mgc pharma

31 October 2022 ASX Code: MXC LSE Code: MXC

September Quarter Activity Report

and Cash Flow Statement

Key Highlights:

- Interim study results from the **CimetrA[™]** clinical trial demonstrates improvement in multiple key parameters for the drug study groups, with no significant COVID-19 related complications compared to 62.5% of the placebo group.
- ArtemiC[™] Support Long COVID study completed, demonstrating ArtemiC[™]'s efficacy in treating symptoms of Long COVID.
- Revised AMC US Supply and Distribution contract to include ArtemiC[™] facilitates a US\$1m order for ArtemiC[™] Rescue.
- September quarter cash inflows from sales of \$1.2m.
- New US\$10m finance facility executed with Mercer Street Capital to provide funding to continue key clinical trials and execution of sales growth strategy with Sciensus Rare.
- Cost reduction strategy implemented, including closure of non-core clinical trials.
- Appointment of London based pharma industry experienced Chief Commercial Officer.

MGC Pharmaceuticals Ltd ('MGC Pharma' or 'the Company') a European based bio-pharma company specialising in the production and development of plant inspired medicines, is pleased to provide its Quarterly Activity Report for the three months ending 30th September 2022.

Roby Zomer, co-founder and Managing Director of MGC Pharmaceuticals, commented: "MGC Pharma continues to make progress on its clinical pipeline, which remains the primary focus of the business, together with driving our immediate sales growth. This will be aided by our new Chief Commercial Officer, Robert Clements, whose 25 years of pharma industry sales experience will be invaluable as we expand our sales and distribution network.

Additionally, the acquisition of the ZAM data collection App has the potential to change the way people engage with their healthcare professionals, and we look forward to updating the market on its progress with our partner, ZAM Software."

Company Activities

Clinical Trial Progress CimetrA[™]

During the September quarter MGC released interim results from its ongoing **CimetrA™** dose finding study currently underway in Israel. The results, from the 16 patients with COVID-19 who had completed the Clinical Trial at the time of the September Announcement, show improvements in multiple parameters measuring the clinical condition of the patient, including respiratory rate and oxygen saturation, both of which showed a vector of improvement against the placebo group.

The data also showed that 62.5% of patients in the placebo group reported adverse events related to the symptoms of COVID-19, with no patients from both drug study groups demonstrating any COVID-19 related adverse events.

Whilst the sample size on which the interim analysis has been performed is small and cannot be used for Inferential statistical analysis, the results thus far are very encouraging and in line with the Company's expectations.



Results from the dose finding study will be used to determine the most effective concentrations of the active ingredients for patients diagnosed with COVID-19. Additionally, the trial incorporates other key parameters, including a full safety and pharmacovigilance profiling, and an extensive pharmacokinetic profile of **CimetrA™**, which are to be used to outline the registration and administrative process required for seeking Market Authorisation.

In July, MGC received study and importation approval from the South African Health Products Regulatory Authority for the Phase IIb dose finding study. This site will be the second trial site for the Phase IIb study, which is currently underway in Israel.

ArtemiC[®]

In July 2022, MGC released results from a clinical study into **ArtemiC Support**[®]'s effectiveness in treating symptoms of Long COVID, which are ongoing health problems that COVID-19 patients can experience after suffering from COVID-19. The study, co-sponsored by Swiss PharmaCann and Glow LifeTech, demonstrated the statistically significant efficacy of **ArtemiC Support**[®] in reducing the severity of a range of Long COVID symptoms, including Dyspnea, Cough, Asthenia, Headache, and Mental Confusion. The study, undertaken in Barcelona, enrolled 150 patients suffering from Long COVID who administered **ArtemiC Support**[®], an Oral Spray, for 6 weeks under supervision of their doctor, with their progress being measured using a Post-COVID Functional Scale (PCFS) and a 10-point Likert scale 1, 2, 3 and 6 weeks after treatment initiation.

CannEpiL®

Results released in August from a double-blind, randomised and placebo controlled clinical study on the effect of **CannEpil®** on driving performance, show that:

- Oral doses of 20:1 CBD to Δ9-THC did not impair overall vehicle weaving, standard deviation of lateral position (SDLP) was not significantly altered in those administered **CannEpil**[®]l compared with placebo across the full drive.
- Standard deviation of speed (SDS) was not increased within 20 minutes after taking the medication.
- Sedation was not significantly increased during testing following **CannEpil®**'s administration, however onset of increased sedation was reported by several participants between three to six hours after **CannEpil®** was administered.
- The 'contentedness', measured by the Bond-Lader Visual Analogue Scale and Profile of Mood States was significantly increased following the driving task with those patients administered **CannEpil**[®].

It is hoped that the findings from this trial, among other things, will help to inform policy guidelines concerning responsible use of medicinal cannabis products.

September Quarter Sales Update

Cash receipts from customers for the September quarter were in line with average receipts over recent Quarters, with sales revenue of \$765k down on prior quarters due mainly to the planned Slovenian GMP manufacturing facility shutdown undertaken to facilitate a production capacity capex upgrade and EU GMP audit in August/September, together with the European summer seasonal impact on **Artemic[™]** sales (with sales peaking during the autumn and winter months).

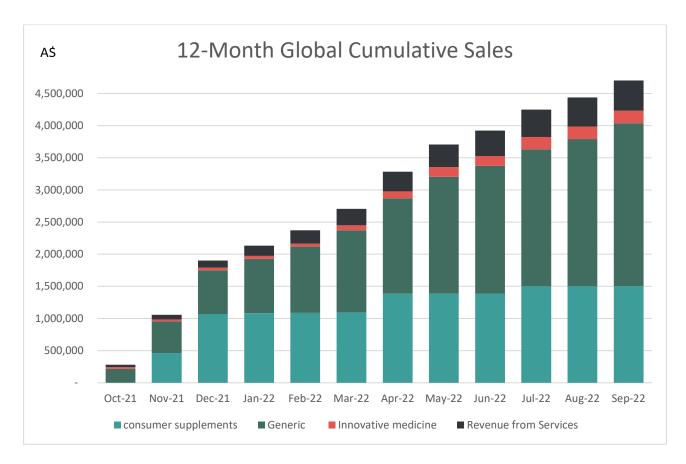
The product sales mix of Generic products across the portfolio has changed, with medical flower sales in the Australian market rapidly increasing and replacing oils sales, a trend MGC will continue to capitalise on. Whilst **CannEpil®** volumes have been resilient over the past quarter MGC anticipates that they will steadily increase as more territories join the early access program scheme.

Category	A \$
Consumer Supplements	103,208
Generic	538,292
Innovative medicine	75,664
Total Product Sales	717,364
Total Services Revenue (incl. clinical services)	47,909
Total Sales Revenue	765,273

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EU GMP Production Facility – 200% Production Capacity Upgrade Completed and GMP Audit

The Company completed a scheduled capex upgrade to its Slovenian EU GMP compounding and production facility during the quarter, which has now increased the production capacity by 200% at the facility. This production line installation and upgrade was completed in August, before the facility went through its regulatory EU GMP audit for renewal of its 3 year permit in September.

The EU GMP certification audit of MGC Pharmaceutical's production facility in Slovenia, was undertaken in Sept 2022, with approval granted in October and formal EU GMP re-certification to be finalised in November. Following the successful completion of the audit, the Company received regulatory approval for the immediate recommencement of production at the facility approved by the regulatory authority, which is now back in production. The recommencement of production at MGC's Slovenian production facility will enable MGC to meet increasing demand for its cannabinoid medicine products alongside its ongoing clinical trials, and specifically to supply product for the Sciensus Rare Supply and Distribution Agreement.

Malta Facility Update - GMP audits in final phase

In addition to the work undertaken at the Company's Slovenian production facility, an audit of the Maltese GMP facility has been completed and critically, met all key GMP audit criteria. As a result, formal EU GMP certification as a production facility is now expected to be formalised in early 2023, at which point the Company will have two, high-quality, EU GMP certified production facilities from which it will be able to manufacture and distribute its proprietary IMP products **CimetrATM**, **CannEpil®** and **CogniCann®** across the EU, and globally.



Commercial Partnerships

During the quarter the MGC entered into a new convertible securities financing agreement with Mercer Street Global Opportunity Fund, LLC, a fund managed by Mercer Street Capital Partners LLC, to provide the Company with up to ~\$14.6m (US\$10m) of funding to execute its business growth strategy and fast track commercial and corporate activities. By the end of September MGC had received ~\$3.6m (US\$2.5m) of funding through the Mercer Facility, with ~\$10.9m (US\$7.5m) remaining available.

In August MGC and AMC Holdings Inc. updated their US Supply and Distribution Agreement, to include **ArtemiC[™]**, which facilitated AMC placing a ~\$1.4m (US\$1m) order for MGC Pharma's **ArtemiC[™]** Rescue. The contract, which originally covered MGC Pharma's **CimetrA[™]**, **CogniCann[®]**, and **CannEpil[®]** products, was amended to include **ArtemiC[™]** as a result of ongoing evaluation of the US market for MGC's product line by AMC.

During the quarter MGC Pharma executed a binding Share Purchase Agreement (SPA) to acquire 40% of ZAM Software Limited (**ZSL**), through the issue of ~\$980,000 (£700,000) of MGC shares. ZSL is the owner of real-time data collection software with proprietary Artificial Intelligence (AI) algorithms, and the developer of the ZAM app. Through the collection of patient entered data, the App will provide users with a more complete understanding of their health, and treatment outcomes. In addition to recording medical data, the ZAM App is intended to provide patients with instructions on how and when to take medication (per their medical practitioner's advice), measure treatment progress, as well as have the ability for a qualified medical practitioner to prescribe alternative medication to patients following an online consultation through telehealth services such as MGC Pharma's MCC telehealth clinic based in Australia.

Corporate News

The Company appointed experienced pharmaceutical industry executive Mr Robert Clements to the newly created position of Chief Commercial Officer, which brings together oversight and leadership of all MGC Pharma's key commercial functions including Business Development, Marketing and Sales. Mr Clements brings with him over 30 years of international experience in the pharmaceuticals sector, having previously held several senior roles in business development, commercial and marketing. Most recently, Mr Clements was Vice President Business Development of the international rare medicines division of Sciensus Rare, an international pharmaceutical services company based in the Netherlands, specialising in the provision of rare disease medicines. The Company recently appointed Ms Yifat Steuer as its Chief Operational Officer. Ms Steuer is a qualified accountant with experience in the pharmaceutical and logistics industries.

In accordance with Section 6 of the accompanying Appendix 4C, the Company advises that during the September 2022 quarter, payments to related parties totalling A\$271k, relate to the payment of both Executive and Non-Executive Director fees.

As detailed in the accompanying Appendix 4C, expenditure for the September quarter includes A\$555k on research and development, A\$643k as final payment for construction costs of the Malta GMP facility, A\$1m on inventories and cost of sales, A\$1.4m on staffing costs (including director fees) and A\$1.6m on administration and corporate costs.

--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, focused on developing and supplying accessible and ethically produced plant inspired medicines, combining in-house research with innovative technologies, with the goal of finding or producing treatments to for unmet medical conditions.

The Company's founders and executives are key figures in the global pharmaceuticals industry and the core business strategy is to develop and supply high quality plant inspired medicines for the growing demand in the medical markets in Europe, North America and Australasia.

MGC Pharma has a robust development pipeline targeting two widespread medical conditions and has further products under development.

MGC Pharma has partnered with renowned institutions and academia to optimise the development of targeted plant inspired medicines, to be produced in the Company's EU-GMP Certified manufacturing facilities.

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 Quarter ended ("current quarter")	
30 116 800 269	30 Sept 2022

Cons	olidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities	1,242	1,242
1.1	Receipts from customers	1,242	1,242
1.2	Payments for	(555)	(555)
	(a) research and development	(555)	(555)
	 (b) product manufacturing and operating costs i) cost of sales / inventory ii) operating costs 	(1,046)	(1,046)
	(c) advertising and marketing	(114)	(114)
	(d) leased assets	-	-
	(e) staff costs	(1,397)	(1,397)
	 (f) administration and corporate costs (including product registrations) 	(1,645)	(1,645)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	24	24
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(2)	(2)
1.7	Government grants and tax incentives	-	-
1.8	Other (maturity of deposit)	-	-
1.9	Net cash from / (used in) operating activities	(3,493)	(3,493)

2.	Cash flows from investing activities	Current quarter \$A'000	Year to date (3 months) \$A'000
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-



Cons	olidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
	(c) property, plant and equipment	(643)	(643)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(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 (cash acquired through assets acquisition)	-	-
2.6	Net cash from / (used in) investing activities	(643)	(643)

3.	Cash flows from financing activities	Current quarter \$A'000	Year to date (3 months) \$A'000
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	3,630	3,630
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
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 entity which where control was gained after quarter-end)	-	-
3.10	Net cash from / (used in) financing activities	3,630	3,630



4.	Net increase / (decrease) in cash and cash equivalents for the period	Current quarter \$A'000	Year to date (3 months) \$A'000
4.1	Cash and cash equivalents at beginning of period	1,886	1,886
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,493)	(3,493)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(643)	(643)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,630	3,630
4.5	Effect of movement in exchange rates on cash held	(468)	(468)
4.6	Cash and cash equivalents at end of quarter	912	912

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	856	1,830
5.2	Call deposits	56	56
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)	912	1,886

6.	Payments to related parties 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	271
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.	

The payments in 6.1 are payments to directors of the company for their service during the quarter.



of those facilities as well.

7.	Financing facilities available 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	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	14,600	3,630
7.4	Total financing facilities	14,600	3,630
7.5	Unused financing facilities available at quarter end	-	10,970
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		

\$14.6M Convertible note facility with Mercer Street Opportunity Fund LLC. Refer to ASX announcement on 29 July 2022 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)	(3,493)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	912
8.3	Unused finance facilities available at quarter end (Item 7.5)	10,970
8.4	Total available funding (Item 8.2 + Item 8.3)	11,882
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	3.4

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.

31 October 2022

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.