ASX Announcement

28 July 2022

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myriad data.
individual care.

Emyria completes Phase 1 trial for EMD-RX5, readies for Phase 3; extends UWA partnership and expands MDMA analogue library

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech developing multiple treatments for unmet needs powered by Real-World Data, is pleased to report on the Company's activities for the quarter ending June 30, 2022.

HIGHLIGHTS

- **Completed EMD-RX5 Phase 1 clinical trial** comparing Emyria's Ultra-Pure cannabidiol *(CBD)* capsule to Epidyolex oil - the sole registered CBD medicine in the US and Australia; Positive results include:
  1. EMD-RX5 demonstrated excellent safety and tolerability
  2. Equivalent bioavailability to Epidyolex with less dose variability, and higher CBD exposures between 3 and 8 hours post-dosing
  3. Twice the bioavailability compared to other, plant-derived CBD products with published pharmacokinetics *(PK)* data

- **Executed agreement with Clinitrials to coordinate the pivotal Phase 3 trial** required to support registration of EMD-RX5 as an over-the-counter medicine with the Therapeutic Goods Administration *(TGA)*;
  Trial to commence following ethics approval

- **Extended MDMA analogue development partnership** with University of Western Australia *(UWA)*; expanded proprietary library of MDMA-*like* analogues and completed additional extensive screening

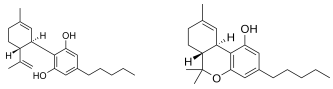
- **Cash available ~$4.68m** to advance multiple drug development programs

Emyria's Managing Director, Dr. Michael Winlo, said: "*Emyria has substantially advanced its drug development programs this quarter.*

We achieved outstanding Phase 1 results for EMD-RX5, Emyria's proprietary, Ultra-Pure CBD capsule and engaged partner Clinitrials to lead the pivotal, multi-site Phase 3 trial required for TGA registration.

We are also delighted to extend our partnership with UWA, enabling us to generate additional proprietary MDMA-like analogues with the potential to become registered treatments for a range of major psychiatric, neurological and non-neurological disorders."

ULTRA-PURE CANNABINOID DEVELOPMENT



Completed Phase 1 clinical trial for EMD-RX5

EMD-RX5 is Emyria's first, wholly-owned proprietary formulation of Ultra-Pure cannabidiol *(CBD)*. The Phase 1 clinical trial assessed the safety, tolerability and bioavailability *(a measure of the amount of the drug reaching the bloodstream)* of EMD-RX5 *capsules* compared to Epidyolex *oil* in 12 healthy human volunteers.

Epidyolex is sold by Jazz Pharmaceuticals (NASDAQ: JAZZ) and is the sole CBD medicine registered with the TGA and Food and Drug Administration (FDA).

EMD-RX5 demonstrated a number of features that are desirable for solid, oral delivery of CBD, such as:

- **Excellent safety and tolerability** with no gastrointestinal upset or adverse events of concern at test dose of 150mg
- **Equivalent bioavailability** to Epidyolex with **less dose variability**
- **Higher CBD exposures 3 to 8 hours after dosing**, indicating EMD-RX5 provides more predictable drug exposure over time; suited for non-acute indications and supporting a preferred once to twice daily dosing regime
- **Twice the bioavailability** compared to other plant-derived CBD products with published pharmacokinetics data *(see Figure 1)*.

Pivotal Phase 3 for EMD-RX5 across 5-6 sites in Australia to commence following receipt of ethics approval and to be coordinated by leading Contract Research Organisation *(CRO)* and Site Management Organisation *(SMO)*, Clinitrials *(See ASX release 13 APR 2022)*.

Cannabinoid product development advanced for EMD-RX7, Emyria's higher dose form of Ultra-Pure CBD intended for registration of prescription-only medicines.

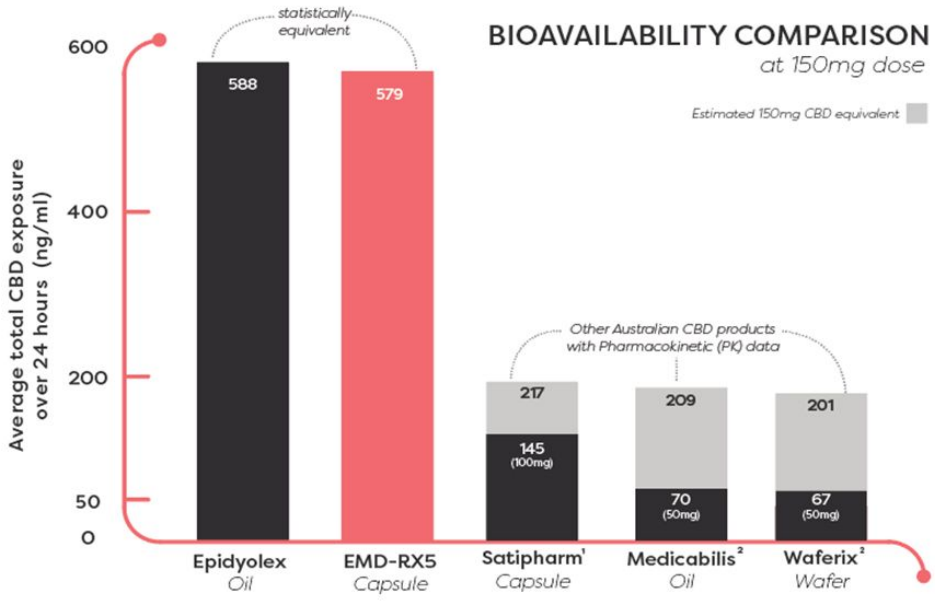
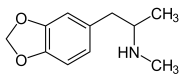


Fig 1. Bioavailability comparison of EMD-RX5 with Epidyolex at 150 mg dose

MDMA ANALOGUE DEVELOPMENT PROGRESS



Expanded MDMA analogue library and UWA agreement

Emyria's extended the partnership agreement with the University of Western Australia, which supports the further expansion of a one-of-a-kind pipeline of new MDMA analogues *(now over 100 compounds)* exclusively optioned to Emyria.

As part of the drug development program, each new compound is extensively screened to reveal both desired and unwanted cell target interactions. These results help direct further compound generation and identify which compounds have the greatest potential to become next-generation psychotherapy adjuncts or treatments for other neurological and non-neurological disorders. *(See ASX announcement 05 Aug 2021)*

Positive initial screening:

- 82 of 85 compounds showed no off-target effects
  (See ASX announcements 08 Dec 2021 and 20 May 2021)
- Selective receptor activity results suggest potential applications as:
  - Novel MDMA analogues to assist with psychotherapy (i.e. "next-generation psychedelic-assisted therapeutics") for major mental health disorders and;
  - New treatments for a range of neurological and non-neurological conditions

Emyria's additional investment is expected to accelerate compound synthesis and screening via team expansion, specialist materials, equipment and software, ongoing commercialisation activities and multiple patent family filings.

CORPORATE

Emyria has $4.7M cash available on hand as of 30 June 2022. This comprises $3.88M cash and an $800k drawdown facility provided by Radium Capital against an expected R&D refund of at least $1.8M for the financial year ending 30 June 2022.

The board of directors were paid $330,000 for the quarter ended 30 June 2022 *(as disclosed in section 6 of the 4C quarterly report)* and this comprised wages, fees and superannuation.

PROMOTIONS DURING QUARTER

Presentation
"Drug Development Webinar"

1 June 2022



https://wcsecure.weblink.com.au/pdf/EMD/02527659.pdf

OUTLOOK

The Company's top priority is to advance the registration and commercialisation of Emyria's drug development assets .

EMD-RX5 is initially seeking registration as an over-the-counter medicine with the TGA as a treatment for the symptoms of psychological distress. However, the unique formulation of EMD-RX5 has the potential to become a registered treatment in other major global markets for a variety of indications. Therefore, we believe EMD-RX5 has the potential to address large unmet health needs globally and represents a significant commercial opportunity for Emyria.

A pivotal Phase 3 clinical trial for EMD-RX5 is expected to commence imminently upon receipt of ethics approval. Emyria's wholly-owned clinical service subsidiary, already operating across Australia, is expected to further accelerate recruitment by helping identify suitable patients who will be referred for formal screening at independent sites managed by Clinitrials.

Emyria continues to evaluate FDA pathways for its other proprietary cannabinoid programs, including EMD-RX5 and EMD-RX7, leveraging the Company's proprietary Real World Data for insights.

In parallel, the Company is using early screening results to guide the expansion of its novel MDMA analogue library with partner the University of Western Australia, creating a proprietary preclinical pipeline of compounds with the potential to become next-generation psychedelic-assisted therapies as well as treatments for major mental health illnesses and neurological disorders.

This announcement has been approved and authorised for release by the Board of Emyria Limited.

For further information:

Dr. Michael Winlo
Managing Director
1300 436 363
mwinlo@emyria.com

Lexi O'Halloran
Investor Relations
+ 61 (0) 404 577 076
lexi@janemorganmanagement.com.au

Andrew Williams
Media Relations
+61 (0) 412 614 125
awilliams@emyria.com

emyria

UPCOMING
DRUG DEVELOPMENT MILESTONES

CLINICAL PROGRAMS
Repurposing "Ultra-Pure" cannabinoids

EMD-RX5 *"direct-to-consumer"* program	**EMD-RX7** *"prescription medicine"* program
Formulation optimisation ✓	**Formulation optimisation** ✓
Phase 1 ✓	**Phase 1**
Ethics submitted for Phase 3 ✓	Pre-IND **(FDA)**
Phase 3 commencement	**Pivotal** trials
Regulatory submission	
Commercial strategy **Australia**	
Commercial strategy **Europe**	
Commercial strategy **USA**	

PRE-CLINICAL PROGRAM

MDMA-like medicine
Screening results for first 85 compounds ✓
First patent family filed ✓
Batch **3** sent ✓
Batch 3 **screening results**
Create and screen additional batches
Metabolic studies
Preclinical assays *(multiple animal models)*
Human cell line assays
Lead selection
Phase 1 trials

ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical stage biotech focussed on accelerating treatment development and improving patient care by:

1. **Collecting and analysing Real-World Data (RWD):** Emyria gathers ethically-sourced clinical evidence with patients across Emyria's independent clinical services *(emeraldclinics.com.au)*. Emyria's proprietary RWD provides deep treatment and drug development insights.
2. **Repurposing promising treatments:** Emyria uses its RWD to improve the formulations of, and find new indications for, select medications. Emyria's first repurposed and proprietary drug products (EMD-RX5 and EMD-RX7) incorporate Ultra-Pure cannabinoids and are targeting global registration opportunities as over-the-counter and prescription-only medicines.
3. **Developing analogues of promising new compounds**: Emyria collaborates with leading institutions to develop new chemical entities inspired by promising molecules. Emyria's first new chemical entity program is focussed on generating novel MDMA analogues with the potential to become registered therapies for a range of major unmet needs.

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	**Quarter ended ("current quarter")**
96 625 085 734	30 June 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	665	1,933
1.2	Payments for		
	(a) research and development	(668)	(1,966)
	(b) product manufacturing and operating costs	(549)	(2,210)
	(c) advertising and marketing	(56)	(353)
	(d) leased assets	(87)	(373)
	(e) staff costs	(375)	(1,734)
	(f) administration and corporate costs	(795)	(2,084)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	13
1.5	Interest and other costs of finance paid	(37)	(52)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,162
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,900)**	**(5,664)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(15)	(53)
	(d) investments	-	-
	(e) intellectual property	(870)	(1,976)
	(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)	-	-
2.6	**Net cash from / (used in) investing activities**	**(885)**	**(2,029)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	5,032
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	7
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 – net payments from cash backed guarantees	10	11
3.10	**Net cash from / (used in) financing activities**	**10**	**5,051**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,661	6,529
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,900)	(5,664)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(885)	(2,029)

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)	10	5,051
4.5	Effect of movement in exchange rates on cash held	(5)	(6)
4.6	**Cash and cash equivalents at end of period**	**3,881**	**3,881**

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	3,881	6,661
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)**	**3,881**	**6,661**

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	330
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** *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	800	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	800	-

7.5	**Unused financing facilities available at quarter end**	800

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 has 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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,900)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,881
8.3	Unused finance facilities available at quarter end (item 7.5)	800
8.4	Total available funding (item 8.2 + item 8.3)	4,681
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.5

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:

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: N/A

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: N/A

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: 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.

Date: 28 July 2022

Authorised by: Simon Robertson
(Name of body or officer authorising release – see note 4)

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.