

27 October 2020

ASX Code: MXC

# September 2020 Quarterly Activity Report

# **Key Highlights**:

- MGC Pharma passes key production and sales milestone at the end of the quarter, with over 7,000 of its proprietary EU GMP cannabinoid-based medicine units sold led by Australia and Brazil
- September delivered substantial increases in week on week unit sales, which continued into mid-October for 6 consecutive record weeks
- The Company strengthened its Board with the appointment of healthcare and biotech industry expert Evan Hayes as an Independent Non-Executive Director, bringing 20+ years of commercial healthcare and biotechnology experience, including senior executive roles within Blackmores Limited
- Agreements signed with IM Cannabis Corp and LYPHE Group for the distribution of CannEpil® in • Israel and Mercury Pharma products in the UK respectively
- ArtemiC<sup>™</sup> Phase II clinical trial on COVID-19 infected patients, designed with the scientific aim • to target inflammatory complications, expanded to additional hospitals in Israel and India
- Phase II interim results from the first 10 patients treated showed ArtemiC<sup>™</sup> met all its primary • end points for the safety and efficacy of the treatment on COVID-19 infected patients
- Recruitment now completed for the Phase II clinical trial, with full final certified results on 50 COVID-19 infected patients on track to be released in November 2020
- Import Licence and a cannabis cultivation research permit awarded from the Australian Office of Drug Control
- Binding term sheet signed with Cannvalate Pty Ltd to acquire 100% of the operating clinic-based assets, data and intellectual property of its wholly owned subsidiary Medicinal Cannabis Clinic

MGC Pharmaceuticals Ltd (ASX: MXC, 'MGC Pharma' or 'the Company'), a European based biopharma company specialising in the production and development of phytocannabinoid-derived medicines, is pleased to announce its Quarterly Activity report for the three months ended 30 September 2020.

# Pharma Operations

As at 30 September 2020, the Company had total accumulated unit sales of 6,973, which is now well in excess of 7,000 units. The growing order pipeline of Mercury Pharma products in Australia, and breaking into new large markets such as Brazil in recent months, is now set to deliver strong December quarter sales and quarterly revenue results for the Company. The substantial recent increase is attributable to a new bulk order strategy and the Import Licence granted to the Company in July (refer ASX release 8 July 2020) which allows for the direct importation and distribution of any MGC Pharma Schedule 4 and Schedule 8 medicinal cannabis products into Australia by the Company.

During July and August some product export permit and transport logistics delays were encountered in Europe due to COVID-19 related complications, which delayed bulk order product deliveries until September, and the related cash receipts for these sales into October. This was rectified and reflected in the recent record week on week sales results as announced for September and October, and the Company is proactively managing this operational risk as best as possible during the new European COVID-19 outbreak, and expects to minimise any future delays with new systems in place.





# Strategic biopharma industry appointments to strengthen Board and leadership

During the quarter the Company strengthened its Board and leadership team with recruitment biopharma industry expertise with the appointment of Evan Hayes as an Independent Non-Executive Director and Strategic Advisor, Sabina Suljaković as Qualified Person and Head of the Quality Assurance in Slovenia and Amir Polak as Chief Technology Officer and Head of Pharmaceutical Production.

Evan Hayes is a highly experienced Board member and brings over 20+ commercial and leadership experience within the healthcare and biotechnology sectors. Mr Hayes graduated with a Master of Science 1st Class Honours (Biotechnology) from the National University of Ireland, Galway and prior to this he finished first in his class from the National University of Ireland, Cork with a Bachelor of Science degree (Honours). Mr Hayes' has also won the Daniel O'Carroll Award for Scientific Research.

Mr Hayes is currently the Asia Pacific Managing Director of Factors Group, Canada's largest natural health company. Prior to this Mr Hayes was the Director of Sourcing and Product Development at Australia's largest natural health company, Blackmores, leading the Procurement, Technical, New product development, and Strategic sourcing divisions and managed a budget of \$250m.

# **Research and Development**

## ArtemiC<sup>™</sup> Phase II clinical trial for COVID-19 infected patients

In May 2020, MGC Pharma commenced a Phase II double-blind, randomized, placebo controlled clinical trial to evaluate the safety and efficacy of a natural anti-inflammatory based formulation ArtemiC<sup>™</sup> on patients diagnosed with COVID-19. This followed receipt of Ethics Committee approval on the 17<sup>th</sup> April 2020 for approval of the trial at Nazareth Hospital EMMS in Israel and on 28<sup>th</sup> of April 2020 at Hillel Yaffe Hospital in Israel.

During September the trial was geographically expanded to the Mahatma Gandhi Mission's Medical College & Hospital in India, and the Rambam Academic Hospital in Israel, where treatment has also commenced.

Interim results of the trial showed ArtemiC<sup>™</sup> met all its primary end points for the safety and efficacy of the treatment on the first 10 patients. The statistically proven results show two (2) important clinical outcomes. Firstly, a significant improvement in clinical parameters of patients in the treatment group, and secondly that no adverse events (AE) occurred, demonstrating the preliminary safety of the treatment based on the initial 10 patients (refer ASX release 20 August 2020).

Patient recruitment of the full 50 patients required to finalise the trial has now been completed with the trial results expected to be available in November 2020.

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### Import licence and cannabis cultivation research permit received

MGC Pharma was awarded an Import Licence and a cannabis cultivation research permit from the Australian Office of Drug Control, progressing the Company's Australian operations and supporting its fully vertically integrated nature to medicine business model.

The receipt of an Import Licence marked a significant step forward for the Company's commercialisation strategy as it allowed the importation of any MGC Pharma Schedule 4 and Schedule 8 medicinal cannabis products into Australia directly by the Company, which was previously facilitated by third parties.

This also allows MGC Pharma to bulk import its products directly resulting in significant cost savings to the Company including logistics and handling costs.

The cannabis cultivation research permit enables the Company to proceed with its botanical research projects in collaboration with Royal Melbourne Institute of Technology which includes cultivating and breeding strains in order to test against cancer cells. The botanical research projects are initially focusing on melanoma and prostate cancers.

## New Malta research and manufacturing facility underway

During the quarter the Company commenced renovation works on a research facility in Malta to be used for in house Clinical Research Organisation (CRO) activities which encompass its R&D and analytics services, with the initial stage of the CRO facility now completed. This is the first part of the Company's stated plans to establish a research and commercial manufacturing base in Malta. The Company has now commenced work to extend the facility for it to be utilised for the commercial manufacturing of ArtemiC<sup>™</sup> in Malta following successful Phase II clinical trial results (results expected in November 2020). The completions of the renovations of the Malta facility would create a European hub for ArtemiC<sup>™</sup> with a distribution agreement in place for the Russian, European and Israeli markets with pharma distributor KS Kim, part of the SK Pharma group.

## **Pharma Distribution**

## First high THC products shipped direct to patients in Brazil

In October 2020, the Company announced it had completed the first shipments of its Mercury Pharma line which includes the high THC ratio products directly to patients in Brazil through its binding supply and distribution agreement with Brazil-based ONIX Empreendimentos e Participações ('ONIX').

In a major operational achievement, MGC Pharma has become the first company globally to ship high THC formulations directly to a patient's door in Brazil under the country's Compassionate Use Program, without the need to visit a pharmacy. This creates potential for immediate development of material new sales and cashflow pipeline - new patients are registering daily in Brazil for MGC Pharma products in the weeks after the first successful patient delivery.

#### Binding term sheet signed for the import and sales of CannEpil® in Israel

The Company executed a binding term sheet with IM Cannabis Corp. (IMC), one of the leading cannabis companies in Israel with operations in Europe, for the exclusive wholesale import, sales and distribution of CannEpil<sup>®</sup> in Israel.

IMC is an international medical cannabis company with a well-known suite of medical cannabis products in Israel. IMC was recently listed on the Canadian Securities Exchange (CSE:IMCC). In Europe, IMC has established a medical cannabis operation first with its distribution subsidiary in Germany and augmented by strategic agreements with EU-GMP standard certified suppliers.

Under the terms of the agreement, IMC will be appointed as the exclusive wholesale importer of CannEpil<sup>®</sup> in Israel for a period of five years provided it meets minimum annual sales level and each purchase order is to be a minimum €50,000. IMC will also be responsible for the promotional activity and distribution of CannEpil<sup>®</sup>.



## UK Distribution agreement signed with LYPHE Group

MGC Pharma signed a distribution agreement with leading UK medicinal cannabis provider LYPHE Group Limited (LYPHE), providing the Company direct access to LYPHE's established distribution channels in the UK. LYPHE has extensive networks and has developed a patient-access and distribution ecosystem which positions it as the leader in the UK's rapidly expanding medicinal cannabis market.

As part of the distribution agreement, LYPHE will prescribe and dispense the Company's affordable Mercury Pharma products under LYPHE labels to patients at its clinics. The Company has received an initial purchase order for 900 units of its Mercury Pharma products as a direct shipment sale.

# Financial and Corporate

#### \$15million financing facility providing funding for future growth and drive sales

The Company has entered into a convertible securities financing agreement (Agreement) with Mercer Street Global Opportunity Fund, LLC (Mercer) a United States based investment group, to provide funding of up to a total of A\$15m.

The \$15m financing facility provides MGC Pharma with access to significant capital in order to fully execute its business commercialisation strategy, accelerate all its clinical trial and research programs, and fund the Company through to its cashflow break-even target of H1CY 2021.

#### Binding term sheet for the acquisition of Medicinal Cannabis Clinic

MGC Pharma signed a binding term sheet with Cannvalate Pty Ltd to acquire 100% of the operating clinic-based assets, data and intellectual property of its wholly owned subsidiary Medicinal Cannabis Clinic (MCC). MCC is a leading Australian medicinal cannabis clinic with a large and existing doctor and patient network. MGC Pharma's acquisition of MCC's assets, along with its import and distribution capability will reduce supply chain costs which will in turn lead to increasingly more affordable, high-quality cannabinoid medications for an expanding patient base across Australia. Settlement of the acquisition is expected to complete in coming weeks.

#### **Cannaglobal Investment Update**

Cannaglobal has recently closed a non-brokered private placement of units to raise an aggregate of \$2.5m at \$0.21 per Unit. The proceeds are anticipated to be used to fund Cannaglobal's ongoing research and development activities through their wholly owned subsidiary Sansero Life Sciences Inc, build out the "A Good Mushroom" brand, and for working capital purposes. Cannaglobal will continue to raise funds over the next two weeks, at which time they plan to execute and a second closing.

Furthermore, Cannaglobal has announced that Sansero has signed a research partnership agreement with the University of Toronto, through which Sansero will be studying the effects of our drug formulation on the mammalian body. The Company's equity holding in Cannaglobal is a non-core investment asset for MGC Pharma, and is held following the sale of the MGC Derma business to Cannaglobal in January 2019.

#### Outlook

With patient recruitment complete for MGC Pharma's ArtemiC<sup>™</sup> Phase II clinical trial, the trial is expected to complete in October with publication of the full results, following independent technical review and statistical analysis, expected in November 2020, per the original project timeline announced. The Company remains confident the full results of the trial will be in line with interim results received in August 2020 which MGC Pharma expects it to create major commercial opportunities for the Company.

The Company's core pharma research and commercial operations have performed strongly in 2020, and with the growing order pipeline of Mercury Pharma products in Australia, and breaking into new large markets such as Brazil in recent months, set to deliver strong December quarter sales and revenue results.



# Appendix 4C

The Company had \$1.4m cash at the end of the September 2020 quarter. In accordance with Section 6 of the attached Appendix 4C, the Company confirms the total \$245k was for executive director fees, non-executive director fees and corporate costs during the quarter.

As detailed in the Appendix 4C, expenditure for the quarter has been spent on \$1.064m for research and development, \$301k for manufacturing and operating costs, \$67k for advertising and marketing, \$301k for staffing costs and \$572k for administration and corporate costs.

--Ends--

## Authorised for release by Roby Zomer, CEO & Managing Director, for further information please contact:

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# About MGC Pharma

MGC Pharmaceuticals Ltd (ASX: MXC) 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 'Nature 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 including recent research highlighting the positive impact of using specific phytocannabinoid formulations developed by MGC Pharma 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 and Brazil and has a global distribution footprint via an extensive network of commercial partners meaning that it is poised to supply the global market.

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Name of entity

# Appendix 4C

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

MGC PHARMACEUTICALS LTD	
ABN	Quarter ended ("current quarter")
30 116 800 269	30 SEPTEMBER 2020
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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	100	100
1.2	Payments for		
	(a) research and development	(1,064)	(1,064)
	(b) product manufacturing and operating costs		
	i) cost of sales	(301)	(301)
	ii) operating costs	(120)	(120)
	(c) advertising and marketing	(67)	(67)
	(d) leased assets	-	-
	(e) staff costs	(301)	(301)
	(f) administration and corporate costs	(572)	(572)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	2
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	423	423
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(1,900)	(1,900)

2.		h flows from investing activities		
2.1	Рау	ments to acquire:		
	(a)	entities	-	-
	(b)	businesses	-	-
	(c)	property, plant and equipment	(1,027)	(1,027)
	(d)	investments	(10)	(10)
	(e)	intellectual property	-	-
	(f)	other non-current assets	-	-

ASX Listing Rules Appendix 4C (17/07/20)

<sup>+</sup> See chapter 19 of the ASX Listing Rules for defined terms



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Cons	olidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	292	292
	(e) intellectual property	-	-
	(f) 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	(745)	(745)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1	1
3.2	Proceeds from issue of convertible debt securities	2,250	2,250
3.3	Proceeds from exercise of options	2	2
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(54)	(54)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (loan to third party)	-	-
3.10	Net cash from / (used in) financing activities	2,199	2,199

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,887	1,887
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,900)	(1,900)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(745)	(745)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,199	2,199

ASX Listing Rules Appendix 4C (17/07/20)

+ See chapter 19 of the ASX Listing Rules for defined terms



Cons	olidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
4.5	Effect of movement in exchange rates on cash		
	held	(12)	(12)
4.6	Cash and cash equivalents at end of quarter	1,429	1,429

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	1,374	1,832
5.2	Call deposits	55	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)	1,429	1,887

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	245
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

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7.	<b>Financing facilities available</b> Note: the term "facility' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	NIL	NIL
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-

7.5	Unused financing facilities available at quarter end	NIL
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7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,900)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	1,429
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	1,429
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	0.75

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:
  - 8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: The Company has implemented a series of admin and operating cost reductions commencing in the March quarter, to manage the business appropriately through the Covid-19 pandemic, and this is ongoing. Also due to Covid-19 related delays to export of bulk product shipments out of Europe during July/August, there was a delay in product sales in these months and related cash receipts. This has been rectified in September and October as announced, with cash receipts from these sales now occurring post September 30 and will be in the December quarter.

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: The Company currently has in place a financing agreement in place with Mercer Street Global Opportunity Fund LLC for funding of up to \$15m. The Board is constantly reviewing its working capital position and the future need for capital raisings or other financing options and is confident of its ability to raise additional funding as required for the operation of the core business.



8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

**Answer:** Yes, the Company is able to continue operations as a going concern, as it has a \$15m financing facility in place together with other funding options available to the Board.

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

## **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.

27 October 2020

Date: .....

[lodge electronically without signature]

Authorised by: .....

Roby Zomer – Managing Director

#### Notes

- 1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- 2. If this quarterly cash flow 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 cash flow 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.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- 5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.