

26 October 2021

ASX Code: MXC

LSE Code: MXC

## September 2021 Quarterly Activity Report

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### Key Highlights:

- **CimetrA™** granted import approval by the government of India for emergency use authorisation process
- US\$24m 3-year Supply and Distribution Agreement executed with US based company, AMC Holdings Inc. (AMC), launching MGC Pharma into the USA Healthcare market
- As part of the Agreement, AMC to obtain a US National Clinical Trial Number to facilitate US based research into MGC Pharma's products
- 1000 units of **CimetrA™** ordered by AMC to fast track the US approval process
- **CannEpil®** becomes the first government reimbursed medical cannabis product in Ireland
- Patent Application submitted for a Cannabinoid Drug Delivery System to European Intellectual Property Office with the patent expected to be granted in 2022
- UK Import permit granted for **CannEpil+**, which has been made available for free on compassionate grounds to ten patients for six months, whose treatment will be monitored as part of an Observational Trial using a data collection App provided by Alta Flora
- **ArtemiC™** approved for sale and granted a Certificate of Free Trade in the European Union
- The September quarter delivered another strong quarter with \$964k of cash receipts, and \$564k of Phytocannabinoid medicine sales for the 3 months ended 30 September
- September and June quarters combined have delivered a record \$2.2m in cash sales receipts for a consecutive 6 month period, with increasing month on month sales generated from new key markets including the United Kingdom and Ireland

**MGC Pharmaceuticals Ltd ('MGC Pharma' or 'the Company')**, a European based bio-pharma company specialising in the production and development of phytomedicines is pleased to provide its Quarterly Activity Report for the three months ended 30<sup>th</sup> September 2021.

**Roby Zomer, Co-founder and Managing Director of MGC Pharma, commented:** *"The September quarter has seen MGC Pharma achieve a number of major milestones which have laid the foundations for the continued growth and future success of the Company.*

*Not only this, but we have secured entry into the largest healthcare market in the world through our US\$24m 3-year Supply and Distribution Agreement with USA based AMC Holdings. These are very exciting developments for MGC Pharma, and come alongside our strongest consecutive quarter on quarter result for cash receipts from sales, delivering over \$2.2m of cash inflows for the 6 months ended 30 September.*

*We have achieved so much this year, and look forward to progressing our ambitious plans to achieve market authorisations for a number of our medicines, and being in a position to provide more patients access to our products."*

### **CimetrA™ approved for import for Emergency Use Authorisation in India**

MGC Pharma has been granted approval to import samples of **CimetrA™** into India by the Indian Central Drugs Standard Organisation in order to facilitate final product testing required for the grant of Emergency Use Authorisation for the treatment of patients with COVID-19. If the final testing phase is successful, the temporary import approval will be converted to a permanent approval once **CimetrA™** has been registered as a medicine in India under the Emergency Use Authorisation Protocols. This process is currently expected to be completed in the December quarter.

MGC Pharma also conducted an open label controlled observational trial for **CimetrA™** at the Mahatma Gandhi Mission's Medical College and Hospital as part of the registration process for **CimetrA™** in India for Emergency Use Authorisation. The Trial was conducted on 20 hospitalised patients, including ten patients who were in need of an oxygen supply, and ten who were on mechanical ventilation. In order to meet the physiological limitation of patients with severe cases of COVID-19, the study used a Nasal Formulation, produced in a food grade GMP facility, and released as **ArtemiC™** to the study. The results demonstrated for the first time the efficacy of **CimetrA™** in the treatment of patients with severe COVID-19.

The Clinical Trial demonstrated a significant reduction in one of the main inflammatory markers related to COVID-19, C-reactive protein (**CRP**), an acute inflammatory protein that increases up to 1,000-fold at sites of infection or inflammation. Within COVID-19 patients, CRP is used as one of the main prognostic factors for the clinical deterioration in hospitalised patients.

### **AMC Holdings Agreement**

On August 26 the Company announced the execution of a landmark supply and distribution agreement with US based company AMC Holdings Inc. (**AMC**), the terms of which include a minimum order of US\$24 million over 3 years, and an initial 1<sup>st</sup> year order commitment of US\$3m, and a US\$750,000 deposit. The Agreement also stipulates that AMC will provide a National Clinical Trial Number to allow for MGC Pharma products to be imported into the US and used in clinical trials. During the September quarter MGC Pharma received an initial order of 1,000 units of **CimetrA™** under the Agreement, with the units to be used by research teams as the products undergo Internal Review Board (**IRB**) examination at a number of institutions. Acceptance by the IRBs is the first step to obtaining a National Clinical Trial Number. This Agreement is a crucial achievement in the expansion of MGC Pharma into the US market and in the Company's overall growth strategy.

### **CannEpil® becomes the first medical cannabis product available in Ireland**

On 15 June 2021 MGC Pharma announced that **CannEpil®** (MGC's phytocannabinoid Investigation Medical Product designed to treat Drug Resistant Epilepsy) had been approved for prescription under Ireland's Medical Cannabis Access Program (**MCAP**) as well as receiving approval from the Country's Health Service Executive to be a fully reimbursed medication, making it free of charge for Irish patients prescribed the treatment under the MCAP. As an update to the 15 June Announcement, MGC Pharma advises that **CannEpil®** was officially launched in Ireland on October 14th and has commenced being prescribed to patients.

### **UK Import Permit granted for CannEpil+™**

In September, the Medicines and Healthcare Products Regulatory Agency (**MHRA**) approved **CannEpil+™** for import into the UK through MGC Pharma's clinical access partner Elite PharmaCo. This was the first time a cannabis-based treatment for Epilepsy, currently in Clinical Trial phase, has been approved for import by UK authorities. The treatment is being made available to ten patients on compassionate grounds for six months with treatment data collected in an App provided by Alta Flora.

### **Certificate of Free Trade in Europe for ArtemiC™**

In September, MGC Pharma was granted a Certificate of Free Trade in Germany, and the European Union for the Company's proprietary nutraceutical food supplement, **ArtemiC™** following the successful completion of a Phase II, multi-centre Clinical Trial, demonstrating the enhanced recovery of patients with COVID-19 over the placebo control group. The German Certificate will accelerate entry of **ArtemiC™** into both the EU and to other markets.

### **ArtemiC™ Canadian License update**

On 28 April 2021, MGC Pharma announced that Glow LifeTech, MGC Pharma's North American **ArtemiC™** distribution partner had submitted an application to Health Canada to obtain product licences for **ArtemiC™** variants, **ArtemiC Rescue** and **ArtemiC Support** as Natural Health Products. MGC Pharma has been recently advised that due to a

significant backlog at the Health Products Directorate caused by COVID-19, response and review times have been extended for obtaining licenses. Applications for both products are still active and Glow Lifetech continues to be in contact with the Directorate to obtain the required approvals.

## Research and Development

### Phase III Clinical Trial for CimetrA™

MGC Pharma commenced the Phase III Clinical Trial for CimetrA™ and recruited the first patient at Rambam Medical Centre, Israel, in order to evaluate the effects of the treatment on hospitalised patients infected with moderate forms of COVID-19. The trial was designed to assess the efficacy and safety of the natural anti-inflammatory formulation of CimetrA™, using a Self-Nano Emulsifying Drug Delivery System to increase bioavailability.

### Submission of Cannabinoid Drug Delivery System Patent

On July 15, MGC Pharma announced that it had submitted a Patent Application for a proprietary Cannabinoid Drug Delivery System to the Slovenian Intellectual Property Office. This is a formulation developed in partnership with Graft Polymer which enables higher concentrations of CBD to pass across biological membranes such as the Blood Brain Barrier, and thereby more effectively treating neurological conditions such as Epilepsy and Dementia. The Application was accepted in Slovenia and the Company anticipates the patent will be issued in the next 10 months.

### Data Collection App

MGC Pharma and Alta Flora have created a bespoke version of the Eva App, a healthcare data platform which enables researchers and the medical establishment to determine how plant-based therapies improve patient quality of life. The system captures Patient Reported Outcome Measures which can be used by regulators, manufacturers, and clinicians to assess the safety and efficacy of new medicines.

### Malta Facility

Construction of MGC Pharma's state-of-the-art production and manufacturing facility in Malta is now significantly advanced with construction to be completed on schedule in October. The Malta facility equipment installation and operational commissioning will commence in November and is expected to take approximately 6 months to be completed.

The Company has commenced the process of hiring personnel for the facility to assist with commissioning and commencing the application process for Good Manufacturing Process (GMP) accreditation, with the aim of first production to commence in mid-2022.

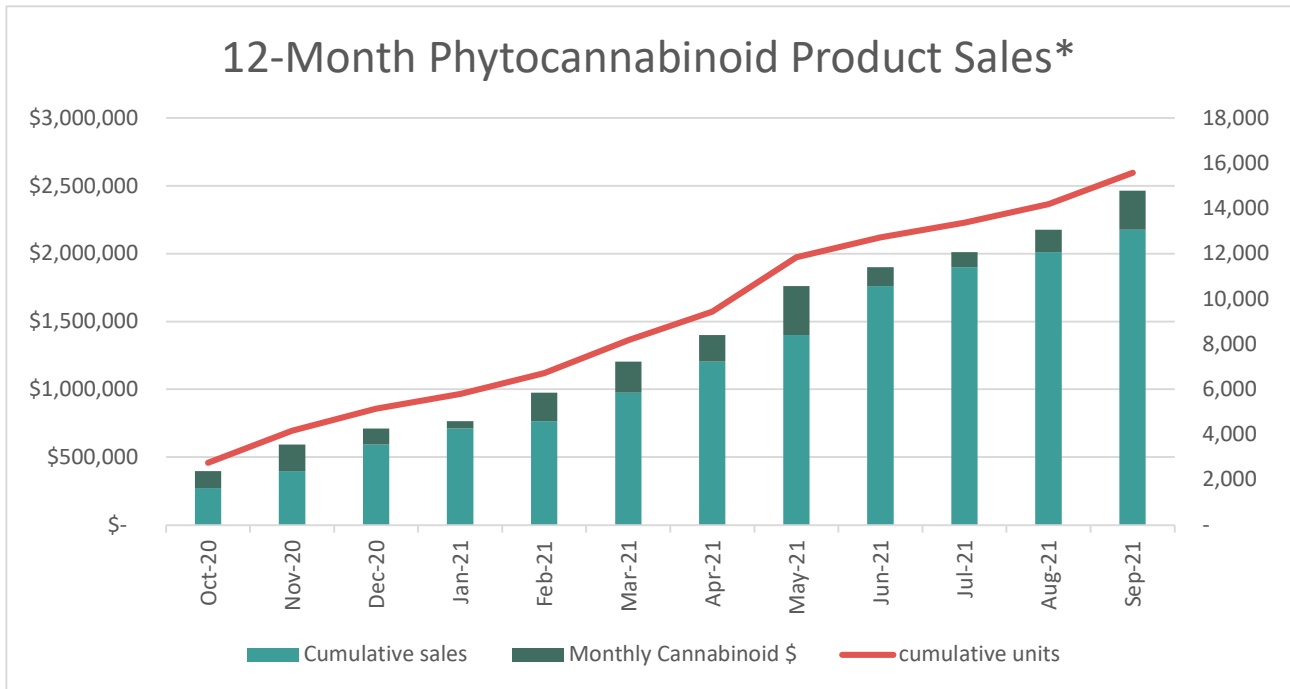
## Financial and Corporate

The Group had ~\$4.2m cash at bank at the end of the September quarter, with access to an additional \$9.25m undrawn from its \$15m financing facility with Mercer Street Opportunity Fund LLC (**Mercer Facility**). In accordance with Section 6 of the accompanying Appendix 4C, the Company confirms that during the quarter payments to related parties totalling \$242k relate to both Executive and Non-Executive Director fees and corporate costs. As detailed in the accompanying Appendix 4C, expenditure for the Quarter includes \$456k for research and development, \$810k for manufacturing and operating costs (including inventory), \$726k staffing costs and \$599k for administration and corporate costs (including Director fees). MGC Pharma received government grants, mostly from Malta Enterprise in relation to the facility being constructed, amounting to \$655k.

## Operations and Sales

The September quarter delivered another strong quarter of sales performance with \$964k of cash receipts from customers, and \$564k revenue from Phytocannabinoid product sales.

Importantly, both the September and June 2021 quarters combined have delivered a record \$2.24m in cash receipts from customers over the 6-month period, with increasing month on month sales generated from new key markets, such as the UK and Ireland. Both markets have started to deliver on their potential to become significant new independent markets and sales pipelines for the Company, delivering a return on the strategic investment that the Company has made in these markets to create opportunities over the past few years.



\*MXC Revenues and product sales Phytocannabinoid products only, excludes supplement sales such as ArtemiC™.

MGC Pharma is proud to advise that sales of **CannEpil®** into Ireland have commenced during October, in Ireland, with CannEpil being granted full insurance coverage by the government, allows for significant and rapid market growth. In the UK, sales through the Company's key distribution partner Lyphe, are increasing and the outlook is very positive, and opportunities for further distribution are expanding as the market in the UK is opening up. Globally MGC Pharma continues to expand its distribution partners for its current portfolio of phototherapeutics.

During the Quarter the Company also introduced flower sales into MGC Pharma's available patient product line, with the flower sales exceeding initial expectations. July was a quieter sales month than expected due to separate COVID-19 logistics disruptions to materials and packaging, and the implementation of a new Australian internal sales, distribution and logistics model which delayed the timing of some revenue recognition for product sales in the quarter. But this was only a minor timing delay and resulting revenues will be carried through and be reflected in the December quarter.

The outlook for the December quarter is very positive, with the monthly sales pipeline for the Company's phytocannabinoid medicines for October expected to continue the trend shown in the month of September, coupled with delivery of the next \$1m ArtemiC order to Swiss PharmaCan. This next large ArtemiC delivery is expected to occur in the next few weeks, as production was completed in October.

MGC Pharma expects strong sales growth and cash receipts in the December quarter as a result of the above, and:

- European purchase orders for the upcoming December quarter have already exceeded the last 2 quarters combined
- Ireland's **CannEpil®** launch in early October already contributing to sales
- Potential **CimetrA™** Emergency Use Authorisation approval in India, which would lead immediately to commercial supply contract negotiations
- **CimetrA™** launch in the USA through strategic medical partner AMC, enabling MGC Pharma to more active in the world's largest pharmaceutical market.

--Ends--

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

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## About MGC Pharma

MGC Pharmaceuticals Ltd (LSE: MXC, 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, 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.

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## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

MGC PHARMACEUTICALS LTD

**ABN**

30 116 800 269

**Quarter ended ("current quarter")**

30 SEPTEMBER 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	943	943
1.2 Payments for		
(a) research and development	(456)	(456)
(b) product manufacturing and operating costs		
i) cost of sales / inventory	(810)	(810)
ii) operating costs		
(c) advertising and marketing	(54)	(54)
(d) leased assets	-	-
(e) staff costs	(726)	(726)
(f) administration and corporate costs	(599)	(599)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	655	655
1.8 Other (maturity of deposit)	366	366
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(681)</b>	<b>(681)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(785)	(785)

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
<b>2.2 Proceeds from disposal of:</b>		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
<b>2.3 Cash flows from loans to other entities</b>	-	-
<b>2.4 Dividends received (see note 3)</b>	-	-
<b>2.5 Other (cash acquired through assets acquisition)</b>	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(785)</b>	<b>(785)</b>
<b>3. Cash flows from financing activities</b>		
<b>3.1 Proceeds from issues of equity securities (excluding convertible debt securities)</b>	-	-
<b>3.2 Proceeds from issue of convertible debt securities</b>	-	-
<b>3.3 Proceeds from exercise of options</b>	508	508
<b>3.4 Transaction costs related to issues of equity securities or convertible debt securities</b>	(21)	(21)
<b>3.5 Proceeds from borrowings</b>	-	-
<b>3.6 Repayment of borrowings</b>	-	-
<b>3.7 Transaction costs related to loans and borrowings</b>	-	-
<b>3.8 Dividends paid</b>	-	-
<b>3.9 Other (loan entity which where control was gained after quarter-end)</b>	(318)	(318)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>169</b>	<b>169</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
<b>4.1 Cash and cash equivalents at beginning of period</b>	5,433	5,433
<b>4.2 Net cash from / (used in) operating activities (item 1.9 above)</b>	(681)	(681)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(785)	(785)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	169	169
4.5	Effect of movement in exchange rates on cash held	67	67
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>4,203</b>	<b>4,203</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	4,147	5,378
5.2	Call deposits	56	55
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>4,203</b>	<b>5,433</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

<b>Current quarter \$A'000</b>
242
-

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.



7.	Financing facilities available <i>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.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	15,000	5,750
7.4	<b>Total financing facilities</b>	<b>15,000</b>	<b>5,750</b>

7.5 **Unused financing facilities available at quarter end** 9,250

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.

\$15M Convertible note facility with Mercer Street Opportunity Fund LLC. Refer to ASX announcement on 10 September 2020 for further information.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(681)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	4,203
8.3	Unused finance facilities available at quarter end (Item 7.5)	9,250
8.4	Total available funding (Item 8.2 + Item 8.3)	13,453
8.5	<b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>19.75</b>

*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:

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: N/A

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: N/A

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: N/A

*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.

26 October 2021

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.