

## **Emyria expands and accelerates MDMA programs following TGA rescheduling; commences dosing in Phase 3 Clinical Trial of EMD-RX5; expands MDMA-analogue library**

**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 **March 31, 2023**.

### **HIGHLIGHTS FOR THE MARCH QUARTER**

#### **Rescheduling of MDMA and psilocybin by TGA to support expansion of Emyria's MDMA-assisted therapy programs**

- Announced plans to support a network of Authorised Prescribers around Australia in the provision of MDMA-assisted therapy
- Secured clinical-grade MDMA supply for Australian patients
- Entered partnership with trauma specialists - PAX Centre - to develop a scalable MDMA-assisted therapy care model

*(See ASX releases 06 Feb, 13 Feb & 07 Mar 2023)*

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#### **Commenced dosing for pivotal Phase 3 Clinical Trial of EMD-RX5, an Ultra-Pure CBD capsule medication aimed at treating stress and anxiety symptoms**

- EMD-RX5 is aiming to be one of the first CBD medications registered with the Therapeutic Goods Administration and available over-the-counter in pharmacies
- 9 clinical trial sites have been activated nationwide; trial is expected to enrol 300 patients
- Hundreds of patients have been pre-screened, Emerald Clinics assisting with recruitment

*(See ASX release 30 Jan 2023)*

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#### **Expanded novel MDMA-analogue library to address mental health and neurological disorders**

- Library now over 150 unique entities related to MDMA, one of the largest in the world
- An additional 19 novel analogues have been sent for preliminary screening
- MDMA and its analogues now have a potential pathway to registration and reimbursement following the TGA rescheduling decision

*(See ASX release 20 Mar 2023)*

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#### **Received a R&D Tax incentive cash refund of over \$2m**

- The R&D tax incentive is an Australian Government program to support Australian companies to undertake R&D activities in Australia. The refund supports:
  - Acceleration of EMD-RX5's journey to registration,
  - Ongoing development of Emyria's high potency, Ultra-Pure CBD capsule
  - Multiple preclinical screening programs for Emyria's novel, MDMA-inspired drug discovery program being developed with the University of Western Australia

*(See ASX release 12 Jan 2023)*

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**Emyria's Managing Director, Dr. Michael Winlo**, said: *"In February, the TGA rescheduling decision for MDMA and psilocybin was a significant milestone for Emyria, and one we have been laying the strategic groundwork on for years."*

*"As the only ASX-listed company offering a clinical service for unregistered medicines and Real-World data generation, we have a distinct advantage in supporting MDMA-assisted therapies in Australia. We have already developed a comprehensive therapy protocol, secured drug supply and partnered with specialist psychiatrists to benefit patients."*

*In addition to our clinical delivery work, our drug development initiatives present investors further opportunities as we advance our MDMA-analogue program alongside our ongoing Phase 3 trial of EMD-RX5, which has made steady progress in recruitment and dosing."*

## CORPORATE

**Emyria had \$2m cash** available on hand as of 31 March 2023.

Subsequent to the closing of the quarter, the Company established an R&D refund facility of **\$917k** and **has commenced a placement of securities to raise additional capital**.

The board of directors were paid \$333,000 for the quarter ended 31 March 2023 (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, in Australia and the USA, remains a top priority for the Company in 2023.

Subsequent to the quarter, Emyria signed a Binding Term Sheet with Aspen Pharmacare Australia to commercialise EMD-RX5.

Emyria is **progressing both MDMA and psilocybin-assisted therapy** programs (*announced post-reporting period*) with PAX Centre and other psychiatry partners following the TGA decision. Emyria will develop clinical delivery and data monitoring protocols while PAX will provide specialists, trained therapists and a facility to administer the therapy safely until a cost model is established that can support on-licensing to other specialists. By developing licensable care programs, securing drug supply and establishing Real World Data, Emyria is well positioned to lead the development of innovative care models and new treatment options for mental health and neuroscience.

The company continues to develop and expand its proprietary preclinical pipeline of MDMA analogues with the potential to become next generation psychedelic-assisted therapies as well as treatments for major mental health illnesses and neurological disorders. Following the TGA rescheduling decision, these MDMA-like compounds now have a potential pathway to registration.

## PROMOTIONS DURING QUARTER

### **March: Broker Briefing Presentation**

<https://wcsecure.weblink.com.au/pdf/EMD/02644264.pdf>

### **February: Investor Presentation**

<https://wcsecure.weblink.com.au/pdf/EMD/02636050.pdf>

### **January: Biotech Showcase San Francisco Presentation**

<https://wcsecure.weblink.com.au/pdf/EMD/02619798.pdf>

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

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## RECENT TRACTION & UPCOMING MILESTONES

CLINICAL PROGRAMS		PRE-CLINICAL + THERAPY PROGRAMS	
<b>"direct-to-consumer"</b>		<b>New Drug Discovery</b>	
Formulation optimisation (RX5) ✓	Formulation optimisation (RX7 > RX9) ✓	Continuous creation & screening ✓	Protocols developed ✓
Phase 1 study done ✓	Preclinical Screening Program for Pain	First patent family filed ✓	Clinical partnerships ✓
Phase 3 commencement ✓	Phase 1	US-focused preclinical program ✓	Real-World Data system ✓
Regulatory submission	Pre-IND (FDA)	Metabolic studies ✓	MDMA supply secured ✓
Commercial strategy Australia ✓	Pivotal trials	Lead selection	Psilocybin-supply secured
Commercial strategy Europe		Phase 1 trials	Therapist training
Commercial strategy USA		Global commercial strategy	First patient
			Global commercial strategy

## ABOUT EMYRIA | [emyria.com](https://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:** 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.

This release has been approved by the Board of Emyria.

**EMYRIA'S INTERACTIVE INVESTOR HUB** | [investorhub.emyria.com](https://investorhub.emyria.com) | Interact with Emyria's announcements and updates by asking questions and comments, which our team can respond to where possible.

**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.

## FOR FURTHER INFORMATION

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## 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 March 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	456	1,392
1.2 Payments for		
(a) research and development	(360)	(1,358)
(b) product manufacturing and operating costs	(409)	(1,431)
(c) advertising and marketing	(51)	(169)
(d) leased assets	(71)	(279)
(e) staff costs	(514)	(1,513)
(f) administration and corporate costs	(489)	(1,438)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	9	16
1.5 Interest and other costs of finance paid	(72)	(72)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,103	2,103
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>602</b>	<b>(2,749)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(5)	(16)
(d) investments	-	-
(e) intellectual property	(683)	(1,956)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(688)</b>	<b>(1,972)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	150	3,000
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)
3.5	Proceeds from borrowings	-	800
3.6	Repayment of borrowings	(800)	(800)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – net payments from cash backed guarantees	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(650)</b>	<b>2,830</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	2,723	3,879
4.2	Net cash from / (used in) operating activities (item 1.9 above)	602	(2,749)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(688)	(1,972)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(650)	2,830
4.5	Effect of movement in exchange rates on cash held	-	-1
4.6	<b>Cash and cash equivalents at end of period</b>	<b>1,987</b>	<b>1,987</b>

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	1,987	2,723
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>1,987</b>	<b>2,723</b>

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>		

<b>7.</b>	<b>Financing facilities</b> <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>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>Unused financing facilities available at quarter end</b>		-
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.		
	In April 2023, Emyria secured a loan facility with Radium Capital for \$917,000 with an interest rate of 15% pa, maturity date of 31 December 2023 and secured against the R&D tax rebate.		

<b>8.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	602
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,987
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,987
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>  <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>	N/A
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:	
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:	
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:	
	<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: 28 April 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.