

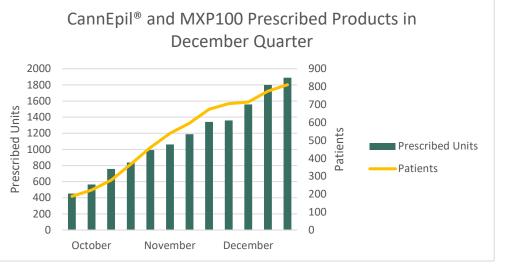
31 January 2020 ASX Code: MXC

# December Quarterly Report – Delivering strong increase in prescription volumes and patient numbers

**MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company')**, a European based 'Seed to Medicine' bio-pharma company specialising in the development and production of phytocannabinoid-derived medicines, is pleased to announce its Quarter Activity report for the three months ended 31 December 2019.

## Key Operational Highlights:

- Strong increase in prescription volumes issued by over 1,500 during the quarter, from 337 at the end of September to 1,890 at quarter end, representing an increase of +450% quarter on quarter
- Patient numbers increased +600% quarter on quarter from 110 to 811
- Delivered material increase in sales of over A\$950,000 for the December quarter, driven by new product demand and increasing return patient numbers as MGC Pharma further establishes a market presence and knowledge of Company's products increases amongst healthcare professionals
- Significant new orders for CannEpil<sup>®</sup> and Mercury Pharma 100 (MP100) received post quarter end in January



- Formal approval received for the sale of CannEpil<sup>®</sup> in Ireland, a key EU member state, following the recommendation by the Health Products Regulatory Authority:
  - The first company, together with Aurora Cannabis Inc., to have cannabinoid-based medicines approved for prescription and sale under the Irish Government's Medical Cannabis Access Programme
  - CannEpil<sup>®</sup> approval in Ireland allows for the approval in other key EU member countries through Mutual Recognition procedure, including Germany and Poland
  - Approval enabled the immediate prescribing of CannEpil<sup>®</sup> in Ireland, manufactured at MGC Pharma's EU-GMP certified production facility in Slovenia



### Key Operational Highlights (continued):

- Execution of strategic 50/50 Joint Venture with BRASILINVEST Global Business and Development ('BrasilInvest') for the dedicated retail sales and marketing of MGC Pharma products into key Brazil and Latin American markets
  - JV Co structure to provide potential new major revenue stream to MGC Pharma by capturing the retail profit margin for sales in Latin America, not just wholesale
  - Distribution in Brazil through MGC Pharma's existing agreement with ONIX Empreendimentos e Participações ('Onix')
  - Import permit received from Anvisa, the National Health Surveillance Agency in Brazil, with first product shipped during December 2019
  - Market in LATAM for the use of cannabis-based medicine is developing rapidly and is expected to be commercially significant for the future sales growth path for MGC Pharma in 2020
- The first bulk shipment of CogniCann<sup>®</sup> arrived in Australia allowing the commencement of the Phase IIb clinical trials in partnership with the University of Notre Dame Western Australia ('UNDWA'), trial to commence imminently
- Significant progress has been made towards the Company's planned London Stock Exchange dual listing, with submission of all final listing documents to the UK regulator in mid-December 2019, and the Company currently waiting for final approvals to be issued
- As part of the Bio-Pharma strategy implementation the company has improved its production costs focusing on Pharma business during the quarter, and the increase of revenues with the ramp up of production
- Post period, launch of new proprietary affordable cannabinoid prescription products, specifically for the Australian and New Zealand markets, to be branded as Mercury Pharma, the first product being 'Mercury Pharma 100'

**Roby Zomer, Co-founder and Managing Director of MGC Pharma**, commented: "The MGC team has delivered tangible results in the last quarter and the continued climb in prescription numbers, which has now passed 2,000, illustrates the clear market demand for our phytocannabinoid derived medicines. We believe this rapid growth trajectory of patients and prescriptions will continue in 2020 - our products are now available on three continents and as the knowledge of MGC Pharma's medicines improves amongst healthcare professionals, we expect continued strong increases in prescription numbers.

"During the quarter, our products received approval to be imported into Ireland and Brazil, together with the recent distribution agreement recently signed with a Peruvian distributor, we will be working to further expand this list and give access to more patients in more countries. It's also noteworthy that the first bulk shipment of CogniCann<sup>®</sup> arrived in Australia, allowing the commencement of the Phase IIb clinical trials in partnership with the University of Notre Dame Western Australia, which is to commence in February.

"I'm also glad to announce that patients in Australia and New Zealand will now have access to a new proprietary, affordable cannabinoid prescription product under the brand name Mercury Pharma. This and all other achievements would have been impossible without the whole MGC Pharma team and their hard work in the last quarter. Thanks to them we've made strong progress and I have full confidence that we will be able to continue delivering growth."



## **Company Strategy**

MGC Pharma remains focussed on delivering its Seed to Medicine business strategy, as was demonstrated during the final quarter of 2019. This strategy includes Research & Development, Manufacturing and Distribution divisions for its phytocannabinoid derived medicines. Firstly, the Research & Development division facilitates the production of cost-effective medicines in collaboration with leading international research institutions and ensures that MGC Pharma remains at the forefront of the sector. Secondly, the Manufacturing division consists of the commercial production of MGC Pharma's phytocannabinoid derived medicines via management of the cultivation, processing and development of the product. Finally, the Distribution division then enables the Company to distribute the final product to its end users.

MGC Pharma's proprietary products are CannEpil<sup>®</sup> and CogniCann<sup>®</sup> which have both been developed internally through the Company's Research and Development division and progressed through to commercialisation. This is in line with the Company's 'Seed to Medicine' strategy with the Company owning all the intellectual property through each stage of a product's development, from the genetics to finished pharmaceutical grade product.

The Company continues to work closely with its designated distributors to onboard further clinics, in addition to independent medical professionals, in each region increasing patient access to its phytocannabinoid derived medicines under the relevant legislation in each jurisdiction.

## Pharma Distribution and Operations

During this financial period, momentum has continued to increase for new prescriptions in Australia, the UK, Brazil and with the recent import approval granted by Ireland, demonstrating the immediate and material revenue generating potential of the Company. Since announcing the 200 prescriptions milestone mid-September 2019 the Company were delighted to see numbers rise significantly over this quarter, sitting at over 2,000 prescriptions in early January 2020. With ~700 new patients added in the December quarter, MGC Pharma had an increase of +600% patients prescribed MGC products. Furthermore, 33% of MXP100 and 43% of CannEpil<sup>®</sup> are repeat prescriptions, these numbers are expected to increase as MGC Pharma further establishes a market presence and knowledge of Company's products increases amongst healthcare professionals.

In addition, MGC Pharma received its first purchase order from the Brazilian distribution partner, ONIX Empreendimentos e Participações ('Onix'), which was manufactured and shipped at the end of December 2019. The agreement with Onix marks the Company's entry into the large Brazilian and Latin American medicinal cannabis markets with a well-established, and strongly credentialed local business partner. The Company has recently received a second purchase order from Onix for patients in Brazil.

Recent passing of key legalisation of cannabis for medicinal uses in Brazil is now expected to have a materially positive impact on prescription numbers from that country. This growth includes patients returning for repeat prescriptions and the Company is observing, on average, over 30 prescription orders per business day. In addition, a number of other patients are being treated with MGC Pharma's products globally via participation in ongoing clinical research. The commercialisation of its portfolio of phytocannabinoid derived medicines is in line with its strategy of becoming a world-leading bio-pharma company through international distribution agreements.

In addition to this, post period the Company signed an agreement with Anden Bio Naturals S.A ('Anden Naturals'), a leading distributor operating in Peru and Bolivia. This exclusive distribution agreement is expected to enhance MGC Pharma's market penetration in Latin America. Partnering with Anden Naturals, which is the first to legally import phytocannabinoid based medicines in Peru, gives MGC Pharma access to their network of over 7,500 pharmacies, private medical clinics and an oncological private insurance system.



Anden Naturals commented: "We firmly believe that cannabis medications have the potential of improving the quality of life of millions of people worldwide. We value the efforts that MGC Pharma has made to put science first and investing in the right pathways that will get medical cannabis recognized as a legitimate (and better) alternative to conventional drugs. Anden Naturals is very excited to work with a company of the calibre of MGC Pharma."

In November, the Company received the first payment of the Grant for \$25,000 from the Australian Commonwealth Government, which is a notable demonstration of Federal Government support for the Company's clinical programs. The Grant supports the CogniCann<sup>®</sup> Phase IIb clinical trial, announced on 28 August 2019, being conducted in collaboration with the UNDWA. The Phase IIb double-blind placebo controlled clinical trial is assessing symptoms associated with dementia and Alzheimer's disease. The trial will include 50 patients, with recruitment underway and treatment expected to begin in February 2020.

### **Expansion into New Markets**

At the end of November MGC Pharma signed a binding term sheet (the 'Term Sheet') with Brazilian business services company, BrasilInvest to establish a Joint Venture Company ('JV Co') for the dedicated retail sales and marketing of MGC Pharma products into key Brazil and Latin American markets. The JV Co is to be incorporated as a 50% (BrasilInvest)/50% (MGC Pharma) ownership structure. This is an important strategic agreement for MGC Pharma, marking its entry into the large Brazilian and Latin American medicinal cannabis markets with a well-established, and strongly credentialed local business partner. Under the Term Sheet executed, JV Co will market and distribute the Company's pharmaceutical products through established retail distribution channels in Brazil and other Latin American countries, including BrasilInvest's extensive network of medical professionals. MGC Pharma will manage the operations of the JV Co.

Along with venturing into the Brazilian market, in December the Company received formal approval for the sale of CannEpil<sup>®</sup> into Ireland following the recommendation by the Health Products Regulatory Authority ('HPRA'). These approvals have now been officially granted by the Irish Ministry of Health, to be one of the first cannabinoid-based medicines approved for prescription and sale under the Irish Government's Medical Cannabis Access Programme.

Access to the Irish market is integral for the Company as not only does it allow MGC Pharma's Good Manufacturing Practice ('GMP') certified medical products to reach more patients in need, but can be seen as a catalyst for fast-tracking follow-on approval applications to prescribe in other European Union ('EU') member state countries such as Germany, Austria, Italy and France. With distribution agreements already in place across Europe, the Company is well positioned for a quick entry to these markets following receipt of the required approvals.

Following this approval, the sale of CannEpil<sup>®</sup> into Ireland is now able to commence, with the first shipment imminent. With an increasing number of patients being treated for drug resistant epilepsy in Ireland, MGC Pharma believe that the high levels of demand from patients and doctors witnessed in the UK and Australia will be replicated in Ireland as doctors and patients familiarise themselves with MGC Pharma's high quality, affordable phytocannabinoid derived medicines.

#### Post Period

In January 2020, the Company launched a new proprietary affordable prescription medicine line, specifically for the Australian and New Zealand markets, to be branded as Mercury Pharma, with the first product being 'Mercury Pharma 100' ('MP100'). MP100, a 100mg/mL CBD solution, will be prescribed by health care professionals in Australia and New Zealand, initially distributed by Australian medicinal cannabis distribution and logistics specialist Cannvalate Pty Ltd and Health House International Pty Ltd in due course.



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Purchase orders for 2,000 units of MP100 have been received in early January, which is set to deliver an immediate positive effect on near term revenues. In addition to the 2,000 prescription mark reached early January 2020, MP100 will help further drive total Australian and New Zealand prescription numbers of MGC Pharma's phytocannabinoid derived medicines in the short term due to the products affordability, and Cannvalate's growing clinical and distribution network.

## Production Facilities – Malta & Slovenia

#### Malta

In August 2019, the Company signed a long-term lease with Malta Industrial Parks for the construction of a ~15,000m<sup>2</sup> (10,482m<sup>2</sup> combined manufacturing facility including GMP certified processing and production, including a 5,240m<sup>2</sup> greenhouse on the roof for cultivation) multi-storey large-scale Good Manufacturing Practice (GMP) compliant pharma production and research facility with a production capacity of over 8,000 units per hour of each product, a material production volume for the pharmaceutical industry. This represented a major event for the Maltese medical cannabis industry as MGC Pharma's facility will be one of the first commercial EU-GMP grade production and research facilities in the country within the cannabis for medicinal use sector.

During the quarter the Company completed all the architectural, structural and GMP designs of the facility and received all construction and planning approvals required to build the fully operating, GMP certified pharma facility. The Company will initiate the civil works and construction works once it completes the listing in the UK, which is the targeted source of funding for the facility construction and fit out.

The facility will allow for the development of expertise for phytocannabinoid derived medicines and research in Malta with subsequent products to be delivered into the European Union and global markets. Construction and planning approvals were received, and site planning completed. The Malta facility will enable MGC Pharma to materially scale up its existing production capacity and future revenue generation potential, which is currently centred on its research and manufacturing facility in Ljubljana, Slovenia.

#### Slovenia

While the works on the Malta production and research facility advances, MGC Pharma's EU-GMP certified Slovenian compounding and manufacturing facility remains the main site for production. The Slovenian facility has the capacity to manufacture up to 12,000 prescription products per month. Once operating at half of the facility's full capacity, and based on a 70% CannEpil<sup>®</sup> and 30% CogniCann<sup>®</sup> sales split at current market pricing as previously announced, the Company expects to start generating positive operating cashflows which will used to fund ongoing research and development costs including clinical trials.

There is the possibility of expanding the production capacity of the facility in Slovenia, and the Company is exploring this potential following the increase in sales and new territories being opened, such as LATAM and more EU countries following the approval of Irish Ministry of Health.

## Corporate

During the quarter the Company significantly advanced its plans to complete a dual listing on the London Stock Exchange ('LSE'), including lodging final documentation during December. The Company had been planning to complete its listing in London by the end of 2019 and remains confident that it will be able to do so, once final procedures with the UK regulatory authorities has been completed. Following the UK legalising the prescription of medicinal cannabis in November 2018, MGC Pharma has positioned itself to be one of the first companies utilising cannabis for medicinal purposes, to list on the LSE, or any major exchange, in the United Kingdom.



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Authorised for lodgement by the Board, for further information, please contact:

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## About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC, OTCQB: MGCLF) is a European based bio-pharma company developing and supplying affordable standardised phytocannabinoid derived medicines to patients globally. 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 phytocannabinoid derived medicines for the growing demand in the medical markets in Europe, North America and Australasia. MGC Pharma has a robust product offering targeting two widespread medical conditions – epilepsy and dementia – and has further products in the development pipeline.

Employing its 'Seed to Medicine' strategy, MGC Pharma has partnered with renowned institutions and academia to optimise cultivation and the development of targeted phytocannabinoid derived medicines products prior to production in the Company's EU-GMP Certified manufacturing facility. MGC Pharma has a number of research collaborations with world renowned academic institutions, and recent research conducted in collaboration with the National Institute of Biology and University Medical Centre Ljubljana, highlighted the positive impact of using specific phytocannabinoid formulations in the treatment of glioblastoma, the most aggressive and so far therapeutically resistant primary brain tumour.

MGC Pharma has a growing patient base in Australia, the UK, Brazil and Ireland and has a global distribution footprint via an extensive network of commercial partners meaning that it is poised to supply the global market. In order to meet the demands of becoming a key global supplier the company is constructing a 15,720m<sup>2</sup> GMP state of the art facility in Malta.

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+Rule 4.7B

# Appendix 4C

## **Quarterly report for entities subject to Listing Rule 4.7B**

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

MG	C PHARMACEUTICALS LTD		
ABN Quarter ended ("current quarter")			
30 116 800 269 31 DECEMBER 2019			
Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	475	888
1.2	Payments for		
	(a) research and development	(1,286)	(2,428)
	(b) product manufacturing and operating costs		
	i) cost of sales	(482)	(1,443)
	ii) operating costs	(748)	(1,397)
	(c) advertising and marketing	(116)	(199)
	(d) leased assets	-	-
	(e) staff costs	(319)	(585)
	(f) administration and corporate costs	(790)	(1,442)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	11
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	457	457
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(2,805)	(6,138)

2.	Cas	h flows from investing activities		
2.1	.1 Payments to acquire:			
	(a)	property, plant and equipment	(150)	(321)
	(b)	businesses (see item 10)	-	-
	(c)	investments	-	(2)



Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(150)	(323)

3.10	Net cash from / (used in) financing activities	(80)	5,380
3.9	Other	-	-
3.8	Dividends paid	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.6	Repayment of borrowings	-	-
3.5	Proceeds from borrowings	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	(80)	(376)
3.3	Proceeds from exercise of share options	-	6
3.2	Proceeds from issue of convertible notes	-	-
3.1	Proceeds from issues of shares	-	5,750
3.	Cash flows from financing activities		

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	4,282	2,354
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,805)	(6,138)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(150)	(323)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(80)	5,380



Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.5	Effect of movement in exchange rates on cash		
	held	(225)	(251)
4.6	Cash and cash equivalents at end of quarter	1,022	1,022

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	968	4,228
5.2	Call deposits	54	54
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,022	4,282

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	440
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Director and executive services fees, and reimbursement of corporate administrative costs

#### 7. Payments to related entities of the entity and their associates

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

#### Corporate advisory costs

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8.	<b>Financing facilities available</b> Add notes as necessary for an understanding of the position	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1	Loan facilities	NIL	NIL
8.2	Credit standby arrangements	-	-
8.3	Other (please specify)	-	-

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

NIL

\$A'000 9. Estimated cash outflows for next quarter 9.1 Research and development 170 9.2 Product manufacturing and operating costs 451 9.3 Advertising and marketing 77 9.4 Leased assets 67 9.5 Staff costs 540 9.6 Administration and corporate costs 301 Other 9.7 -9.8 Total estimated net cash outflows 1,606

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-



#### **Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

[lodged electronically without signature]

Sign here:

Group Chief Financial Officer

Date: 31 January 2020

Print name: Rutchi Kaushal

#### Notes

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- 2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.