

ASX Announcement

31 Jan 2023

Emyria accepted into National Institutes of Health (NIH) program; completes \$3m placement; expands MDMA-analogue library, commences Phase 3 trial recruitment

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech, is pleased to report on the Company's activities for the quarter ending December 31, 2022.

HIGHLIGHTS FOR THE DECEMBER QUARTER

Accepted into the NIH HEAL Initiative® National Institute of Neurological Disorders and Stroke (NINDS) Preclinical Screening Platform for Pain (PSPP) program. NINDS is part of the U.S. National Institutes of Health (NIH), and the leading funder of neurological research in the USA:

- The PSPP will evaluate Emyria's proprietary formulations of Ultra-Pure cannabinoids for suitability as treatments for pain
- Emyria will focus its EMD-RX7 program on US-FDA registration pathways

(See ASX release 28 Nov 2022)

Expanded our MDMA-analogue library with partners UWA to over 140 proprietary, neurologically active compounds.

- 14 compounds were shipped for safety screening with Eurofins
- 5 compounds sent to Psychogenics in the USA for advanced preclinical screening.
- Additional metabolic studies commenced with an Australian CRO to help evaluate the half-lives of a set of "MDMA 2.0" compounds in mice, rat and human liver cells.

(See ASX release 18 Oct 2022)

Commenced recruitment for pivotal Phase 3 clinical trial of EMD-RX5

After receipt of ethics approval last quarter, recruitment and planning for a Phase 3 trial of EMD-RX5 got underway ahead of the trial's dosing commencement in Jan 2023.

Completed a \$3m placement supported by existing shareholders including Tenmile

Funds raised from the placement will be used to:

- Advance the Phase 3 clinical trial supporting registration and commercialisation activities of EMD-RX5 as an over-the-counter treatment with the TGA
- Support the ongoing development of EMD-RX7, Emyria's high dose CBD
- Advance multiple preclinical screening programs for Emyria's novel MDMA-inspired drug discovery program being developed with the University of Western Australia
- Business development and working capital

(See ASX release 23 Nov 2022)

[1] Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221.

emyria

Emyria's Managing Director, Dr. Michael Winlo, said: "We closed 2022 with a lot of momentum in our drug development programs with the successful initiation of recruitment for our Phase 3 clinical trial for our leading asset, EMD-RX5, and the expansion of our preclinical R&D pipeline of MDMA analogues.

Emyria also strengthened its network of world-leading research partners via acceptance into a prestigious program managed by the NIH and we boosted our cash position with the closing of a \$3 million placement setting us up for a strong 2023 and beyond."

CORPORATE

Emyria had \$2.7m cash available on hand as of 31 December 2022.

Subsequent to the closing of the quarter, the Company received its R&D refund of **\$2.1m**.

The board of directors were paid \$333,000 for the quarter ended 31 December 2022 (as disclosed in section 6 of the 4C quarterly report) comprising wages, fees and superannuation.

OUTLOOK

Advancing the registration and **commercialisation** of Emyria's proprietary drug products is the Company's top priority in 2023.

Active **recruitment** and dosing for the Company's pivotal **Phase 3 clinical trial** of EMD-RX5 is underway. Identifying commercial partners for the EMD-RX5 platform will be a major focus for the company over the coming months.

Emyria expects to advance its **partnership** with the **NIH** to evaluate the potential of its proprietary Ultra-Pure CBD formulations to address pain and opioid dependence indications. Additional **US-focussed registration programs** are expected to be initiated with Emyria's **prescription strength Ultra-Pure CBD** formulations, like EMD-RX7.

Further, Emyria will continue to advance the most **promising MDMA analogue candidates** within three leading clinical series; (1) faster-acting MDMA for MDMA-assisted therapy, (2) movement disorder treatments (eg. Parkinson's) and (3) 5HT2B antagonist treatments for fibrosis. The Company notes the TGA is also expected to deliver a final notice on the rescheduling application of MDMA on February 8th, 2023.

- This release has been approved by the Board of Emyria. -

FOR FURTHER INFORMATION

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DRUG DEVELOPMENT

CLINICAL PROGRAMS
Ultra-Pure cannabinoid delivery platform

NEW DRUG DISCOVERY

PRE-CLINICAL PROGRAM
MDMA-like analogues

EMD-RX5 "direct-to-consumer"	
Formulation optimisation	✓
Phase 1 study	✓
Ethics approved for Phase 3	✓
Phase 3 commencement	✓
Regulatory submission	
Commercial strategy Australia	
Commercial strategy Europe	
Commercial strategy USA	

EMD-RX7 "prescription medicine"	
Formulation optimisation	✓
Phase 1	
Pre-IND (FDA)	
Pivotal trials	

MDMA-like drug development	
Continuous creation & screening	✓
First patent family filed	✓
US-focused preclinical program	✓
Metabolic studies	✓
Preclinical assays (multiple animal models)	✓
Human cell line assays	✓
Advanced assay development	
Lead selection	
Phase 1 trials	
Global commercial strategy	

ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical drug development and care delivery company focused on accelerating drug development and improving patient outcomes in neuroscience and mental health via:

- **Drug Development:** Emyria is developing multiple, proprietary, Ultra-Pure cannabinoid dose forms suitable for registration against multiple indications. Emyria's first dose form, EMD-RX5, is in Phase 3 trials.
- **New Drug Discovery:** Inspired by MDMA, Emyria is developing one of the world's largest libraries of MDMA-like compounds with partner, the University of Western Australia.
- **Proprietary Real-World Data (RWD):** Emyria gathers robust and ethically-sourced data with patients cared for at Emyria's own specialist clinical service (Emerald Clinics). Emyria RWD can help support drug development and care model improvement.

EMYRIA'S

[Investorhub.emyria.com](https://investorhub.emyria.com)

INTERACTIVE

Interact with Emyria's announcements and updates by asking questions and comments, which our team can respond to where possible.

INVESTOR

HUB

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represents the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Appendix 4C

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

Name of entity

EMYRIA LIMITED

ABN

96 625 085 734

Quarter ended ("current quarter")

31 December 2022

Consolidated 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	557	937
1.2 Payments for		
(a) research and development	(641)	(998)
(b) product manufacturing and operating costs	(458)	(1,023)
(c) advertising and marketing	(52)	(118)
(d) leased assets	(100)	(208)
(e) staff costs	(529)	(998)
(f) administration and corporate costs	(355)	(950)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	4	7
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(1,574)	(3,351)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(2)	(11)
(d) investments	-	-
(e) intellectual property	(582)	(1,274)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
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 (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(584)	(1,285)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	2,850	2,850
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(170)	(170)
3.5	Proceeds from borrowings	-	800
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – net payments from cash backed guarantees	-	-
3.10	Net cash from / (used in) financing activities	2,680	3,480

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,202	3,879
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,574)	(3,351)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(584)	(1,285)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,680	3,480
4.5	Effect of movement in exchange rates on cash held	-1	-
4.6	Cash and cash equivalents at end of period	2,723	2,723

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	2,723	2,202
5.2	Call deposits	-	-
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)	2,723	2,202

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	333
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>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	800	800
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	800	800
7.5	Unused financing facilities available at quarter end		-
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. Emyria set up a loan facility in July 2022 for \$800,000 with Radium Capital secured against its R&D Tax Incentive claim with an interest rate of 14% per annum. The facility was fully utilised at 31 December and was repaid in January 2023.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,574)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,723
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	2,723
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.73
	<i>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.</i>	
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	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: The company received its R&D tax refund (\$2.1m) in January 2023 which will reduce the net operating cash flows in the March 2023 quarter, otherwise the current level of net operating cash flows is expected to continue.	
8.6.2	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: Yes. The company has received its R&D Tax refund in January 2023 for \$2.1m.	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	Answer: Yes, based on R&D Tax refund.	
	<i>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.</i>	

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.

Date: 31 January 2023

Authorised by: By the Board

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.