

31 January 2022 ASX Code: MXC LSE Code: MXC

December Quarterly Activities Report and Cash Flow

Key Highlights:

- US\$3m (€2.6m) order for CimetrA[™] received from AMC Holdings Inc. under the 3-year US\$24m US Supply and Distribution Agreement, with a US\$750k cash deposit received.
- Strongest quarterly sales, with product sales totalling ~\$1.8m, including continued strong sales growth from the phytocannabinoid medicine line of products.
- December Quarter ~\$1.8m sales revenue excludes the US\$750k cash deposit received from AMC during the Quarter.
- UK institutional and US fund led £5.5m capital raising successfully completed.
- Production completed for A\$1m order of ArtemiC[™] for global distribution partner, Swiss PharmaCan AG.
- Construction of CimetrA™ production facility in Malta completed on time and within budget.
- CimetrA™ Dose Finding Clinical Trial sites established in Israel, and submitted to Ethics Committees in the US, South Africa and Russia.
- Clinical Study on the influence of ArtemiC[™] Support on patients with Long COVID commenced in Spain.
- Cash on hand at 31 December 2021 of ~\$8.1m

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 Activities Report for the three months ending 31st December 2021.

Roby Zomer, co-founder and Managing Director of MGC Pharmaceuticals, commented: "The last quarter of 2021 has encapsulated the year as a whole, with projects coming to fruition as a global business. We have achieved several major landmarks for the growth of the Company, and look forward to building on these successes during 2022. We are particularly proud of the strides that we have made in the advancement of both CimetrA™ and ArtemiC™, as we work towards gaining regulatory approval on these products into key global markets."

Company Activities

AMC USA US\$3m Purchase Order for CimetrA™

In October, MGC Pharma received the first purchase order, valued at US\$3m, from US-based supply and distribution partner, AMC Holdings Inc. (AMC), under the US Supply and Distribution Agreement signed in August 2021. Following which the Company received an upfront US\$750k cash deposit against the US\$3m order from AMC in November. The order represents over 110,000 units of CimetrATM, which is the largest single order that the Company has received for any product to date. AMC and MGC Pharma continue to work towards the grant of import and sales approval for CimetrATM from US authorities, and in conjunction with this process, AMC, along with the University of South Florida and the Holy Cross Hospital in Fort Lauderdale, is preparing to submit applications to facilitate the establishment of clinical trial sites for a number of MGC's products, including CogniCann® and CannEpil® in the US. With Clinical Trial applications for CimetrATM already submitted to the local Ethics Committees in the US hospitals.



Malta Production Facility

Construction of the Company's new production facility located in Malta was completed during the Quarter. The new facility, which is to be used for the manufacture of **CimetrA™**, was completed on schedule and within budget.

MGC Pharma received a ≤ 3.1 million cash grant from the Maltese Government, and once certified, the fully compliant EU GMP production facility will have the capacity to produce over 20,000 units in liquid dose form per day, double that originally planned, making it an important part of MGC's strategy to meet the expected near-term demand for CimetrATM.

The facility will form part of a European manufacturing hub for **CimetrA**TM and other liquid form dose medicines, putting MGC Pharma in a strong position to streamline global distribution through convenient shipping access.

Delivery of A\$1m order of ArtemiC to Swiss PharmaCan AG

During the December Quarter MGC Pharma completed production and delivery of a A\$1m order of **ArtemiC™** for global neutraceuticals distributor partner, Swiss PharmaCan AG (**SPC**). MCG Pharma are anticipating increased order volumes from SPC for **ArtemiC™** following the grant of the Certificate of Free Trade for the product in Germany (granting further access to a wider European market) in September 2021, and the recent approval by Indian authorities for the import and sale of **ArtemiC™** in India (refer ASX announcement dated 7 January 2022).

Application for Emergency Use Authorisation in India

During the December Quarter the Company continued to work with its local Indian partner to secure the registration for Emergency Use Authorisation of **CimetrA**TM in India, with a further patient study now required to be conducted in India to confirm the efficacy of the product for local patients. As announced in the September 2021 Quarter, the Company had made a submission to the Indian Drugs Standard Control Organisation to apply for Emergency Use Authorisation for **CimetrA**TM. The grant of Emergency Use Authorisation would expedite the authorisation process to allow for the commercial import and distribution of **CimetrA**TM in India. The approval process remains ongoing and the Company expects to receive a response from the Indian authorities in Q2 2022.

In line with the Company's strategy to gain access to the Indian market for its products, subsequent to the end of the December Quarter a small batch of MGC Pharma's **ArtemiCTM** Rescue neutraceutical was imported into India after MGC's global supply Partner, Swiss PharmaCan AG was granted import and sales approval for the product by the Indian Authorities. The importation of the batch was used to validate SPC's Indian supply and import processes.

Like **CimetrA[™]**, **Artemic[™]** Rescue is a propriety formulation of MGC Pharmaceuticals Ltd used to treat the symtoms of patients suffering mild COVID-19.

Sales Update

The December Quarter saw the Company achieve its strongest quarterly sales result to date, with sales of ~\$1.8 million. This figure excludes the US\$750,000 deposit received from AMC during the Quarter, which will be recognised as revenue in future months when the products are dispatched to AMC.

The increase in sales revenue for the Quarter was largely influenced by the strong sales of **ArtemiCTM**, the Company's COVID-19 treatment, with sales of **ArtemiCTM** during the Quarter totalling ~\$1.07 million, representing ~60% of the recorded sales. During the December Quarter MGC Pharma also achieved record sales of its cannabinoid products with sales revenue of ~\$720,000 for this category, up ~\$27,000 from the previous high recorded in the June 2021 Quarter. Within the Cannabinoid product range, sales of **CannEpil®** have also seen a significant increase on previous Quarters, with the addition of the product to Ireland's Primary Care Reimbursement Service, which provides the product free of charge to patients prescribed the product, driving the increase in sales.

The Company expects to see increased sales of **ArtemiC[™]** over the next half year as a result of the recent approval for import and sales of the product into India.





Research and Development Update CimetrA™ Dosing Study

In November 2021 the MGC Pharma announced that a dose finding study for CimetrA[™] had been approved by the Israeli Ministry of Health and the Rambam Medical Center's Ethics Committee. The study is being used to determine and define key parameters for the product, including the most effective dosages of the active ingredients, as well as looking at further validating the anti-inflammatory and immune-modulatory effects of CimetrA[™] in a larger scale trial. 240 patients will be recruited to the study across proposed sites in Israel, the USA, South Africa, and Russia, which includes a 28-day observational period in order to exclude long term complications of COVID-19, such as Long COVID and post-COVID.

In December 2021 the Company submitted an application for the establishment of a number of Clinical Trial sites in South Africa to further expand the Clinical Trial program, with regulatory approval for the South African sites expected to be received in early Q1 2022, and as noted above, AMC has submitted the trial with several US hospitals and is currently in the process of preparing applications for the FDA study approval. 5 patients have so far been recruited to the study in Rambam Medical Center, Israel.

The findings of the Dosing Study will be used to inform the dosing used for the **CimetrA**TM Phase III Clinical Study and will be used to further demonstrate the anti-inflammatory profile of the drug, including its affect on cytokines and chemokines production.

Clinical Study on Long COVID

On 20 December MGC Pharma announced that a Clincial Study into the influence of **ArtemiCTM** Support on patients suffering from Long COVID had received Ethics Committee Approval from Spanish reseach foundation IDIAP Jordi Gol on 9th December. The study, co-sponsored by MGC Pharma, will enroll a total of 150 patients for a six week period, under the supervision of their doctor, and is expected to be completed in Q1 2022. Long COVID or Post-acute COVID



syndrone refers to the ongoing health issues that people can experience four or more weeks after first being infected with SARS-CoV-2, the virus reponsible for COVID-19.

Cognicann Phase II Clinical Study Update

The Phase II Clinical Trial for **Cognicann®**, MGC Pharma's Investigational Medicinal Product (IMP) designed to treat patients with Dementia and Alzheimer's disease, and being undertaken by the University of Notre Dame in Perth Western Australia, is currently scheduled for completion early in the June 2022 Quarter. The delay in completing the trial, previously scheduled for December 2021, has been the result of logistics issues affecting the supply of the IMP into Australia, and the restrictions on access to Aged Care Facilities implemented throughout the COVID-19 pandemic, which has hampered the ability of the Clinical Trial staff to access trial participants.

The Phase II **Cognicann**® study is a randomised double blind cross-over study designed to evaluate the potential behavioral benefits **of Cognicann**® on patients with Dementia and Alzheimer's disease. The findings of the current study will be used to determine the future direction of the Clinical Trial process for **Cognicann**®.

Financial and Corporate

£5.5m UK Capital Raising Completed

During December the Company completed a UK Institutional focused £5.5million share placement which saw strong support from institutional investors in the UK and from US based fund Mercer Street Global Opportunity Fund LLC. The proceeds of the Raising will be used to advance Emergency Use Authorisation applications and testing procedures, and the costs of additional CimetrATM dosing trials in the USA, South Africa and Russia; clinical trials for epilepsy treatment, CannEpil® in the USA; and general working capital.

MGC Pharma had ~\$8.1m cash at bank at the end of the December Quarter, with access to an additional \$9.25m undrawn from its \$15m financing facility with Mercer Street Global Opportunity Fund LLC (Mercer Facility). In accordance with Section 6 of the accompanying Appendix 4C, the Company advises that during the December 2021 Quarter, payments to related parties totalling \$461k, relate to the payment of both Executive and Non-Executive Director fees and corporate costs, of which \$153k relates to Placement Fees incurred during the abovementioned capital raising, paid to an entity controlled by Mr Zomer and Mr Mitchell, for services provided to secure funding from Mercer Street Global Opportunity Fund LLC. As detailed in the accompanying Appendix 4C, expenditure for the Quarter includes \$814k for research and development, \$2.1m for manufacturing and operating costs, \$1.3m staffing costs (including Director fees) and \$2.0m for administration and corporate costs. The December Quarter's operating costs were higher than usual with ~\$733k paid to third party consultants for services provided in the preparation and lodgement of applications for Market Authorisation in various countries, in relation to the Company's CimetrATM and ArtemiCTM products.

--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 phytomedicines 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

Quarter ended ("current quarter")

30 116 800 269

31 DECEMBER 2021

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	2,619	3,562
1.2	Payments for		
	(a) research and development	(814)	(1,270)
	(b) product manufacturing and operating costs		
	i) cost of sales / inventory	(2,082)	(2,892)
	ii) operating costs (market authorisations)	(733)	(733)
	(c) advertising and marketing	(345)	(399)
	(d) leased assets	-	-
	(e) staff costs	(1,268)	(1,993)
	(f) administration and corporate costs	(1,307)	(1,907)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	1
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	4	659
1.8	Other (maturity of deposit)	-	366
1.9	Net cash from / (used in) operating activities	(3,925)	(4,606)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities	148	148
	(b) businesses	-	-
	(c) property, plant and equipment	(1,646)	(2,431)



Cons	olidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
	(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	(1,498)	(2,283)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	10,194	10,194
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	508
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(891)	(912)
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)	-	(318)
3.10	Net cash from / (used in) financing activities	9,903	9,472



4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,203	5,433
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,925)	(4,606)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,498)	(2,283)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	9,303	9,472
4.5	Effect of movement in exchange rates on cash held	13	80
4.6	Cash and cash equivalents at end of quarter	8,096	8,096

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	8,040	4,147
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)	8,096	4,203

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	461
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.	



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)	15,000	5,750
7.4	Total financing facilities	15,000	5,750
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)	(3,925)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	8,096
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)	17,346
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	4.42

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

- 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 January 2022
Date:	
Authorised by:	[lodge electronically without signature]
Authorised by.	The Board of Directors

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.