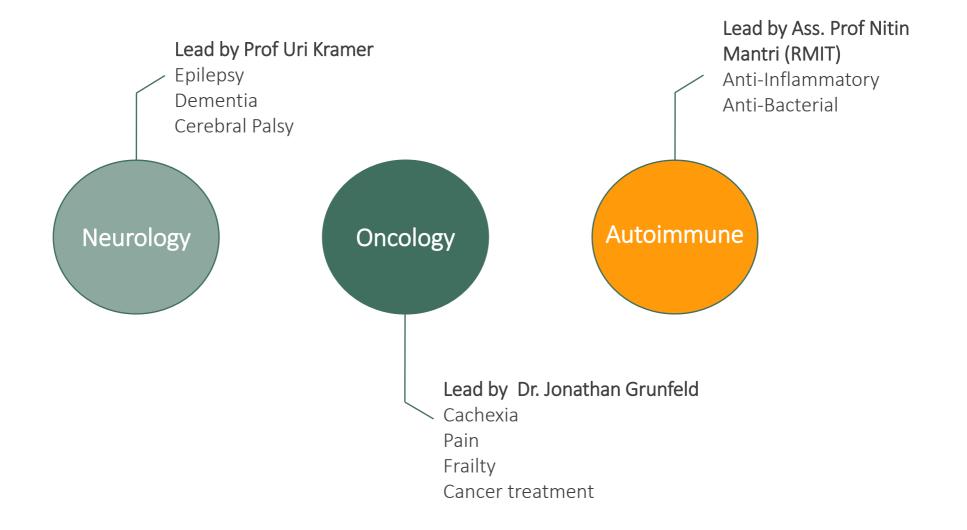
- Maltese Facility to become primary operations hub
- Supply chain with easy access to European markets
- To involve a 10,480m<sup>2</sup> combined manufacturing facility including GMP certified processing and production, with a 5,240m<sup>2</sup> greenhouse on the roof for cultivation



#### MGC Pharma | Company Presentation

## MGC Clinical Research & Development

3 research areas based on medical experience and large data collections





OVERVIEW

# Investigational Medicinal Products

Targeting specific medical conditions such as epilepsy and dementia

Epilepsy

CANNEPIL

- Oral oil solution to treat seizures associated with drug resistant epilepsy
- Based on long term observation research published in Israel by Prof. Uri Kramer
- Phase IIb submitted in Slovenia for EMA
- Early access schemes in Australia and UK

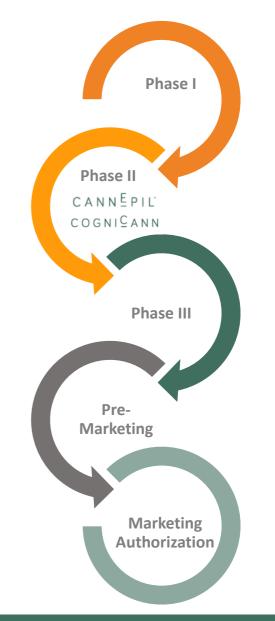
COGNI

Oral spray utilising a specific THC:CBD ratio for relief of dementia symptoms

Dementia

& Alzheimer's Disease

- Based on longitudinal research in Israel
- Phase IIb submitted in Australia, patient recruitment started
- Early access scheme in Australia



### FURTHER PRODUCT PIPELINE

Pipeline of phytocannabinoid derived products, APIs and unique formulations all manufactured under GMP certified facilities to be used in pharmaceutical treatment and research

### **CannEpil**<sup>®</sup>

### CannEpil<sup>®</sup> is a Phytocannabinoid derived IMP used as a treatment for refractory epilepsy

### CANNEPIL®

• Available to prescribe in Australia and UK as an Investigational Medicinal Product through early patient access schemes

#### Target Market:

- Over 1,900,000 people have epilepsy in Europe (over 480,000 epilepsy patients in UK)
- Over 200,000 epilepsy patients in Australia
- Approximately 25% of people with epilepsy have a drug-resistant (DRA) form
- Estimated population at launch of marketing authorisation is over 200,000 people with DRA (in Europe and Australia)
- Expected time to marketing authorisation
  4 years

CannEpil<sup>®</sup> is an oral oil solution of 20:1 cannabidiol (CBD) and (-)- trans-∆9tetrahydrocannabinol (THC).

Produced from two proprietary, preselected, specifically bred genotypes of the cannabis plant with a stable and specific ratio of cannabinoids.

MGC's first pharmaceutical-grade product targeted for drug resistant (refractory) epilepsy, which accounts for approximately 25% of the people diagnosed with epilepsy.

Estimated yearly average treatment costs per patient: £6,000 - £8,000

### Neurological Disorders

### Epilepsy

The global epilepsy market is expected to be ~£7.3bn by 2023

# MARKET

### CogniCann™

CogniCann<sup>™</sup> is MGC Pharma's second Phytocannabinoid derived IMP designed to improve dementia and Alzheimer's disease patients quality of life

### COGNI⊆ANN<sup>™</sup>

• Available to prescribe in Australia as an Investigational Medicinal Product through Early Patient Access Scheme

#### Target Market:

- Over 690,000 people with mild dementia in Europe (over 200,000 mild dementia patients in UK)
- Over 135,000 mild dementia patients in Australia
- Total estimated with mild dementia population 950,000 at marketing authorisation launch (in Europe and Australia)
- Expected time to marketing authorisation
  5 years

CogniCann<sup>™</sup> is a oromucosal spray of cannabidiol (CBD) and (-)- trans-∆9- tetrahydrocannabinol (THC).

Produced from two proprietary, preselected, specifically bred genotypes of the cannabis plant with a stable and specific ratio of cannabinoids.

Contains a 3:2 mix of THC (25mg/mL) and CBD (17mg/mL)

Estimated yearly average treatment costs per patient : £4,400

### Neurological Disorders

#### Dementia

The global dementia medication market is expected to exceed ~£23bn by 2026

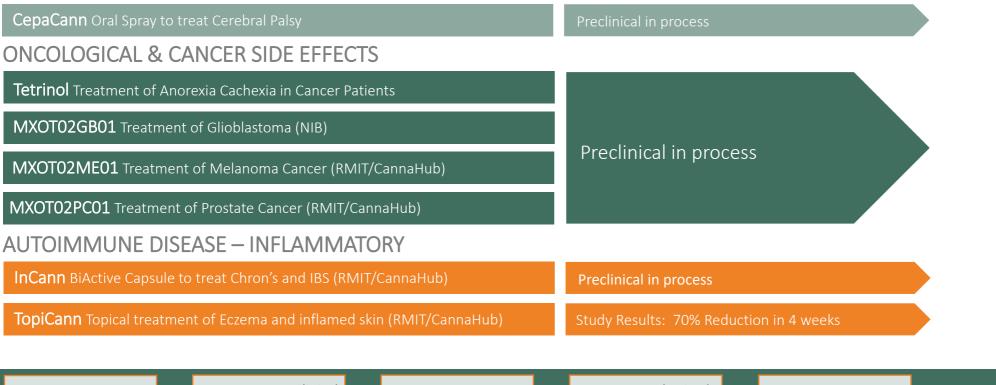
Source of target market: <u>Alacrita Market Projections Report</u>; Source of estimated average treatment costs (within the EU): <u>Alacrita Market Projections</u> <u>Report</u> and Internal Company Evaluation; Source of dementia medication market: <u>Coherent Market Insights through GlobalNewswire</u>

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# Research and Development – Potential Products

- Developing medicines that leverage its proprietary medical cannabis formula through clinical trials in Europe and Australia
- Enable future medical product sales across the EU, Australia and other geographies, following the legal and regulatory approvals

#### NEUROLOGICAL





MARKET

# MGC Drug Delivery Development

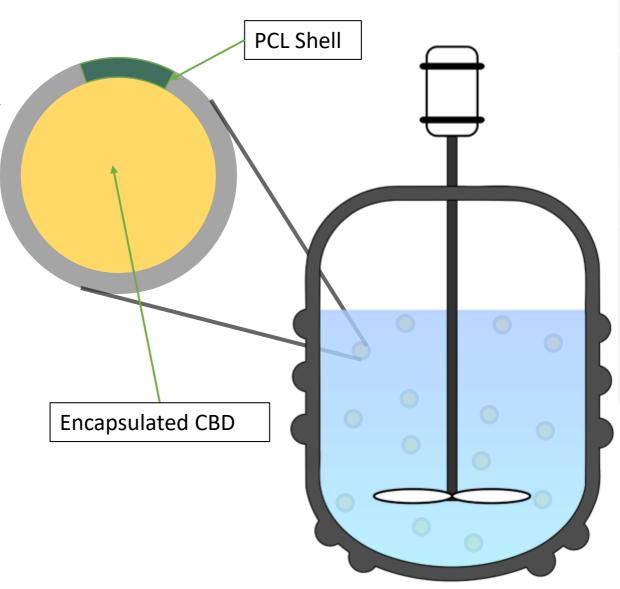
Smart nanostructured materials for drug delivery

### Nano-emulsion, Nano particles & Core-shell microcapsules

MGC is currently conducting research on smart nanostructured materials to deliver drugs to the target sites with reduced dosage frequency and in a controlled manner, to mitigate the side effects experienced with traditional therapies.

In particular, for them to allow resolving the main critical issues encountered with conventional pharmaceutical treatments such as:

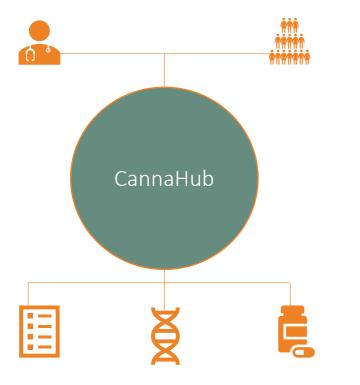
- nonspecific distribution
- rapid clearance
- uncontrollable release of drugs
- low bioavailability



### Strategic Partnership with RMIT



MGC Pharma and RMIT developing CannaHub, a digital research hub for the application of Phytocannabinoid derived medicines including the International Library of Cannabinoids (ILC)



CannaHub provides an interface connecting doctors and patients with clinical research and information on cannabinoid sequences and their potential treatments

#### INTERNATIONAL LIBRARY OF CANNABINOIDS

- ILC is the World's first library of cannabis medicine where details of medical cannabis clinical research, cannabinoid sequences and their treatments can be found
- ILC will collect data from diverse clinical studies, academic publications, patient feedback as well as diverse cannabinoid strains
- Collected and analysed data from the ILC will assist and enhance the work of doctors and researchers and improve industry efficacy estimates of cannabinoid treatment of various disorders
- ILC could be utilised for the design and implementation of clinical trials via its mobile and web-based applications

### CULTIVATION

- Active engagement with multiple cultivation sites to meet increasing global demand
- Specialised controlled cultivation also underway for research into breeding and genetics, in partnership with leading institutions and academia
- Raw material used for extraction and isolation into Active Pharmaceutical Ingredients (API)

OBJECTIVE: To refine and regulate MGC's genetic bank to guarantee the ability to produce flawless, high quality products globally

#### Key Partnerships:

- University of Ljubljana Bio faculty research into the development of new genetic strains
- IHPS (HOP institute Slovenia) research into the improvement of technical growing parameters
- Safe Pharma Macedonia commercial cultivation partner

#### Jurisdictions:

- 2016-18 Czech Republic
- Slovenia and, Malta from 2021

### PRODUCTION

- Production of high quality pharmaceutical products to be used as part of a prescribed medical treatment plan
- Pharmaceutical products initially targeting treatment of epilepsy, IQL in dementia and Alzheimer's, Oncological care and Autoimmune diseases
- Also includes compounding of phytocannabinoid based API

OBJECTIVE: The production of high quality, consistent, cost effective medicines targeting common illnesses and diseases

#### Key Partnerships:

- University of Ljubljana Clinical Centre Research in Epilepsy
- National Institute of Biology (NIB) Research in Brain Cancer
- Royal Melbourne Institute of Technology (RMIT) Research in Brain Cancer and Autoimmune diseases

#### Jurisdictions:

• Slovenia, Australia and upcoming, Malta

# Expansion Plan: Malta – a Centralised Hub

Establishing a fully integrated medical cannabis "Seed to Medicine" operation in the EU

### Signed long-term lease on 6,000m<sup>2</sup> site for full medical cannabis facility providing direct access to the EU

One of the first cannabis industry companies to sign a long-term lease agreement with the Maltese government to develop a fully integrated GMP compliant medical cannabis production facility in Malta. Facility will include cultivation, production and research of MGC Pharma cannabinoid derived medicines for global distribution.

First federal bill on legalising medicinal cannabis in Malta passed in parliament during March 2018.



### Medical Cannabis legalised in Malta – provides direct access to the EU

Malta is highly strategic for the success of the Company's EU focused business and operations plan.

Climate is ideal for cannabis cultivation and allows three crop cycles per year.

As part of the EU, Malta is favourable for the construction of large scale operations.

- MGC will establish turnkey "Seed to Medicine" state-of-the-art EU GMP production facility to provide its medicines globally
- Large scale, eco friendly commercial facility will be a 15,720m<sup>2</sup> multi-story facility with production capacity of over 8,000 units per hour of each product
- Access to existing operational and distribution pipelines in Europe and Australia
- Direct access to key emerging markets through the FDA Mutual Recognition agreement signed with Austria, Croatia, France, Italy, Malta, Spain, Sweden and the UK

# Key Wholesaler Partner

### LENIS – A FULL-SERVICE PHARMACEUTICAL DISTRIBUTOR

Lenis specializes in the distribution of unlicensed drugs and niche therapeutic areas (licensed in the source country but not in the destination country). This includes:

- New drugs not yet approved in a country
- Discontinued cost-effective drugs (e.g. infertility, ophthalmology, infectious diseases)
- Product alternatives during drug shortages (e.g. oncology)
- Comparator drugs for clinical trials

Lenis provides added value products in niche therapeutic areas and the distribution of innovative pharmaceutical products and generic pharmaceuticals with limited number of competitors.

Lenis is the Company's wholesaler/exporter to all distributors globally and is also a direct distributor to key European markets.

Its core principal is Gilead Sciences, Inc.

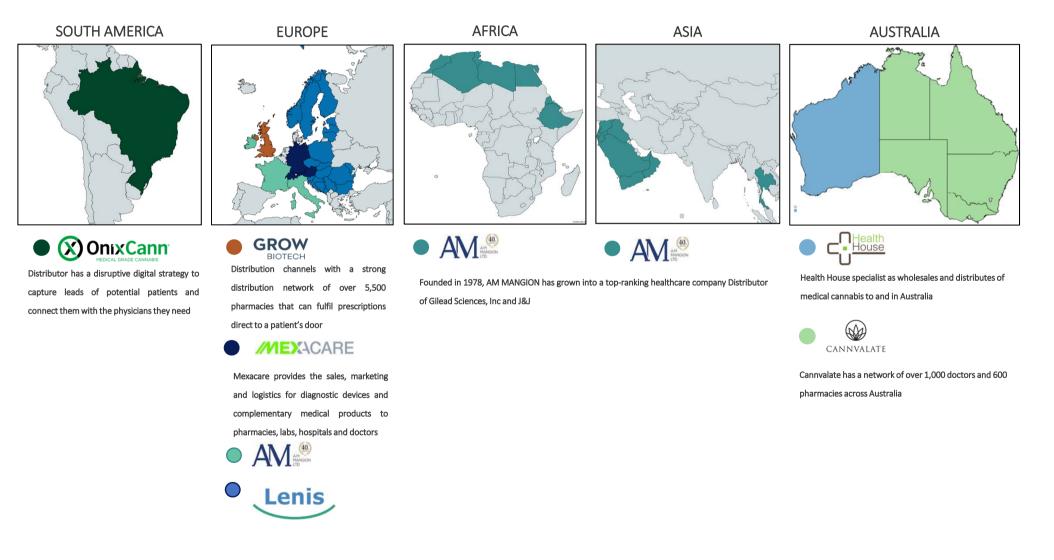
Lenis partnership provides the Company with:

- Knowledge on regulatory affairs
- Market access
- Medical Support
- Marketing & Sales
- Wholesale & Distribution
- Pharmacovigilance



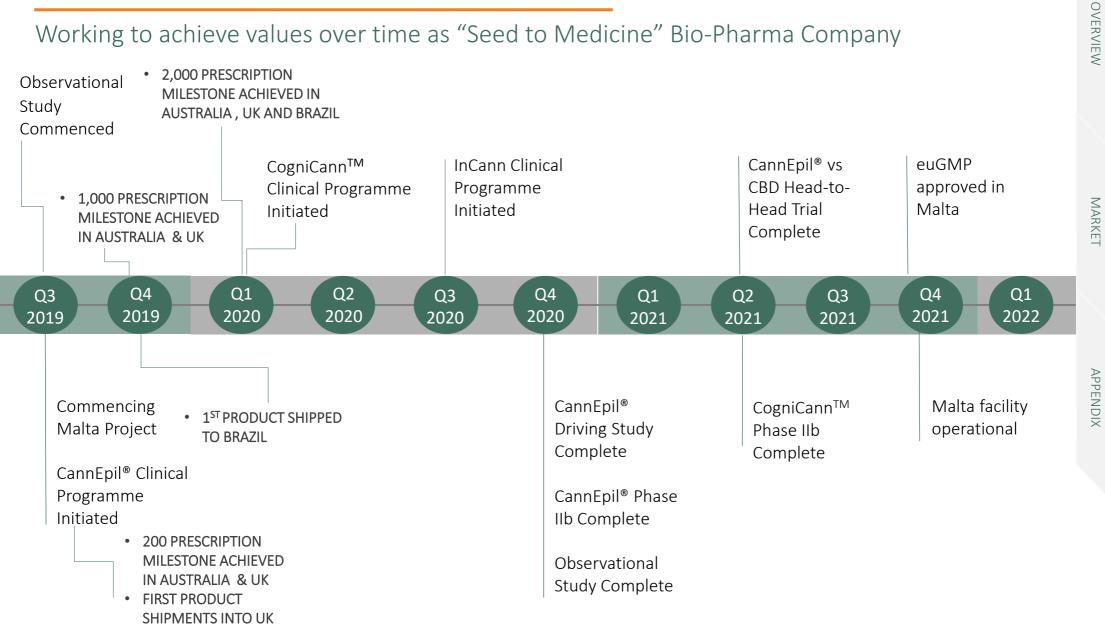
# Key Distribution Partners

Extensive network in place providing access to hospitals, pharmacies and research institutions around the world



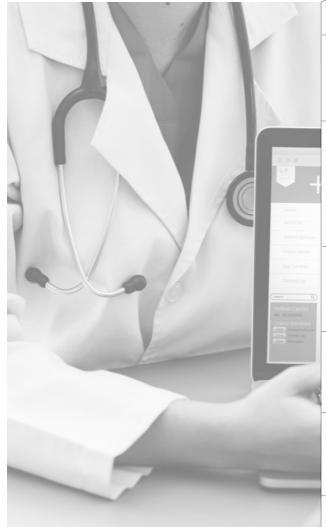
# **Projected Timelines**

### Working to achieve values over time as "Seed to Medicine" Bio-Pharma Company



### Investment Case

### Fully Integrated Model: Grow $\rightarrow$ Develop $\rightarrow$ Commercialise



### Built on Decades of Experience

Technical team of globally recognised scientists and doctors

### Focussed Operations

Core divisions: Research and Development Manufacturing and Distribution

### Strategically Located

Operational bases close to key markets supported by corporate headquarters

### Robust Product Offering

Portfolio of established and upcoming products targeting key markets

#### International Reach

Network of research and commercial partners globally

### Strong Market Outlook

Global phytocannabinoid market gaining traction

