

29 April 2022
ASX Code: MXC
LSE Code: MXC

March 2022 Quarterly Activity and Cash Flow Reports

Key Highlights:

- Strong phytocannabinoid product sales continue in key markets
- Strategic EU and UK distribution agreement for CannEpil and CogniCann signed with leading “at home” medicine supplier, Sciencus Rare
- Malta EU GMP production facility fitout continuing towards full operational status and GMP Certification
- University of Florida Internal Review Board in final stages of approval process to participate in Cimetra™ clinical trials, as a key stage for entry to the USA market
- AMC finalising documentation to lodge US FDA Investigational New Drug Application for Cimetra™

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 31 March 2022.

Roby Zomer, co-founder and Managing Director of MGC Pharmaceuticals, commented: *“This quarter has seen strong consolidation on our Company strategy as we affirm key partnerships with industry leaders and advance our clinical pipeline. We continue to make progress against our key goals, and cement our position as a bio-pharmaceutical company producing treatments for some of the most debilitating conditions globally.”*

Company Activities

Malta Production Facility

During the March Quarter work continued on the equipment fit out at the Company's newly constructed Production Facility in Malta after the Company took possession of the facility in November 2021.

Work throughout the current quarter focused on preparing the facility for EU Good Manufacturing Practice (GMP) certification later in the year, with all medicinal products manufactured or imported into Malta and the EU required to be manufactured in accordance with the principles and guidelines of GMP, proof of which is certification of the facility in which they are manufactured.

Work undertaken during the quarter included:

- Continued work on fitting out the building towards operational design capacity
- Process and system validation work
- Establishing and documenting operating and administrative procedures, including preparation of documentation required to be supplied as part of the GMP certification process.
- Hiring of key administrative and operational staff

Once completed and fully operational, the GMP certified Malta Facility will have the capacity to produce over 20,000 units in liquid form per day, double that originally planned.

Construction of the Malta Facility has been partly funded by the Maltese Government's €3.1 million grant provided through its dedicated economic development authority, Malta Enterprise.

Sales Division Update

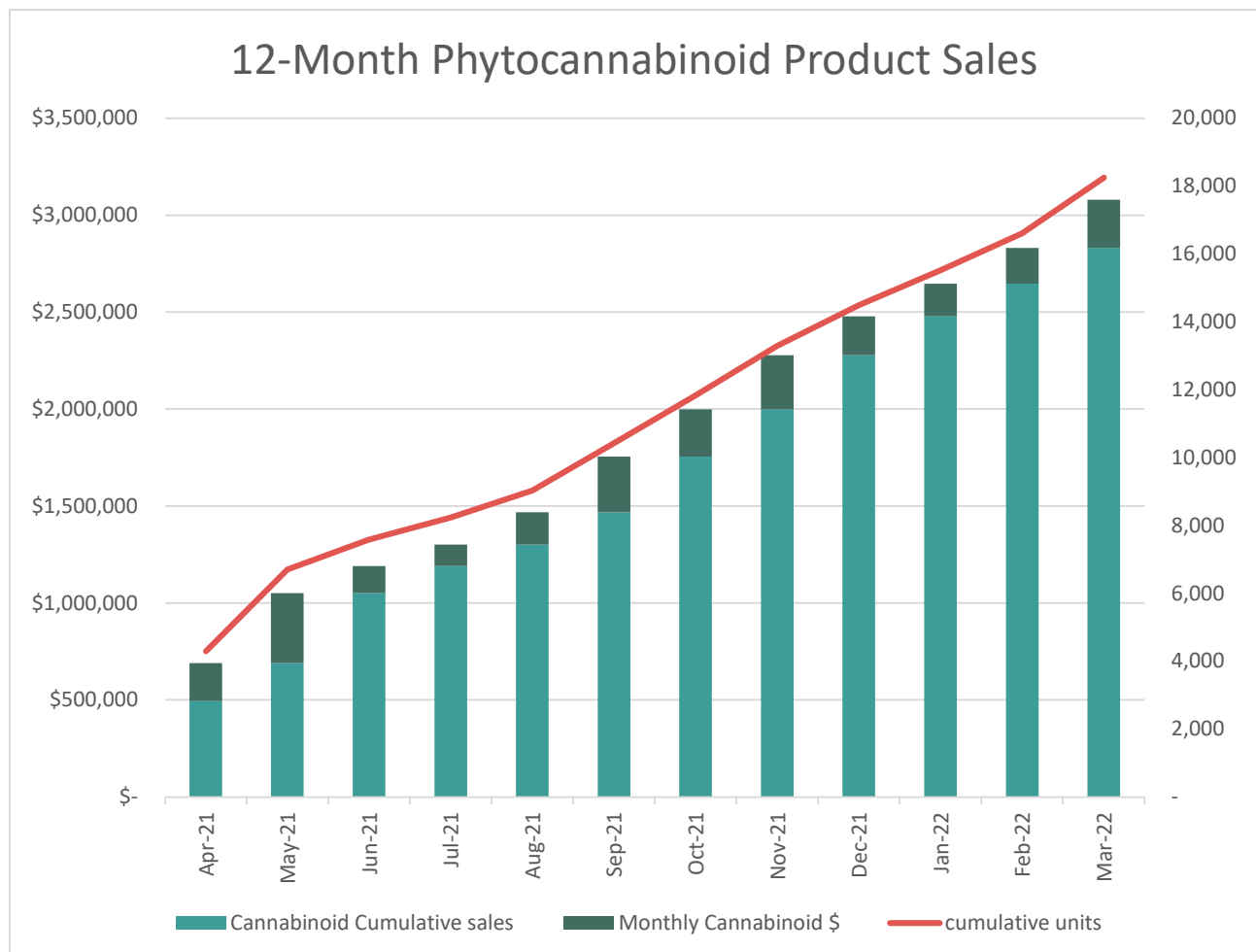
Q3 FY22 produced sales of \$625K, the majority of sales coming from the phytocannabinoid portfolio and the core Australian market, without any material **ArtemiC™** sales in the quarter.

MGC pharma is solidifying its international expansion with a new distribution agreement signed with international partner Sciensus Rare initially focusing on four EU countries and the United Kingdom and plans to expand these initial territories to the whole of Europe. Sciensus Rare is an international pharmaceutical company based in the Netherlands, specializing in the provision of rare disease medicines through decentralised clinical trials and medical early access programs, with over 30-year of experience in providing health care services, and expanding medical access for products in Western Europe.

To further strengthen MGC's presence in Europe, MGC is now selling **CannEpiL™** into the UK with MGC's additional distribution partner in the UK PCCA from Q3 FY22.

MGC is confident that these new European partners, along with a substantial presence in both Ireland and Australia, will contribute significantly to the MGC phytocannabinoid revenue stream for the remainder of 2022 and beyond.

The expected commercial sales from **CimetrA™** is dependent upon Emergency Use Approvals being granted in key target markets including India and the USA, which are still being advanced although progress to formal approvals have taken longer than the Company anticipated to complete.



US Activities – AMC Sales and Distribution Agreement

MGC Pharma has a broad scope Sales and Distribution Agreement with US company AMC Holdings Inc. (**AMC**) which includes AMC facilitating the establishment of clinical trials for MGC Pharma's leading products in the USA. AMC is a privately held, US based distribution and marketing company bringing cutting edge bio-pharmaceutical products currently in clinical trials or commercial production overseas, into the US healthcare marketplace, which arranges for

leading US researchers, academic institutions, and physicians to join existing clinical trials abroad, and establish US based trials for promising bio-pharmaceutical products.

AMC is currently working with the University of Florida to finalise the process to enable the university to participate in ongoing clinical trials for **CimetrA™**. As part of this process AMC is will also lodge an Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA) for **CimetrA™**, which, once approved, will authorise the use of **CimetrA™** in US clinical trials. To assist with the **CimetrA™** IND application AMC are in the process of engaging an experienced pharmaceuticals consultancy to manage the application process on their behalf.

Sciensus Rare

Post-quarter end, MGC Pharma announced an exciting partnership with Sciensus Rare, a dedicated and enhanced rare disease medicines service business, for the distribution of **CannEpil** and **CogniCann** in the EU and the UK. With a strong pharmaceutical reputation and presence in Europe, and established relationship with regulatory bodies in the region, Sciensus will assist MGC in obtaining market authorisations for the products. And further to this, with their existing sales team infrastructure, Sciensus will be able to contribute immediate revenue for MGC Pharma in Europe by through the early access cannabis programs.

Patent Approval - CimetrA™

Subsequent to the end of the March Quarter MGC Pharma was advised by the Slovenian Intellectual Property Office (SIPO), that it had been granted a Patent for the Company's proprietary medicine **CimetrA™**. In May 2021 MGC Pharma announced that a Patent Application for **CimetrA™** lodged with SIPO in the April 2021 had been accepted by SIPO, giving the application priority for lodging subsequent applications with other IP Agencies in a number of additional jurisdictions.

The grant of the Patent provides MGC Pharma with commercial protection for the intellectual property associated with **CimetrA™**'s unique formulation and manufacturing process for a period of 20 years.

CimetrA™ is a nano-micellular pharmaceutical synergetic composition consisting of Curcumin, Boswellia, Vitamin C and optionally, Artemisinin, Cannabinoids and/or Nitroxides. The composition can be manufactured in liquid or solid pharmaceutically acceptable carriers, and has antioxidant, anti-inflammatory, and immuno-modulating properties. **CimetrA™** is designed for multiple therapeutic applications utilising Graft Polymer's GraftBio™ self-nanoemulsifying drug delivery system (SNEDDS).

Product and Clinical update MGC Proprietary Products

CimetrA™

CimetrA™ is a nanoparticle micellar formulation based on a pharmaceutical synergetic composition consisting of Curcumin, Boswellia and Vitamin C, and can be designed for multiple therapeutic applications including the prevention of severe inflammation by its control of increased Cytokine production, the forerunner of a Cytokine Storm, which is believed to be the main reason for mortality in severe COVID-19 patients. Due to its anti-inflammatory and immunomodulatory effects on preventing a generalised inflammation and Cytokine Storm, **CimetrA™** is expected to have beneficial effects for people suffering from a range of viral respiratory diseases, including heavy variants of influenza, as well as treating the over production of Cytokines associated with various forms of cancer¹.

A Phase IIb, double blind, controlled Clinical Trial designed to evaluate the effect of **CimetrA™** in patients diagnosed with COVID-19 (referred to as the **Dosing Study**) is currently underway at 2 sites in Israel. 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.

In December 2021, the Company applied to establish a number of clinical trial sites for the Phase IIb study in South Africa, to further expand the clinical trial program. Conditional approval has been obtained and the final regulatory approval for the South African sites is expected to be received later in the year, and as noted above, AMC has submitted an application with the University of Florida's Internal Review Board to facilitate the university participating in the ongoing clinical program, and is in the process of preparing a US FDA Investigational New Drug Application for use of **CimetrA™** in the American clinical trials.

1. [www.ncbi.nlm.nih.gov/pmc/articles/PMC7531591/#:~:text=%E2%80%9CCytokine%20storm%E2%80%9D%20or%20%E2%80%9CCytokine,in%20graft%20versus%20host%20disease;](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7531591/#:~:text=%E2%80%9CCytokine%20storm%E2%80%9D%20or%20%E2%80%9CCytokine,in%20graft%20versus%20host%20disease;https://blog.dana-farber.org/insight/2021/07/what-is-a-cytokine-storm/)
<https://blog.dana-farber.org/insight/2021/07/what-is-a-cytokine-storm/>

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

The Phase III Clinical Trial for **CimetrA™**, commenced in 2021, has ceased enrolling new patients while the Company awaits results of the Dosing Study, which will be used to determine dosages used in the Phase III trial.

In September 2021, MGC Pharma announced that it was seeking Emergency Use Authorisation in India for **CimetrA™** for the treatment of patients with COVID-19. This process is ongoing, with a further patient study required by the Indian Regulatory authority in order to confirm the efficacy of the product for local patients.

ArtemiC™

In January 2022 import approval was granted for MGC's proprietary nutraceutical product **ArtemiC™** Rescue by Indian authorities.

The nutraceutical, developed by MGC Pharma, and incorporating distribution partner Swiss PharmaCan AG's award winning MyCell™ technology, underwent a small batch trial import, which passed all regulatory requirements, resulting in the product being granted a Food Safety and Standards Authority of India license allowing the sale of **ArtemiC™** Rescue across India.

CogniCann®

MGC Pharma's medical cannabis based pharmaceutical product **CogniCann®** has a THC:CBD ratio specifically formulated to treat key symptoms of Dementia and enhance specific cognitive functions.

A Phase II Clinical Trial undertaken by the University of Notre Dame in Western Australia has recently concluded after experiencing delays associated with the Western Australian government's restrictions on entering Aged Care facilities due to the COVID-19 pandemic.

The Clinical Trial was designed to evaluate the potential behavioural benefits of **CogniCann®** on patients with Dementia and Alzheimer's disease.

With the Clinical Trial now completed results from the trial, which enrolled 20 patients at a number of aged care facilities in Western Australia, are expected mid-year.

In addition to the above Notre Dame Clinical Trial, under MGC Pharma's broad scope US Sales and Distribution Agreement with AMC, AMC is also seeking to undertake additional clinical trials for **Congicann®** in the US, subject to receiving requisite US FDA approvals.

CannEpil®

CannEpil® is a phytocannabinoid-derived Investigational Medicinal Product (IMP) drug, designed to treat drug-resistant (refractory) epilepsy with a high CBD, low THC formula.

The drug is currently undergoing a randomised controlled trial investigating the effect of high CBD/low THC on driving performance, sedation and mood, in partnership with the Swinburne University of Technology in Australia (**SUT**). This trial was also affected by Australian COVID-19 isolation rules which had delayed the ability of SUT to enrol and undertake testing of participants. With the COVID-19 restriction now largely removed, SUT is now expending to complete the trial mid-year and results published shortly thereafter.

Corporate

During the March Quarter there were a number of changes to the corporate team located in MGC Pharma's Perth office, including the transition to a London based Chief Financial Officer (CFO) and Group Financial Controller for the Company as announced in April, and Mrs Rachel Kerr, having returned from maternity leave, transitioning from her role as Joint Company Secretary to a part time position with the Company's sales department.

Subsequent to the Quarter end, MGC announced the appointment of a London based CFO, Angela-Marie Graham, to oversee the Company's accounting and finance functions as part of its business strategy to establish the Company's corporate office in the UK to support its European operational centres, following its listing on the London Stock Exchange in February 2021.

--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

30 116 800 269

Quarter ended ("current quarter")

31 March 2022

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	1,291	4.853
1.2	Payments for		
	(a) research and development	(1,307)	(2,577)
	(b) product manufacturing and operating costs		
	i) cost of sales / inventory	(1,179)	(4,071)
	ii) operating costs		
	(c) advertising and marketing	(44)	(443)
	(d) leased assets	-	-
	(e) staff costs	(848)	(2,842)
	(f) administration and corporate costs (including product registrations)	(1,658)	(4,284)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	1
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	659
1.8	Other (maturity of deposit)	-	366
1.9	Net cash from / (used in) operating activities	(3,745)	(8,338)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities	-	148
	(b) businesses	-	-
	(c) property, plant and equipment	(150)	(2,581)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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	(150)	(2,433)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	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	(1)	(913)
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	(1)	9,471

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,096	5,433
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,745)	(8,338)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(150)	(2,433)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1)	9,471
4.5	Effect of movement in exchange rates on cash held	(196)	(129)
4.6	Cash and cash equivalents at end of quarter	4,004	4,004

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	3,948	8,040
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)	4,004	8,096

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	189
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 <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	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)	(3,745)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	4,004
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)	13,254
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	3.54

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:

- 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

- 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

- 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.

29 April 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.