

# MGC Pharmaceuticals

## Cannabis-based medicines and cosmetics

Initiation of coverage

Pharma & biotech

22 October 2018

**Price** **A\$0.07**

**Market cap** **A\$84m**

€/A\$ 0.66

Net cash (A\$m) at 30 June 2018 9.9

Shares in issue 1,212.8m

Free float 78.9%

Code MXC

Primary exchange ASX

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs 36.0 11.5 78.9

Rel (local) 41.7 17.2 76.5

52-week high/low A\$0.12 A\$0.05

### Business description

MGC Pharmaceuticals (ASX: MXC) is an Australia-headquartered specialist medical cannabis biopharma company, which has most of its operations based in Europe. Management has many years of technical, clinical and commercial experience in the medical cannabis industry.

### Next events

Shareholder vote on MGC Derma sale November 2018

Initiate CogniCann dementia Phase II Q119

Initiate CannEpil epilepsy Phase II TBA

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**MGC Pharmaceuticals is a research client of Edison Investment Research Limited**

MGC Pharmaceuticals is developing cannabis-based pharmaceutical products, initially in Australia and Europe. It has cannabis-growing operations in Europe and plans to supply cannabis-based active pharmaceutical ingredients (API), as well as developing registered pharmaceutical products for refractory epilepsy and dementia. MGC has signed a binding term sheet for the sale of its MGC Derma cannabis-based cosmetics business to Cannaglobal for up to C\$15m (A\$16m). We arrive at an initial valuation of A\$140m or A\$0.11 per share.

| Year end | Revenue (A\$m) | PBT* (A\$m) | EPS* (c) | DPS* (c) | P/E (x) | Yield (%) |
|----------|----------------|-------------|----------|----------|---------|-----------|
| 06/17    | 0.1            | (8.5)       | (0.9)    | 0.0      | N/A     | N/A       |
| 06/18    | 0.3            | (9.0)       | (0.8)    | 0.0      | N/A     | N/A       |
| 06/19e   | 2.2            | (5.7)       | (0.5)    | 0.0      | N/A     | N/A       |
| 06/20e   | 8.9            | (6.6)       | (0.5)    | 0.0      | N/A     | N/A       |

Note: \*PBT and EPS are normalised, excluding exceptional items.

## Cannabis growing and extraction in Europe

MGC is already growing medicinal cannabis crops in the Czech Republic and has established in Slovenia one of the few fully GMP-certified resin extraction and separation plants in Europe, in order to produce cannabis resins for use in its own pharmaceutical products, and for sales to drug and cosmetics manufacturers. The company plans to establish larger-scale cannabis-growing and processing operations in Malta under a contract awarded by the Maltese government in April.

## Seeking epilepsy and dementia drug approvals

The company intends to develop CannEpil and CogniCann as registered pharmaceutical treatments for refractory epilepsy, and to improve quality of life in dementia patients, respectively. It plans to conduct randomised, placebo-controlled Phase II crossover studies to generate high-quality evidence to support further development of these pharmaceutical products. It has received Therapeutic Goods Administration (TGA) authorisation for CannEpil to be prescribed as an Investigational Medicinal Product in Australia.

## Selling cosmetics business to focus on pharma

MGC has signed a binding term sheet for the sale of its MGC Derma business to the unlisted Canadian cannabis investment company, Cannaglobal, for up to C\$15m (A\$16m), subject to shareholder approval. Consideration includes C\$9m of Cannaglobal shares up front, up to C\$3.5m of potential milestones (payable as shares), eventual repayment of a C\$2.5m working capital loan and a five-year supply agreement. The sale will allow MGC to focus fully on the pharmaceutical business.

## Valuation: A\$140m or A\$0.11 per share

Our initial valuation is A\$140m or A\$0.11/share, based on a risk-adjusted net present value (rNPV) analysis. The sales of flowers and resin from the cannabis-growing operations contributes over 60% of our valuation, with the CannEpil and CogniCann registered pharmaceutical products providing potential upside. Current cash of A\$9.9m should support operations into FY20.

## Investment summary

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### Company description: Cannabis-based biopharma

MGC Pharmaceuticals is an Australia-listed company with operations in central and southern Europe. Its key focus is supplying cannabis-based API and finished medicines in Australia and Europe. It has already established licensed growing operations in the Czech Republic and Slovenia, and has built a resin extraction plant in Slovenia, which has received full GMP certification. The Maltese government recently gave the company approval to establish a full medical cannabis cultivation and production facility in that country. The company intends to conduct Phase II studies of its lead products, CannEpil and CogniCann, for the treatment of refractory epilepsy and dementia, respectively. These trials represent the first step towards seeking approval as registered pharmaceutical products in Europe and Australia. It has signed a binding term sheet to sell its MGC Derma cosmetics business to Canadian cannabis investment company, Cannaglobal, for up to C\$15m (A\$16m).

### Valuation: A\$140m or A\$0.11 per share

We arrive at an initial valuation of A\$140m or A\$0.11 per share, based on a risk-adjusted net present value (rNPV) analysis. The sales of cannabis flowers and resin from the cannabis-growing operations contribute over 60% of the enterprise value, with the CannEpil and CogniCann registered pharmaceuticals providing potential upside. Our valuation assumes that the company will increase its cannabis-growing greenhouse space tenfold to 10,000m<sup>2</sup> by 2022. We model A\$6m of additional funds being required in FY20 to support construction in Malta.

### Sensitivities: Ongoing regulatory risk

MGC faces the typical risks of a development-stage biopharma company, including the unpredictable outcome of trials, regulatory decisions, success of competitors, financing and commercial risks, coupled with unique regulatory risks associated with its medicinal cannabis focus. The investment case hinges on establishing expanded, GMP-certified, medicinal cannabis growing and processing facilities in Malta. Obtaining regulatory approval for CannEpil in refractory epilepsy and CogniCann in dementia will be crucial to its ability to drive additional sales growth in the competitive medicinal cannabis space. GW Pharmaceuticals (GW) recently gained FDA approval in two severe epilepsy syndromes for Epidiolex, which is a highly purified formulation of cannabidiol (CBD), the main ingredient in CannEpil. It has also filed for approval in Europe. If CannEpil's efficacy is not comparable to Epidiolex, it may be difficult to capture a significant market share. GW has an extensive patent estate, which affects the extraction, purification and use of CBD in refractory epilepsies. While the company's advice is that the GW patents will not impinge on its freedom to operate, there is a risk that GW could pursue legal action if it believes that its patents have been infringed. Finally, the company could potentially face competition from supplies of synthetic CBD from API manufacturers in South Asia.

### Financials: Sufficient cash support ongoing operations

MGC has been loss making since its re-listing in February 2016, reporting losses of A\$6.2m in FY16, A\$8.5m in FY17 and A\$9.0m in FY18. We forecast smaller PBT losses of A\$5.7m and A\$6.6m in FY19 and FY20 respectively, as it commences commercial sales of API in Europe and of CannEpil as an Investigational Medicine in Australia. We assume that expansion of cannabis-growing and API extraction capacity to support 10,000m<sup>2</sup> of greenhouse space, to be constructed by 2021 and fully operational in 2022, will require capital expenditure of A\$10m. The company raised net proceeds of A\$10.5m from stock issues in FY16, A\$9.8m in FY17 and A\$4.7m in FY18. We estimate that additional funds of A\$6m will be required in FY20, which we model as long-term debt.

## Company description: End-to-end cannabinoids from greenhouse to pharmacy

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MGC Pharmaceuticals (MGC, ASX:MXC) is an Australian Securities Exchange-listed company, headquartered in Perth and with its principal operations in the Czech Republic, Slovenia and Malta. Its main product lines are cannabis-based active pharmaceutical ingredients and cannabis-based finished medicines, including CannEpiI for the treatment of severe refractory epilepsy.

A number of the key personnel at MGC have extensive experience in producing and prescribing medicinal cannabis products in Israel. MGC has drawn on this experience in the selection of the formulation of its lead products, the cannabis extracts CannEpiI and CogniCann. CannEpiI's formulation is supported by the results of a retrospective study of 74 patients with refractory epilepsy, which reported that 51% of children with refractory epilepsy experienced at least a 50% reduction in seizures when they were treated with a cannabis oil containing the same 20:1 CBD/THC ratio as CannEpiI.<sup>1</sup>

MGC listed on the ASX in February 2016 via a reverse takeover of the mining exploration company Erin Resources. At the time of listing, its business strategy was to develop and supply high-quality, non-psychoactive cannabidiol (CBD) to the growing European and international cosmetics and medical market; the CBD resin was to be manufactured from hemp crops (low THC cannabis sativa strains) grown outdoors in Slovenia. However, in order to access wider market opportunities, it has revised the business strategy to include growing cannabis that contains high levels of the psychoactive compound tetrahydrocannabinol (THC) in secure greenhouse facilities in the Czech Republic and Malta, establishing a GMP-certified cannabis resin extraction and separation facility for API production, and developing finished cannabis-based medicines. As part of this revised strategy it intends to seek approval for its cannabis-based CannEpiI formulation for the treatment of refractory epilepsy, initially for children and young adults in Europe and Australia, with the option to pursue US approval later. It also intends to seek approval for CogniCann in dementia patients.

The strategy of producing cannabis-based medicines from seed to finished registered medical products, as well as being a supplier of cannabis-based APIs, differentiates MGC from the majority of companies operating in the medical cannabis market. One key differentiator is that few companies are seeking to achieve regulatory approval for their cannabis-based medicines as registered pharmaceutical drugs.

In addition to its strategy of seeking registration of CannEpiI and CogniCann as pharmaceutical products, the company plans to generate near-term revenues from the sale of CannEpiI and other medical cannabis products in markets where regulations allow their sale without obtaining registration. As part of this strategy, it has entered into a supply and distribution agreement with Lenis covering 12 European countries, and has signed a definitive exclusive supply agreement for the distribution of CannEpiI under an import licence in Australia. MGC recently obtained authorisation from the TGA for CannEpiI to be available for prescription in Australia as an Investigational Medicinal Product through specialist prescribers under the Authorised Prescriber Scheme. It expects sales in Australia to commence by December.

### Brief introduction to medicinal cannabis

Cannabis, also known as marijuana, is usually recognised by two main types, cannabis sativa, which originated in the western hemisphere and cannabis indica, which originated in central and south Asia.

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<sup>1</sup> Tzadok et al. Seizure 35 (2016) 41–44

The cannabis plant contains a complex blend of more than 70 compounds called cannabinoids. The two principal components believed to be the key contributors to the medicinal properties attributed to cannabis are the psychoactive compound tetrahydrocannabinol (THC), which is principally responsible for the cannabis 'high', and the non-psychoactive cannabidiol (CBD). However, other minor cannabinoids may also contribute to the medicinal properties.

## Producing high-quality products at a competitive price

The core strategy of MGC's Botanic division is to produce high-quality, cannabis-based products at a competitive price. The low cost of goods produced will be a key driver of the ongoing profitability of the company. As a first step towards this goal, it has established cannabis-growing operations in the Czech Republic and Slovenia and has constructed a GMP-approved cannabis resin extraction facility in Slovenia. The next phase will be to establish larger-scale cannabis-growing and processing operations in Malta under a binding letter of intent signed with the government of that country in April 2018.

MGC has established research collaborations in the Czech Republic, Slovenia and Australia in order to maximise yields, to develop high-yielding strains, to optimise growing conditions and to identify new cannabis-based products for treating additional medical conditions.

## Second crop at greenhouse facility in Prague nears harvest

MGC harvested 400kg of medicinal cannabis biomass from 1,100m<sup>2</sup> of outdoor greenhouse space at its Panax operation in Prague in 2017, as shown in Exhibit 1. A second crop was planted in early Q218, and is expected to be harvested in the current quarter.

MGC acquired 80% of Panax Pharma (Panax) in February 2017 in exchange for a commitment to fund the first year of operations, capped at €0.7m. MGC has an option to acquire the remaining 20% of Panax for €0.6m of shares in MGC. Panax has a strategic partnership with the Institute of Experimental Botany at the Academy of Sciences of the Czech Republic (IEB) in Prague, which holds a medical cannabis breeding licence and provides access to 1,100m<sup>2</sup> of dedicated greenhouse growing space.

**Exhibit 1: Cannabis plants growing at the company's outdoor greenhouse in Prague**



Source: MGC Pharmaceuticals



## **Extraction facility in Slovenia granted full GMP certification**

The company completed the construction of a clean room and CO<sub>2</sub> extraction facility in Ljubljana in Slovenia in April 2017. In July it was formally granted full GMP certification of the processing facility and a manufacturing licence for the production of cannabis-based medicines. Receipt of the licence enables the commercial-scale production of GMP-grade medical cannabis pharmaceutical products. It will enable MGC to be licensed for distribution of CannEpil, CogniCann and other medicinal cannabis products.

In October 2017 MGC harvested 4,000kg of biomass from a low-THC cannabis strain (hemp) crop at its open field farm on leased farmland in Slovenia. A proportion of the hemp crop will be processed to produce food-grade CBD for use in the company's nutrient and MGC Derma cosmetics products, with the remainder sold in the European market as Aquiol.

## **Larger-scale cannabis growing and processing in Malta**

In April 2018 MGC received a binding Letter of Intent granting approval and a contract by Malta Enterprise Corporation to establish a medical cannabis production and cultivation facility on 4,000m<sup>2</sup> of land. MGC is in the process of obtaining a formal contract to commence construction of the facility, which will also house a research hub and, once approved, a GMP-certified production and manufacturing facility. Under the terms of the contract, MGC will be obliged to spend a minimum of €4.3m (A\$6.5m) over the first three years on the construction and operation of the facility, and to employ at least 25 Maltese people as part of the local workforce.

Thanks to its warm Mediterranean climate, the Maltese facility should produce high-yielding cannabis crops with a relatively low cost of production.

The establishment of the facility in Malta will be a key part of the company's plan to expand its greenhouse growing capacity to around 5,000 m<sup>2</sup> over the next three years. While we model a further expansion of growing capacity to 10,000 m<sup>2</sup> by 2022, at this stage it is not clear whether this further expansion would take place in Malta or in another location.

## **Research and breeding programmes underway in three countries**

MGC has established R&D collaborations with universities in each of the countries where it has operations, including the IEB in the Czech Republic, the University of Ljubljana in Slovenia and the Royal Melbourne Institute of Technology (RMIT) and the University of Sydney in Australia. The goals of the collaborations include:

- optimising growing conditions to maximise cannabinoid yield per square metre of greenhouse space;
- breeding new high-yielding cannabis strains, including high-CBD and high-THC strains;
- identifying cannabis strains suited to treating specific disease symptoms; and
- conducting preclinical studies of the use of cannabinoids to treat a range of medical conditions, including cancers such as melanoma.

## **Distribution agreements in place for wholesale supply**

MGC has started putting in place supply and distribution agreements as it prepares for commercial sales of its pharmaceutical-grade cannabis products.

The first agreement was an exclusive regional distribution deal with Mikro+Polo for the sale in Slovenia, Croatia and Bosnia of the API material that will be produced from MGC's extraction facility in Slovenia.

Separately, the company has entered into a five-year supply and distribution agreement with the European pharmaceutical distribution company Lenis in eight countries in central and eastern Europe; in addition, Lenis and MGC will jointly market the products into Germany, Croatia, Greece and Italy. Lenis will distribute MGC's medicinal products, which include cannabis flower products and its CannEpil epilepsy medicine. The flower products will be available in pharmacies in select countries for use in a variety of medical conditions such as nausea, vomiting, pain, Tourette's syndrome, multiple sclerosis, severe uncontrollable epilepsy and inflammatory bowel diseases. In addition, the agreement covers the future supply of MGC's finished pharmaceutical products once they have been registered in the EU for sale.

Furthermore, in November 2017 MGC signed a definitive exclusive supply agreement with HL Pharma, a specialist Australian pharmaceutical distributor, to bring CannEpil to the Australian market for treating epilepsy patients. The company plans to sell CannEpil in Australia as a 50ml bottle containing 100mg/ml of CBD, 5mg/ml of THC (ie a total of 5,000mg CBD and 250mg THC) plus small amounts of other cannabidiols. A 50ml bottle will retail for less than A\$800, which is significantly lower on a price per mg basis than the most similar current competing product in the market, which is supplied by the privately owned Canadian company, Tilray.

In Australia, certain cannabis-based Investigational Medicinal Products can be dispensed by pharmacies for treatments prescribed by doctors who are registered under the Authorised Prescriber Scheme (APS). The TGA has approved an initial group of doctors as authorised prescribers of CannEpil, who will provide access to a pool of more than 100 patients. The formal TGA authorisation follows endorsement from the St Vincent's Hospital Melbourne Human Research Ethics Committee for the use of CannEpil in the treatment of adults with drug-resistant epilepsy.

The company has already established links with the patient support group, Epilepsy Action Australia (EAA). The EAA estimates that up to 240,000 people are currently living with epilepsy in Australia. However, we base our forecasts on an estimate of 154,000 Australians with active epilepsy, based on the estimated global prevalence of active epilepsy of 6.4 cases per 1,000 people (see pages 8-9 for details).

MGC anticipates the initial base of 100 patients generating revenues of A\$1m; we conservatively model a more modest uptake, with sales of CannEpil as an investigational product in Australia assumed to reach A\$1.0m in FY21. We will look to revise our forecasts as MGC establishes a track record of sales in Australia.

## **Phase II clinical trial in treatment-resistant epilepsy awaiting final regulatory approval**

MGC has announced that it intends to undertake a Phase II safety and efficacy study of six weeks of treatment with the company's CannEpil medicinal cannabis formulation in children and adolescents with treatment-resistant epilepsy at the University Children's Hospital Ljubljana, Slovenia. CannEpil is a whole plant extract-based medicinal cannabis formulation with a high (20:1) CBD/THC ratio. Over 65 volunteers have been identified to participate in the study, which aims to recruit over 100 subjects. The Phase IIa crossover study will compare the response to six weeks of treatment with CannEpil to treatment of the same individuals with a pure synthetic CBD that has already been studied at the hospital. The primary endpoint of the study will be a reduction in the frequency of seizures. The company has received ethics approval for the study, but it is awaiting final sign-off from the regulators in Slovenia before the trial can commence.

A positive outcome to the study would potentially lead to a Phase III pivotal study to support an application to register the product in the EU and Australia.

## **US approval a potential long-term opportunity**

The company's near-term strategy does not include plans to seek regulatory approval in the US market as it focuses its resources on the European development programme. However, if the efficacy of CannEpil in the planned trials in children and young adults with refractory epilepsy is in line with expectations, we see a potential opportunity to subsequently commence a development programme to support an application for approval in the US. We do not expect the company to make any plans to seek approval in the US until it has evaluated CannEpil in a Phase III trial in Europe. We do not currently include any sales in the US in our model, so this represents a potential upside opportunity.

## **Regulatory changes create opportunities in medicinal cannabis**

As cannabis is considered to be an illicit drug in most jurisdictions, its medical use is highly regulated. However, following recent changes, regulations in Australia and all countries in the EU now permit clinical treatment with cannabinoids and other medicinal cannabis products under defined conditions. In some jurisdictions, this is limited to products that contain CBD but not THC, or allow only low levels of THC in the products.

Countries with more liberal regulations that allow doctors to prescribe medical cannabis products containing higher levels of THC include Germany, Italy, Switzerland, the Netherlands, Croatia, the Czech Republic, Macedonia and Greece.

However, despite the relaxation of some restrictions, the growth and processing of cannabis products remains tightly regulated to reduce the risk that products may be diverted to the illicit drug market or for recreational use. For example, the growth of cannabis in Slovenia is regulated under the Production of and Trade in Illicit Drugs Act (referred to as the ZPPPD act). MGC will require a licence from the governments of Slovenia and the Czech Republic to export the cannabis products that it produces.

In addition to the regulations that apply specifically to cannabis products, the company will face the typical regulatory challenges of gaining pharmaceutical drug approval and GMP certification (which it has already obtained for its Slovenian facility). However, if MGC can successfully negotiate the regulatory hurdles to produce and sell pharmaceutical-grade cannabis products, these same regulations would become barriers to entry that may limit the number of competitors that it faces in the marketplace.

## **Targeting development of CannEpil as a registered pharmaceutical for drug-resistant epilepsy**

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MGC intends to seek regulatory approval for CannEpil as a treatment for severe, refractory epilepsy in Europe and Australia. Epilepsy is a common and devastating neurological disorder characterised by repeated unprovoked seizures. Antiseizure drugs are routinely used to control seizures, but about one-third of epilepsy patients are drug-resistant and continue to suffer from uncontrolled seizures despite pharmacotherapy.<sup>2</sup> Commonly used anti-epileptic drugs include clobazam, valproic acid, levetiracetam, lamotrigine and rufinamide.

The company's expectation that CannEpil will be effective at reducing seizure frequency in refractory epilepsy is supported by the fact that GW Pharmaceuticals has already demonstrated in well-controlled clinical studies that Epidiolex, a highly purified plant-derived CBD extract, is effective at reducing seizures in treatment-resistant patients with the severe epilepsy disorders Dravet

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<sup>2</sup> Tang et al 2017. Drug-Resistant Epilepsy: Multiple Hypotheses, Few Answers. *Front. Neurol.* 8:301. doi: 10.3389/fneur.2017.00301

syndrome and Lennox-Gastaut syndrome (LGS). The FDA approved Epidiolex for these two disorders in June 2018. The company has also filed for approval in Europe.

GW has reported positive results from three Phase III studies in Dravet and LGS patients, as shown in Exhibit 2. The average reduction in seizure frequency for Epidiolex doses of 10-20mg/kg in the three studies ranged from 37-44%, compared to 13-22% for placebo.

**Exhibit 2: Phase III trials of GW Pharmaceuticals' Epidiolex in Dravet and LGS**

| Indication  | Doses tested        | Number of patients | Average age | Average number of AEDs currently prescribed | Number of previously tried AEDs | Median baseline seizure frequency | Epidiolex seizure reduction             | Placebo seizure reduction | p-value                                     | Dropouts due to AEs                 |
|-------------|---------------------|--------------------|-------------|---|---------------------------------|-----------------------------------|---|---------------------------|---|-------------------------------------|
| Dravet      | 20mg/kg             | 120                | 10          | 3   | 4                               | 13 convulsive seizures            | -39%<br>(20mg/kg)                       | -13%                      | 0.0123                                      | 13%                                 |
| LGS Trial 1 | 20mg/kg             | 171                | 15          | 3   | 6                               | 74 drop seizures                  | -44%<br>(20mg/kg)                       | -22%                      | 0.0135                                      | 14%                                 |
| LGS Trial 2 | 20mg/kg and 10mg/kg | 225                | 16          | 3   | 7                               | 85 drop seizures                  | -42%<br>(20mg/kg),<br>-37%<br>(10mg/kg) | -17%                      | 0.0047<br>(20mg/kg),<br>0.0016<br>(10mg/kg) | 8%<br>(20mg/kg),<br>1%<br>(10mg/kg) |

Source: Edison Investment Research, GW Pharmaceuticals

### Transdermal CBD fails in adult epilepsy, highlighting clinical risk remains

Despite the proven efficacy of CBD in severe forms of epilepsy, the failure of Zynerba's CBD gel in adult epilepsy shows there is no certainty that a particular product or clinical trial will deliver a positive result.

Zynerba, which has been developing ZYN002, a synthetic transdermal cannabidiol gel for adult epilepsy patients with focal seizures, announced that the compound failed to show significance in any of the primary or secondary endpoints in its Phase II trial (known as STAR 1). Whereas Epidiolex was able to show a ~40% reduction in seizure frequency in its three Phase III trials, ZYN002 was only able to show an 18.4% reduction at the lower dose (195mg daily total) and a 14.0% reduction at the higher dose (390mg daily total).

### Other new epilepsy drugs on the horizon

In September 2017, Zogenix announced positive Phase III results for ZX008 (fenfluramine) in treatment-resistant Dravet Syndrome. The responder rate (at least 50% reduction in seizures) was 75% for the high dose, 41% for the low dose and 7.5% on placebo. In a confirmatory Phase III reported in July 2018, the responder rate for an intermediate dose was 54% for ZX008 vs 7% for placebo. If it is approved ZX008 is likely to compete with cannabinoid drugs for market share.

### The severe refractory epilepsy market

Epilepsy is a severe neurological disorder that is estimated to affect more than 70 million people worldwide.<sup>3</sup> Based on a meta-analysis of epidemiology studies, Fiest et al calculated the average prevalence of active epilepsy to be 6.4 patients with active epilepsy per 1,000 head of population.<sup>4</sup>

Following a review of the epidemiology of epilepsy in Europe, Forsgren et al reported that ~20-30% of patients experience at least one seizure per month.<sup>5</sup> Combining the higher 30% estimate of patients with frequent seizures with the fact that one-third of patients have treatment-resistant epilepsy (due to likely overlap between the two groups), we estimate that 10% of all patients with active epilepsy have frequent seizures that are resistant to antiseizure drugs.

3 Ngugi et al. Incidence of epilepsy: a systematic review and meta-analysis. *Neurology* (2011) 77:1005–12. doi:10.1212/WNL.0b013e31822cfc90.

4 Fiest et al. Prevalence and incidence of epilepsy. *Neurology* 2017;88:296–303

5 Forsgren et al. The epidemiology of epilepsy in Europe...*European Journal of Neurology* 2005, 12: 245–253



We assume that this 10% of patients with severe refractory epilepsy represent the main target market for CannEpiL. Applying this 10% factor to the prevalence of 6.4 patients with active epilepsy per 1,000 head of population, we estimate the addressable patient population with severe, treatment-resistant epilepsy to be ~69,000 young people aged less than 20 years and 260,000 adults aged over 20 in Europe, 3,900 young people and 11,600 adults in Australia, and 56,000 young people in the US.

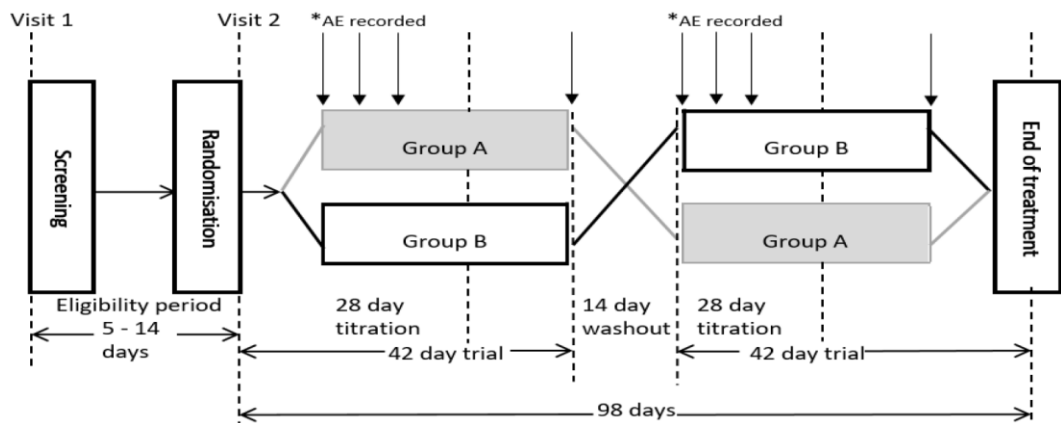
## CogniCann for dementia: A second pharmaceutical candidate

MGC has announced plans to conduct a Phase II clinical trial of CogniCann in patients with mild dementia and Alzheimer’s disease (AD). CogniCann is MGC’s GMP-certified medical cannabis pharmaceutical product, which has been specifically formulated for the treatment of key dementia symptoms and improving specific cognitive functions. Each 10m bottle of CogniCann contains 250mg THC and 170mg CBD. The trial leverages IP secured through the company’s Medical Advisory Board, led by Professor Uri Kramer, which is based on experience gained through the use of medicinal cannabis products in Israel.

Ethics approval has been received to conduct the study in partnership with the Institute for Health Research at the University of Notre Dame in Western Australia. The trial, which will recruit a total of 50 subjects aged 65 years and older, is expected to commence in early 2019, subject to TGA approval. The 16-week trial will use a randomised, double blind, crossover, placebo-control design to evaluate behavioural changes, quality of life, level of discomfort and pain in dementia patients living in residential aged care facilities (Exhibit 3).

CogniCann’s impact on dementia symptoms will be assessed by validated questionnaires such as the Mini-Mental State Examination (MMSE), Neuropsychiatric Inventory (NPI), Cohen-Mansfield Agitation Inventory, Quality of Life – Alzheimer’s Disease (QoL-AD) and the Abbey Pain Scale.

**Exhibit 3: Trial design for the CogniCann Phase II in dementia patients**



Source: MGC Pharmaceuticals announcement. Note: \*Adverse events (AE) will be recorded with each dose in the titration phase and on the last dose of the intervention phase.

## Medicinal cannabis and dementia

Cannabis targets a system in the brain known as the endocannabinoid system, which comprises receptors called CB1 and CB2. The endocannabinoid system is involved in memory, appetite regulation and response to stress. Memory loss is a key feature of AD, and agitation and aggression are commonly observed symptoms in AD and other forms of dementia. This has prompted a number of investigators to explore the potential for cannabis and cannabinoids to ameliorate dementia symptoms.

## Preclinical studies show potential efficacy of cannabinoids in AD

Several studies in cell culture and animal models have shown that cannabinoids can reduce oxidative stress, neural inflammation, and the formation of amyloid plaques and neurofibrillary tangles, the key hallmarks of AD.<sup>6</sup> Some studies have shown that cannabinoids appear to remove the amyloid plaques that are a hallmark of AD from nerve cells grown in the lab.<sup>7</sup> A study in an animal model of AD found that a combination of THC and CBD preserved memory, reduced learning impairment and decreased levels of soluble beta amyloid<sup>1-42</sup>, a key component of amyloid plaques found in the brains of patients with AD.<sup>8</sup> Some researchers believe that targeting the CB2 receptor (eg with CBD) could control the activity of microglia cells, preventing the potentially harmful overactivation of the immune system in the brain seen in AD.

## Clinical studies in dementia have focused on THC monotherapy, with mixed results

Most clinical studies of cannabinoids in dementia have focused on THC monotherapy, rather than THC/CBD combinations like CogniCann. A scientific review published in 2015 identified four small studies, all using THC monotherapy, in a total of 60 dementia patients suffering from behavioural disturbances. While the studies were either not randomised or included a limited number of participants, they observed reduced levels of disturbed behaviour and agitation in THC-treated patients (Ahmed et al 2015). However, a subsequent 60-patient randomised study (van den Elsen et al 2015, clinicaltrials.gov identifier [NCT01608217](https://clinicaltrials.gov/ct2/show/study/NCT01608217)) found that there was no benefit of low-dose oral THC in dementia-related neuropsychiatric symptoms such as agitation and aggression, or in quality of life.<sup>9</sup>

In contrast to the negative findings from the van den Elsen study, in July 2018 the synthetic cannabinoid nabilone (Cesamet, Mylan/Meda Pharmaceuticals) successfully met its primary endpoint of reducing agitation and aggression in a randomised 39-patient Phase II/III study in AD patients ([NCT02351882](https://clinicaltrials.gov/ct2/show/study/NCT02351882)).<sup>10</sup> Nabilone is a synthetic cannabinoid analogue of THC that causes minimal euphoria. In addition to meeting the primary endpoint of improving agitation as measured by the Cohen-Mansfield Agitation Inventory, nabilone also improved quality of life, cognition and overall neuropsychiatric symptoms. Although the treatment was well tolerated, there was an increase in sedation (drowsiness/sleepiness, 45% on nabilone vs 16% on placebo).

Despite the fact that the results of the investigator-sponsored Phase II/III study of nabilone are positive, larger trials and replication would be needed to make recommendations that would change clinical practice.<sup>11</sup> Nabilone is currently approved in the US and certain European countries for the treatment of chemotherapy-related nausea and vomiting. The study was sponsored by the Sunnybrook Research Institute in Canada, and we could not find any evidence that Mylan plans to conduct a confirmatory study of nabilone in dementia.

In addition to the completed trials above, our search of clinicaltrials.gov identified two ongoing studies of cannabis or cannabinoids in dementia. The first was a 60-patient randomised Phase II study in dementia-related agitation and aggression ([NCT03328676](https://clinicaltrials.gov/ct2/show/study/NCT03328676)). This study, which is being conducted by TO Pharmaceuticals, a subsidiary of Tikun Olam, is investigating the effect of Avidekel, a low THC cannabis oil (THC:CBD 1:20). The study commenced in December 2017 and is expected to complete in November 2019.

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6 Ahmed et al [2015](#). Clinical Pharmacology & Therapeutics 96 (6):597-606

7 Currais et al [2016](#). npj Aging and Mechanisms of Disease. 2, Article number: 16012

8 Aso et al [2015](#). J. Alzheimers Dis. 43, 977–991.

9 van den Elsen et al [2015](#). Neurology;84:2338–2346

10 Lanctot et al [2018](#). Alzheimer's Association International Conference; Abstract F4-02-04

11 <https://www.medpagetoday.com/meetingcoverage/aaic/74214>

The second study is an investigator-sponsored, 160-patient Phase II pilot study of dronabinol for the treatment of agitation in AD ([NCT02792257](#)). The trial, which commenced in March 2017, is expected to report top-line results in August 2020. Dronabinol (Marinol, AbbVie), a synthetic oral formulation of THC, is FDA-approved for anorexia/weight loss in AIDS and for nausea/vomiting associated with chemotherapy.

The successful nabilone study and the ongoing studies of dronabinol and Avidekel raise the possibility that CogniCann could face competition from an established cannabinoid-based therapy for dementia-related AD symptoms by the time MGC generates efficacy data for CogniCann for this indication.

## Other potential drugs for agitation in dementia on the horizon

Neither the FDA nor EMA has approved any drugs to treat neuropsychiatric symptoms such as agitation in dementia patients. Non-pharmacological interventions are suggested as first-line treatment, but are not effective for every patient. Currently, these symptoms are treated by off-label use of psychotropic medications such as antipsychotics, antidepressants, benzodiazepine sedatives and anti-convulsants. These drugs have modest efficacy and their use can produce harmful side effects.

A number of candidate drugs are in Phase III development for the treatment of agitation in dementia, including the antipsychotic brexpiprazole, the antidepressant citalopram, and the novel compounds AVP-786 (deuterated-dextromethorphan/quinidine combination) and Lumateperone (ITI-007).<sup>12</sup> These drugs could be potential competitors for CogniCann (if approved).

## The Alzheimer's disease and dementia market

A recent meta-analysis found that the prevalence of dementia worldwide for people aged 60 years or older ranged from 5-7%; the prevalence in the US was 6.5% while in Western Europe it was 7.3%.<sup>13</sup> Dementia is estimated to affect 50 million people worldwide currently, with the number expected to triple to 152 million by 2050. About two-thirds of dementia patients have AD; other common dementia syndromes include vascular dementia, mixed dementia, Lewy body dementia or frontotemporal degeneration.<sup>14</sup>

Over 90% of people with dementia experience at least one neuropsychiatric symptom over the course of their disease. Agitation, psychosis and mood disorders are the three main neuropsychiatric syndromes of dementia. Agitation (including aggression and non-aggressive agitation) occur in 20% of people with AD living in the community and in 40-60% of individuals with dementia living in care facilities.<sup>15</sup>

As we do not have data on the proportion of dementia patients living in care facilities, we conservatively assume that the addressable market of patients with agitation or other neuropsychiatric symptoms that are not adequately controlled by non-pharmacological interventions represents 10% of dementia patients. This represents 550,000 patients in North America, 950,000 patients in Central and Western Europe and 40,000 patients in Australia.

The market research group EvaluatePharma estimated that the market for AD drugs was valued at ~US\$2.4bn in 2018 and forecasts it to grow to US\$5.7bn by 2024. The approved AD drugs fall into two drug classes. Cholinesterase inhibitors, such as donepezil, galantamine and rivastigmine, slow down the breakdown of the neurotransmitter acetyl choline, which is involved in memory and

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12 Porsteinsson et al [2017](#). Expert Opinion on Pharmacotherapy, 18:6, 611-620

13 Prince et al [2013](#). Alzheimers Dement. Jan;9(1):63-75

14 World Alzheimer Report [2018](#)

15 Ballard and Corbett [2010](#). CNS Drugs 2010; 24 (9): 729-739

judgement. Memantine helps control a different brain chemical needed for learning and memory. Namzaric is a combination of memantine and donepezil. These drugs have been shown to improve cognition and behaviour in people with AD, but do not slow down disease progression.

## **Estimating the potential medical cannabis resin market in Europe**

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The market research group Grand View Research recently estimated that the global medical marijuana market was worth US\$11.4bn in 2015, and forecasts it to grow to US\$55bn by 2025 due to the increasing number of territories that have legalised the use of medical cannabis and the increasing demand for cannabis in medical applications. It estimated that North America accounted for a 49% share of the current global market, with chronic pain the largest indication, accounting for a 40% revenue share.

We use the current experience of medical cannabis use in Israel as the basis to estimate the underlying potential demand for cannabis resin in Europe for use in investigational medicinal products. Sales of medical cannabis are licensed by the Israeli Ministry of Health for a number of indications, including oncology-related pain and side effects of chemotherapy, phantom pain and pain related to multiple sclerosis, diabetic neuropathy, post-traumatic stress disorder, intractable epilepsy, intractable Crohn's disease and severe fibromyalgia. In 2016, there were 23,500 active licences in the Ministry of Health registry,<sup>16</sup> representing ~0.3% of the total population.

We use the 0.3% uptake of medical cannabis products in Europe as a guide to the potential underlying demand that is likely to exist in Europe. If uptake in the EU was to reach a similar level to that seen in Israel, and assuming a low average dose of 1mg/kg/day (the lowest dose used in the Tzadok et al epilepsy study in Israel), we estimate the potential demand for cannabis in the EU of approximately 37,000kg of cannabis resin equivalent each year.

At the wholesale price of €50 per gram of CBD resin that we model in our forecasts, this would be worth €1.9bn per year. In practice, this demand would likely be met by a combination of cannabis resin and cannabis flower products.

At present, the medical cannabis regulations in most countries in Europe are more restrictive than those in Israel. If we restrict the analysis to the 195 million people in the eight European countries with more liberal medical marijuana laws (listed on page 7), we estimate the underlying demand for medical cannabis in those countries to be equivalent to 14,000kg of resin per year. We model MGC's API production in 2023 to be equivalent to 500kg of resin, which is approximately 3% of estimated underlying demand in these eight countries.

## **Terms agreed for sale of MGC Derma**

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MGC has signed a binding term sheet for the sale of its MGC Derma business to the unlisted Canadian cannabis investment company Cannaglobal for up to C\$15m (A\$16m), and a five-year CBD and cosmetic materials supply agreement. The supply agreement includes an upfront order and payment of C\$1m for the purchase of raw materials from MGC. The sale is subject to shareholders voting to approve the sale at the AGM in early November, and there being no material adverse change in either MGC or Cannaglobal.

Consideration for the sale comprises C\$9m in ordinary shares in Cannaglobal at settlement, C\$3.5m of shares payable on the achievement of certain revenue milestones, plus the future

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<sup>16</sup> Tzadok et al. Seizure 35 (2016) 41–44

repayment of the existing C\$2.5m working capital loan owed to MGC by MGC Derma. As Cannaglobal is an unlisted entity, we are unable to independently confirm the value of their shares.

MGC Derma (previously known as Ananda Cosmetics) is a joint venture company that was owned 51% by MGC and 49% by the Slovenian cosmetics manufacturer Dr M Burstein (Burstein). To complete the Cannaglobal transaction, MGC has acquired the 49% of MGC Derma held by Burstein for C\$1.25m (Burstein's share of the MGC Derma working capital loan). In turn, Burstein will benefit from the five-year cosmetic materials supply agreement that is part of the transaction.

## **Contract default notice issued to Korean cosmetics manufacturer Varm Cosmo**

On 20 October 2017, the company announced that its MGC Derma division had signed a binding terms and conditions supply agreement for the supply of A\$40m per year of white-label (unbranded) cosmetic products to the Korean cosmetics manufacturer Varm Cosmo. Ten days later, it signed the first binding sales agreement with Varm Cosmo, for a minimum contracted volume of A\$8m of product.

However, Varm Cosmo failed to meet its commercial obligations under the agreement, including the payment of a A\$1m deposit. On 25 September 2018, MGC issued a formal contract default notice to Varm Cosmo and will seek a minimum of A\$0.5m from the company as restitution, plus additional damages.

## **MGC Derma's range of CBD-based cosmetic products**

MGC Derma has developed a range of CBD-based cosmetic products, including the Derma Plus range of dermatologically tested products that have shown efficacy in improving a range of highly irritated or inflamed skin conditions. The Derma Plus range includes products for the relief and prevention of psoriasis, acne and seborrheic conditions, including its CBD Herbal Repair Cream, Herbal Balm and Herbal Replenish Cream. Successful safety studies have allowed the company to register the products with the European Cosmetic Products Notification Portal (CPNP), allowing them to be sold in Europe as 'dermatologically tested' products.

MGC Derma is marketing its mgc derma range of CBD-based cosmetic products through its online [shop](#) and through wholesale reseller agreements in Spain, Italy, Romania and the Czech Republic. It has signed supply agreements with leading online retailer Cult Beauty and the prestigious department store Harvey Nichols to sell the range of cosmetic products internationally.

## **Sensitivities**

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MGC faces the typical risks of a development-stage biopharma company, including the unpredictable outcome of trials, regulatory decisions, success of competitors, financing and commercial risks, coupled with unique risks associated with its medicinal cannabis focus.

The investment case hinges on establishing expanded, GMP-certified, medicinal cannabis growing and processing facilities in Malta. The ability to obtain regulatory approval for CannEpiL for the treatment of refractory epilepsy will be crucial to its ability to drive additional sales growth in the competitive medicinal cannabis space.

Due to the highly regulated nature of the medicinal cannabis market, the company is vulnerable to regulatory changes that either restrict its ability to operate or alternatively leave it open to increased competition from new entrants.

We note that the inclusion of low levels of psychoactive THC in CannEpiL could potentially increase the incidence of side effects such as drowsiness or nausea in patients.



GW Pharmaceuticals has gained FDA approval and is currently seeking approval in Europe for Epidiolex in two severe epilepsy syndromes. Epidiolex is a highly purified formulation of cannabidiol (CBD), the main ingredient in CannEpi. If the efficacy of CannEpi is not comparable to Epidiolex, it may be difficult to capture a significant market share. GW has an extensive patent estate, which affects the extraction, purification and use of CBD in refractory epilepsies. While the company's advice is that the GW patents will not impinge on its freedom to operate, there is a risk that GW could pursue legal action if it believes that its patents have been infringed.

Finally, the company could potentially face competition from suppliers of synthetic CBD from API manufacturers in South Asia.

## Valuation

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We arrive at an initial valuation of A\$140m, based on a 15-year, sum-of-the-parts risked DCF valuation model of the company's CannEpi product for epilepsy and CogniCann for dementia in Europe and Australia, as well as API sales of cannabis flowers and resin. We assume 3% annual market growth but do not include any terminal value. We include a valuation of MGC Derma based on the proposed sale consideration. Taking into account the 1,213m shares in issue and 100m performance shares, our valuation is equivalent to A\$0.11 per share. On a fully diluted basis our valuation is A\$0.10 per share, after taking into account 95m performance rights and options that would be in-the-money if the stock traded in line with our basic valuation. Exhibit 4 summarises the key assumptions and constituent parts of our valuation. We use a 12.5% discount rate and apply an average tax rate of 10% from 2022 onwards. The company does not currently have patent protection for its product pipeline.

## CannEpi in treatment-resistant epilepsy

As described earlier, we estimate the number of patients with severe, refractory epilepsy who make up the main target market for CannEpi to be ~69,000 young people aged less than 20 years and 260,000 adults aged over 20 in Europe, 3,900 young people and 11,600 adults in Australia, and 56,000 young people in the US.

We give the programme to develop CannEpi as a registered pharmaceutical product for epilepsy in Europe and Australia a 20% probability of success, supported by the positive results reported for a similar formulation in Israel and the fact that GW Pharmaceuticals has already demonstrated in Phase III studies that CBD, the main component in CannEpi, significantly reduces seizure frequency in children with two different, severe refractory epilepsy syndromes. Although MGC has announced plans for a Phase II trial in Slovenia, it has not yet commenced recruiting patients. We include modest pre-approval sales of CannEpi as an investigational medicine in our model with a probability of 100%.

We do not include CannEpi for juveniles in the US in our valuation at this stage, as we do not expect the company to decide whether to commence development for this indication in the US until it has completed a Phase III study in Europe.

We assume that the company will commence sales of CannEpi in Europe and Australia during the current financial year as an investigational medicine. We expect it to achieve penetration of 0.5% to 1% of the addressable market for young people as an investigational medicine in select countries including Australia, Germany, Italy, Croatia, Greece, Macedonia and the Czech Republic, and penetration of 10% in young people and 5% of adults if it is approved as a registered pharmaceutical. We model a launch price as an Investigational Medicinal Product equivalent to €4,800 per year and A\$8,900 per year for children in Europe and Australia respectively (assuming 90% compliance). This compares to the list price for GW's Epidiolex for children in the US of US\$32,500 (A\$43,000) per year. For the higher dose of CannEpi required for adults, we assume

Investigational Medicinal Product pricing of €8,000 per year and A\$14,900 per year in Europe and Australia respectively. We assume a modest 10% price increase if relaunched as a registered pharmaceutical.

We model clinical trials and regulatory submissions in Europe and Australia to cost €7.0m for juvenile epilepsy and €6m for adults.

## **CogniCann for dementia patients**

We model an addressable market for CogniCann of 990,000 dementia patients in Central and Western Europe and Australia with neuropsychiatric symptoms that are not adequately controlled by non-pharmacological interventions, as described on page 12. We model a 5% market penetration and assume a low 5% probability of success given the low success rate typical of dementia trials. We assume pricing 15% below that for CannEpil, ie €6,800 per year and A\$12,600 per year in Europe and Australia respectively

We model clinical trials and regulatory submissions for CogniCann in Europe and Australia to cost A\$15m.

For both CannEpil and CogniCann we model the company earning an average gross profit margin of 35% on sales, after allowing 35% for COGS and a 30% average distributor margin.

## **Cannabis flowers and resin API and food-grade resin**

The company intends to sell a proportion of cannabis flowers and THC and CBD resins produced at its facilities in Malta, the Czech Republic and Slovenia as APIs in addition to using the resin to manufacture CannEpil and other finished products, and for the supply of food-grade CBD resin to MGC Derma and other customers for the manufacture of cosmetic products. It is currently growing cannabis in 1,100m<sup>2</sup> of greenhouse space in the Czech Republic and has received full GMP certification for its resin extraction facility in Slovenia.

We expect the company to expand its greenhouse space to 5,000m<sup>2</sup> by 2020 and 10,000m<sup>2</sup> by 2022 and increase its resin extraction capacity at a total cost of ~A\$10m. This would allow it to grow 5,000kg of cannabis flowers (on a dry matter [DM] basis) from two crops per year by 2023. We assume that by 2023, 90% of the crop will be used for the production of resin and flowers for sale as API, and 10% will be used for the production of food-grade CBD for cosmetics and other products.

We assume that the flowers for API production contain 7% THC and 7% CBD, and that the company achieves an 80% extraction efficiency. We model cannabis flower sales priced at €3.5 per gram with a growing cost of €0.7 per gram and a 30% distributor margin. According to the company, at present in Europe API-grade, GMP-certified CBD resin is selling for €45-50/g and GMP-certified THC resin is selling for €200/g. We assume that the prices will decrease over time as supply increases, and conservatively model all API-grade resin sales at an average price of €50/g, with a cost of production of €25/g.

We assume that food-grade CBD resin is sold for €25 per g. The lower-purity requirement for food-grade resin results in a lower cost of production. This is due to both the lower expenditure on quality assurance testing and the higher extraction yields that result from a wider proportion of the CBD profile being collected during flash chromatography separation. We assume cost of production of €16 per g for food-grade resin.

## **MGC Derma**

We assume that shareholders will approve the sale of MGC Derma, and that the transaction is completed according to the announced terms. We value the Cannaglobal shares to be issued as

upfront consideration at face value of C\$9m, and include the C\$2.5m working capital loan, which is to be repaid in the future as cash or shares. At this stage, we do not include the C\$3.5m of shares payable on the achievement of certain revenue milestones; we will review this once we have more visibility as to the sales trajectory.

| <b>Exhibit 4: MGC Pharmaceuticals rNPV valuation</b> |            |                        |               |             |                   |                             |
|--|------------|------------------------|---------------|-------------|-------------------|-----------------------------|
| Product  | Launch*    | Peak sales**<br>(A\$m) | NPV<br>(A\$m) | Probability | rNPV***<br>(A\$m) | rNPV/share<br>(cents/share) |
| Juvenile epilepsy Europe & Australia                 | 2019/2024# | 90                     | 50            | 20%-100%    | 7.5               | 0.6                         |
| Adult epilepsy Europe & Australia                    | 2025       | 300                    | 138           | 20%         | 25.8              | 2.0                         |
| Dementia Europe and Australia                        | 2025       | 830                    | 395           | 5%          | 16.8              | 1.3                         |
| Flower and resin API & food-grade resin sales        | 2018       | 60                     |               | 20%-100%    | 85.7              | 6.5                         |
| MGC Derma/Cannaglobal                                |            |                        |               |             | 12.5              | 1.0                         |
| Admin and unallocated R&D costs                      |            |                        |               | 20%-100%    | (11.8)            | (0.9)                       |
| Net cash end FY19e                                   |            |                        |               | 100%        | 3.4               | 0.3                         |
| <b>Valuation</b>                                     |            |                        |               |             | <b>139.8</b>      | <b>10.7</b>                 |

Source: Edison Investment Research. Notes: \*Financial year of product launch; #sales of investigational CannEpi begin in FY19 at 100% probability, registered pharmaceutical in FY23 at 20% probability; \*\*peak sales estimates rounded to nearest A\$10m; \*\*\*risk-adjusted R&D costs are offset against income for each drug development project.

## Financials

MGC has been loss making since listing in February 2016, reporting losses of A\$6.2m in FY16, A\$8.5m in FY17 and A\$9.0m in FY18. We forecast smaller PBT losses of A\$5.7m and A\$6.6m in FY19 and FY20 respectively, as it commences commercial sales of API in Europe and of CannEpi as an Investigational Medicinal Product in Australia. We forecast R&D expenses of A\$1.3m in FY19 and A\$5.8m in FY20.

We assume that expansion of cannabis-growing and API extraction capacity to support 10,000m<sup>2</sup> of greenhouse space by 2021 will require capital expenditure of A\$10m. The company raised net proceeds of A\$10.5m from stock issues in FY16, A\$9.8m in FY17 and A\$4.7m in FY18. The current cash balance of A\$9.9m should be sufficient to support operations into FY20. We estimate that additional funds of A\$6m will be required in FY20 to support construction of the new facilities in Malta, which we model as indicative long-term debt.

**Exhibit 5: Financial summary**

|  | A\$'000s | 2016    | 2017     | 2018     | 2019e   | 2020e   |
|--|----------|---------|----------|----------|---------|---------|
| Year end 30 June                         |          | AASB    | AASB     | AASB     | AASB    | AASB    |
| <b>PROFIT &amp; LOSS</b>                 |          |         |          |          |         |         |
| Sales                                    |          | 2       | 120      | 297      | 2,250   | 8,934   |
| Other                                    |          | 0       | 0        | 0        | 0       | 0       |
| Revenue                                  |          | 2       | 120      | 297      | 2,250   | 8,934   |
| Cost of Sales                            |          | (15)    | (158)    | (119)    | (929)   | (3,817) |
| Gross Profit                             |          | (13)    | (38)     | 177      | 1,321   | 5,117   |
| R&D expenses                             |          | 0       | 0        | (951)    | (1,269) | (5,846) |
| SG&A expenses                            |          | (6,247) | (8,508)  | (8,080)  | (5,707) | (5,672) |
| Other                                    |          | 0       | 0        | 0        | 0       | 0       |
| EBITDA                                   |          | (6,260) | (8,546)  | (8,854)  | (5,656) | (6,401) |
| Operating Profit (before GW and except.) |          | (6,276) | (8,629)  | (9,182)  | (5,763) | (6,659) |
| Intangible Amortisation                  |          | 0       | 0        | 0        | 0       | 0       |
| Exceptionals                             |          | 0       | 0        | 0        | 0       | 0       |
| Operating Profit                         |          | (6,276) | (8,629)  | (9,182)  | (5,763) | (6,659) |
| Net Interest                             |          | 46      | 127      | 192      | 99      | 34      |
| Profit Before Tax (norm)                 |          | (6,230) | (8,502)  | (8,990)  | (5,664) | (6,625) |
| Profit Before Tax (reported)             |          | (6,230) | (8,502)  | (8,990)  | (5,664) | (6,625) |
| Tax benefit                              |          | 0       | 0        | 0        | 0       | 0       |
| Profit After Tax (norm)                  |          | (6,230) | (8,502)  | (8,990)  | (5,664) | (6,625) |
| Profit After Tax (reported)              |          | (6,230) | (8,502)  | (8,990)  | (5,664) | (6,625) |
| Average Number of Shares Outstanding (m) |          | 603.6   | 966.3    | 1,125.5  | 1,257.8 | 1,312.8 |
| EPS - normalised (c)                     |          | (1.03)  | (0.88)   | (0.80)   | (0.45)  | (0.50)  |
| EPS - diluted                            |          | (1.03)  | (0.88)   | (0.80)   | (0.45)  | (0.50)  |
| Dividend per share (A\$)                 |          | 0.0     | 0.0      | 0.0      | 0.0     | 0.0     |
| <b>BALANCE SHEET</b>                     |          |         |          |          |         |         |
| Fixed Assets                             |          | 7,331   | 8,335    | 8,490    | 10,383  | 15,125  |
| Intangible Assets                        |          | 7,084   | 7,076    | 7,083    | 7,083   | 7,083   |
| Tangible Assets                          |          | 211     | 1,258    | 1,334    | 3,228   | 7,970   |
| Investments                              |          | 36      | 0        | 73       | 73      | 73      |
| Current Assets                           |          | 9,030   | 12,485   | 11,504   | 4,955   | 2,036   |
| Stocks                                   |          | 157     | 508      | 712      | 593     | 882     |
| Debtors                                  |          | 477     | 613      | 932      | 932     | 893     |
| Cash                                     |          | 7,896   | 11,364   | 9,859    | 3,430   | 261     |
| Other                                    |          | 500     | 0        | 0        | 0       | 0       |
| Current Liabilities                      |          | (4,612) | (4,966)  | (7,231)  | (6,495) | (7,163) |
| Creditors                                |          | (456)   | (596)    | (961)    | (225)   | (893)   |
| Short term borrowings                    |          | (1,075) | 0        | 0        | 0       | 0       |
| Other                                    |          | (3,080) | (4,370)  | (6,270)  | (6,270) | (6,270) |
| Long Term Liabilities                    |          | (20)    | (65)     | (73)     | (73)    | (6,073) |
| Long term borrowings                     |          | (20)    | (20)     | (22)     | (22)    | (6,022) |
| Other long term liabilities              |          | 0       | (45)     | (51)     | (51)    | (51)    |
| Net Assets                               |          | 11,729  | 15,789   | 12,691   | 8,771   | 3,925   |
| <b>CASH FLOW</b>                         |          |         |          |          |         |         |
| Operating Cash Flow                      |          | (3,255) | (4,751)  | (6,007)  | (4,528) | (4,203) |
| Net Interest                             |          | 34      | 95       | 120      | 99      | 34      |
| Tax                                      |          | 0       | 0        | 0        | 0       | 0       |
| Capex                                    |          | (248)   | (1,131)  | (459)    | (2,000) | (5,000) |
| Acquisitions/disposals                   |          | 0       | 500      | 119      | 0       | 0       |
| Equity Financing                         |          | 10,528  | 9,810    | 4,701    | 0       | 0       |
| Dividends                                |          | 0       | 0        | 0        | 0       | 0       |
| Other                                    |          | (403)   | 0        | 0        | 0       | 0       |
| Net Cash Flow                            |          | 6,657   | 4,523    | (1,527)  | (6,429) | (9,169) |
| Opening net debt/(cash)                  |          | (146)   | (6,800)  | (11,344) | (9,837) | (3,408) |
| HP finance leases initiated              |          | 0       | 0        | 0        | 0       | 0       |
| Other                                    |          | (3)     | 21       | 21       | 0       | 0       |
| Closing net debt/(cash)                  |          | (6,800) | (11,344) | (9,837)  | (3,408) | 5,761   |

Source: MGC Pharmaceutical accounts, Edison Investment Research

|  |  |  |  |
|--|--|--|--|
| <b>Contact details</b>   |  | <b>Revenue by geography</b>  |  |
| 1202 Hay St<br>West Perth WA 6005<br>Australia<br>+61 8 6382 3390<br>www.mgcpharma.com.au  |  | N/A  |  |
| <b>Management team</b>   |  | <b>Executive chairman: Brett Mitchell</b>  |  |
| <b>CEO and executive director: Roby Zomer</b>  |  | Mr Mitchell is a corporate finance executive with over 20 years' experience in the finance, technology and resources industries. He has been the co-founder of a number of ASX and private companies across these sectors, and holds executive and non-executive directorship roles with his key business interests. His executive management responsibilities cover capital markets, corporate finance, new business strategy and treasury for these companies. |  |
| <b>Founder and managing director: Nativ Segev</b>  |  |  |  |
| Mr Segev founded MGC Pharma in 2014 with the goal of expanding into international markets and raising the quality of medicinal phytocannabinoid products, in addition to making them accessible to patients all over the world. Prior to establishing MGC Pharma, Mr Segev was leader in the medical cannabis industry with a sizeable patient-base. |  |  |  |
| <b>Principal shareholders</b>  |  | <b>(%)</b>   |  |
| Nativ Segev  |  | 4.3  |  |
| <b>Companies named in this report</b>  |  |  |  |
| GW Pharmaceuticals, Tilray, AbbVie, Mylan  |  |  |  |

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