

30 January 2023 ASX Code: MXC LSE Code: MXC

# December 2022 Quarter Activity Report and Cash Flow Statement

# Key Highlights:

- Clinical trials to be used in the US FDA Investigational New Drug submission continue to demonstrate the efficacy and the anti-inflammatory effects of CimetrA<sup>™</sup>.
- Clinical study to assess the impact of **ArtemiC<sup>™</sup>** Support on patients suffering from Long-COVID completed, demonstrating **ArtemiC<sup>™</sup>** Support's ability to allieviate physical syptoms and mental confusion of study participants.
- Peer reviewed Glioblastoma research findings published in international scientific research journal MDPI.
- Upgrade and EU GMP recertification of Slovenian production and research facility completed, along with independent audit and inspection by key EU/UK distribution partner Sciensus Rare.
- Key US and EU commercial partnerships expanded, with delivery of \$1m order of **ArtemiC™** to US supply and distribution partner, AMC Holdings Inc., completed.
- As a result of a strategic review of its business operations, the board has implemented further cost reductions, with ~35% reduction in director fees, and key executive officers of the Company agreeing to a 10-20% reduction in their cash remuneration, effective 1 Dec 2022.
- Executive restructure finalised with appointment of Chief Operational Officer, and UK captial markets advisor, SW4 Partners, appointed.

**MGC Pharmaceuticals Ltd ('MGC Pharma'** or **'the Company')**, a European based pharmaceutical company specialising in the production and development of plant inspired medicines, is pleased to provide its Quarterly Activity Report for the three months ending 31<sup>st</sup> December 2022.

**Roby Zomer, co-founder, Managing Director and CEO of MGC Pharmaceuticals, commented**: "MGC Pharma has made significant strides in advancing its products along the clinical pipeline, fulfilling additional regulatory conditions required for the IND application for CimetrA in the US, as well as continuing to undertake and publish research across MGC's sectors of interest, and are proud of the progress achieved thus far. The new year has begun, and with it, new opportunities to continue the progress that was made in the December Quarter."

# **Company Activities**

# Clinical Trial Progress CimetrA<sup>™</sup>

During the December quarter MGC Pharma continued to progress its proprietary Investigation Medicinal Product (IMP), **CimetrA<sup>™</sup>**, through the clinical trial pathway in preparation for lodging an Investigational New Drug (**IND**) application with the US Food



and Drug Administration, with the completion of a clinical trial to further assess the efficacy of **CimetrA<sup>™</sup>**. The study assessed the efficacy of a range of dosages of the **CimetrA<sup>™</sup>** formulation on rodents exhibiting symptoms of the cytokine storm, and as in previous studies, including a human Phase II clinical trial, demonstrated the anti-inflammatory effect of the treatment. The successful results from this study, a requirement for the US FDA IND application, supports the Company's continued focus on progressing the IND application, which if successful, is the first stage of the regulatory process to allow **CimetrA<sup>™</sup>** to be sold in the US, globally one of the largest markets for pharmaceuticals.

## ArtemiC™

In October, MGC Pharma released the results of a clinical study, sponsored by Swiss PharmaCann AG, which assessed the impact of **ArtemiC<sup>™</sup> Support** on patients suffering from Post-acute COVID Syndrome ("**Long COVID**")<sup>1</sup>. The study monitored post-symptomatology and biological markers in regular blood tests from 60 vaccinated patients suffering from Long COVID across Spain. The nutraceutical was shown to alleviate symptoms associated with Long COVID including pain, mental confusion and depression, sleep disorders, and inflammation. The blood tests demonstrated a reduction of inflammation and enterohepatic involvement, as well as liver reactant proteins in the patients. The study is an important and exciting step forward in proving the clinical benefits of **ArtemiC<sup>™</sup>** Support for people suffering from Long COVID.

#### **Pre-clinical Research collaboration**

MGC Pharma's research, in collaboration with the National Institute of Biology in Slovenia, on the effect of Cannabidiol (**CBD**) and Cannabigerol (**CBG**) extracts on Glioblastoma<sup>2</sup> cells was published in the November 2022 edition of the peer review science journal, MDPI<sup>3</sup>. The research tested the effect of CBD and CBG extracts provided by MGC Pharmaceuticals, on Glioblastoma cells. The study found that the GPR55 and TRPV1 receptors were the best targets for the antagonistic cannabinoids CBD and CBG (in an optimised mixture) to eliminate Glioblastoma (**GBM**) stem cells, and avoided using tetrahydrocannabinol (THC) a psychoactive compound found in cannabis, which is potentially harmful, particularly in older GBM patients, with MGC Pharma looking to undertake further tests in animal experiments and clinical trials.

#### **GMP Certification update**

During the December quarter MGC Pharmaceuticals completed the upgrade of its GMP certified production facility in Slovenia, increasing production capacity by ~200%. The facility also underwent a GMP audit, a requirement for its ongoing GMP certification, with the facility's GMP certification extended to February 2027.

The commissioning of MGC Pharma's Maltese production facility continued during the quarter with EU GMP certification expected in early 2023. Once granted, the GMP certification will allow MGC to manufacture and distribute its proprietary IMP products **CimetrA™**, **CannEpil®**, and **CogniCann®** from the Maltese facility globally.

#### **December Quarter Sales Update**

In early December, the Company completed the delivery of its largest order of **ArtemiC<sup>™</sup>** to US supply and distribution partner, AMC Holdings Inc. The US\$1,000,000 (~A\$1,389,000) order was the first substantial commercial delivery of the product under the US distribution agreement and was made available online and through independent pharmacies. Fulfilment of the **ArtemiC<sup>™</sup>** order resulted in a significant increase in sales revenue for the December quarter on quarter-on-quarter basis.

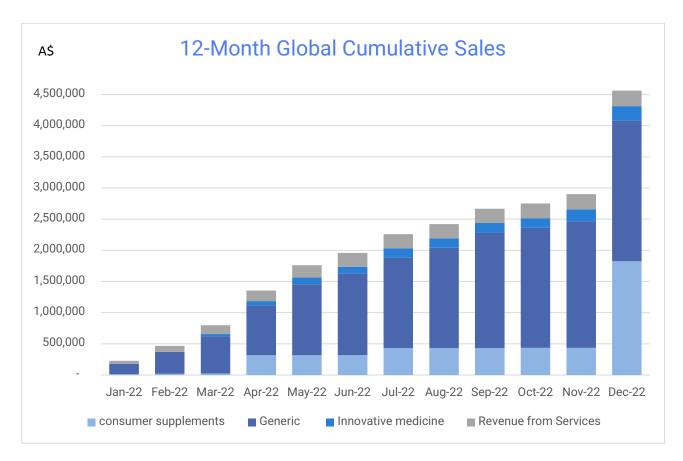
<sup>&</sup>lt;sup>1</sup> ASX release, 25 October 2022, titled "Long COVID Clinical Study Results for Artemic<sup>™</sup> Support" (https://www.asx.com.au/asxpdf/20221025/pdf/45gq3m3ql684jc.pdf) <sup>2</sup> Glioblastoma is an aggressive form of cancer affecting the central nervous system.

<sup>&</sup>lt;sup>3</sup> Research Paper "The Cytotoxic Effects of Cannabidiol and Cannabigerol on Glioblastoma Stem Cells May Mostly Involve GPR55 and TRPV1 Signalling"

<sup>(</sup>https://www.mdpi.com/2072-6694/14/23/5918/pdf)



Category	A\$
Consumer Supplements	1,390,000
Generic	404,000
Innovative medicine	82,000
Total Product Sales	1,876,000
Total Services Revenue (incl. clinical services)	19,000
Total Sales Revenue	1,895,000



#### **Corporate and Commercial News**

#### Sciensus Rare partnership - Commencement of CannEpil® distribution to UK/EU markets

MGC Pharma and Sciensus Rare have continued to build on their pharma distribution relationship during the quarter, completing a number of key steps including the completion of a supply chain quality assurance audit by Sciensus Rare of MGC Pharma's manufacturing facilities in Malta and Slovenia.

MGC and Sciensus are planning for the distribution of the first **CannEpil**® units within EU territories and the UK during Q1 2023, with the completion of key compliance and import approval documentation required for Early Access Distribution in the UK, including the issue of a Non Objection to Import (NOI) notice by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), which allows the initial importation of **CannEpil**® for the supply on request by UK clinicians. A UK Home Office import licence application is currently in progress with stock to be supplied once all required approvals are in place.

As part of the expansion into the EU an application for the admission of **CannEpil**® to the Danish Medical Cannabis Pilot Programme (DMCPP) will be made by a local Danish entity partner. Once admission of **CannEpil**® into the programme has been approved, doctors may commence prescribing the product.



MGC Pharma and Sciensus are also working with AIFA, the Italian medicines regulatory agency, to achieve a Licenza messa in commercio limitata (temporary license to commerce) which will be used to supply networks with large patient cohorts already identified.

In both Portugal and Spain clinicians have been identified to apply for "named patient" use of **CannEpil**®, and detailed clinical product meetings arranged with these networks, with the expectation that submissions will be made during February 2023.

In addition to further EU territories which will come on stream, the partnership with Sciensus Rare has been expanded to cover additional territories across Central and Eastern Europe, along with the Middle East and North Africa. The companies are working closely together to supply **CannEpil**® as a vital Early Access Medicine for unmet medical need to as substantial a cohort of patients as possible.

## Appointment of advisor

Due to a recent restructure of the Company's financial and corporate advisor, Hannan & Partners, with their life sciences team moving to UK Advisory firm SW4 Partners, SW4 have replaced Hannam & Partners as the Company's advisors. SW4's team are highly regarded across the UK capital markets and are specialists in the life science and cannabis sectors.

# **Personnel changes**

MGC's leadership team has been enhanced with the appointment of Yifat Steuer as COO / Deputy CEO, while Chairman Brett Mitchell's role as Chairman of the Company's board of directors has transitioned from an executive to a non-executive role.

# **Internal Costs Reductions**

As a result of the ongoing strategic review of its business operations, the board has implemented further cost reductions which enable the Company to direct a greater portion of its working capital to advancing its clinical trial and research programs in 2023. As a result of this review the board agreed to an immediate ~35% reduction in director fees, effective from 1 December 2022. And in addition to the reduction in director fees, the key executive officers (i.e. non-directors) of the Company also agreed to a 10-20% reduction in their cash remuneration, with only the key executive officers to be issued MGC shares in lieu of the reduction in their cash salary.

# Branding

During the December quarter MGC Pharma completed its rebranding process (including the launch of its new website) to fully reflect MGC Pharma's developing position as a pharmaceutical company focussed on the development and production of high-quality plant-inspired medicines to meet international health care demand.

# Funding and Cash Flow Reporting

In the December quarter MGC Pharma received ~A\$1.74m (~US\$1.13m) in funding from Mercer Street Global Opportunity Fund, LLC under the US\$10 million Convertible Securities Financing Facility signed in July 2022, with the proceeds to fund ongoing operations, including progressing clinical trials.

At the end of December, the Company had ~A\$1.134m of cash on hand, and ~\$9.23m (US\$6.4m) of funding capacity available under the Mercer US\$10m Convertible Securities facility.

Accompany this Activity Report is a Cash Flow Report for the Quarter ending 31 December 2022.

In accordance with ASX Listing Rule 4.7C.3 the Company advises that during the December 2022 quarter, payments to related parties totalled \$489K, which consisted of fees paid to executive and non-executive directors of the Company.



As detailed in the accompany Appendix 4C (Quarterly Cash Flow Report), cashflows during the quarter included \$1.01m cash outflows associated with inventory production, \$2.86m for administration costs (including product registration costs), and cash inflows of \$1.16m received by the Company in Government Grants, comprising a \$371k R&D incentive received from the Australian government, and \$789k grant from the Maltese government, and \$1.74m in funding received from the drawdown of the Mercer Convertible Security facility.

--Ends--

### Authorised for release by the Executive Chairman, 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	ABN Quarter ended ("current quarter")		
	30 116 800 269	31 December 2	022
Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		2 9 2 1
1.1	Receipts from customers	1,579	2,821
1.2	Payments for	(504)	(4, 225)
	(a) research and development	(681)	(1,235)
	<ul><li>(b) product manufacturing and operating costs</li><li>i) cost of sales / inventory</li></ul>	(1,014)	(2,059)
	ii) operating costs	(2)	(2)
	(c) advertising and marketing	(211)	(325)
	(d) leased assets	-	-
	(e) staff costs	(1,656)	(3,053)
	<ul><li>(f) administration and corporate costs (including product registrations)</li></ul>	(1,202)	(2,847)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	20	44
1.5	Interest and other costs of finance paid	(0)	(0)
1.6	Income taxes paid	(0)	(3)
1.7	Government grants and tax incentives	1,160	1,160
1.8	Other (GST/VAT refund)	619	619
1.9	Net cash from / (used in) operating activities	(1,388)	(4,880)

2.	Cash flows from investing activities	Current quarter \$A'000	Year to date (6 months) \$A'000
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-

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

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



Cons	olidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
	(c) property, plant and equipment	(60)	(703)
	(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	(60)	(703)

3.	Cash flows from financing activities	Current quarter \$A'000	Year to date (6 months) \$A'000
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	1,736	5,366
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	1,736	5,366



4.	Net increase / (decrease) in cash and cash equivalents for the period	Current quarter \$A'000	Year to date (6 months) \$A'000
4.1	Cash and cash equivalents at beginning of period	912	1,886
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,388)	(4,880)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(60)	(703)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,736	5,366
4.5	Effect of movement in exchange rates on cash held	(66)	(535)
4.6	Cash and cash equivalents at end of quarter	1,134	1,134

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	1,108	856
5.2	Call deposits	26	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)	1,134	912

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	489
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.



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	5,366
7.4	Total financing facilities	14,600	5,366
7.5	Unused financing facilities available at quarter end	-	9,234
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.		

\$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)	(1,388)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	1,134
8.3	Unused finance facilities available at quarter end (Item 7.5)	9,234
8.4	Total available funding (Item 8.2 + Item 8.3)	10,367
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	7.5

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.

30 January 2023

Date:

[lodge electronically without signature]
Authorised by:

Roby Zomer – Managing Director/CEO

#### 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.