ASX Announcement

31 Oct 2022

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Emyria receives ethics approval for EMD-RX5 Phase 3 trial; Expands MDMA analogue library and commences preclinical program with leading US neuroscience CRO, PsychoGenics

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 September 30, 2022.

HIGHLIGHTS FOR THE SEPTEMBER QUARTER

Received Human Research Ethics Committee Approval to commence a pivotal Phase 3 Clinical Trial of EMD-RX5. Having completed all necessary safety and efficacy evaluations of EMD-RX5, Emyria is now commencing the recruitment process with Clinitrials, supported by subsidiary Emerald Clinics *(See ASX release 16 Aug 2022)*

Expanded trial sites to support Phase 3 clinical trial. Emyria qualified 8 clinical trial sites across Western Australia, Queensland, New South Wales, South Australia and the Australian Capital Territory to support the pivotal Phase 3 trial for EMD-RX5 *(See ASX release 26 Sep 2022)*

Received further positive screening results for third batch of MDMA analogues. 19 additional novel compounds demonstrated no significant interactions with selected 'anti-targets' bringing total library of novel chemical entities inspired by MDMA to over 125 *(See ASX releases 18 Jul 2022 and 18 Aug 2022)*

Commenced multiple preclinical programs to support MDMA-inspired drug discovery.

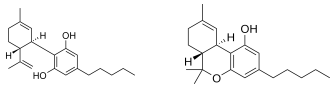
- US-based specialist neuroscience CRO, PsychoGenics, to use proprietary SmartCube(™) platform to help select promising candidates for neuropsychiatric indications *(See ASX release 19 Sep 2022)*
- Institute of Respiratory Health to conduct human cell-line studies on MDMA analogues suggested to have 'anti-fibrosis' effects *(See ASX release 04 Aug 2022)*

Subsequent to quarter end - Conducted $3m Placement cornerstoned by Tattarang's Tenmile Ventures and Sixty Two Capital, complementing expected R&D refund in excess of $2m in November 2022

Emyria's Managing Director, Dr. Michael Winlo, said: "*The Phase 3 trial for EMD-RX5 is a momentous step in our drug development program, with the receipt of ethics approval a major milestone this quarter.*

In addition, we've launched multiple, global preclinical programs with highly-regarded and innovative specialists, such as University of Western Australia, PsychoGenics and the Institute of Respiratory Health, to advance our MDMA-inspired drug discovery."

ULTRA-PURE CANNABINOID DEVELOPMENT



Received ethics approval for Phase 3 Clinical Trial for EMD-RX5

Emyria received Human Research Ethics Committee (HREC) approval to commence a pivotal Phase 3 clinical trial of its Ultra-Pure CBD capsule, EMD-RX5.

Successful completion of the Phase 3 trial will support the registration of EMD-RX5 with the Therapeutic Goods Administration (TGA) as a Schedule 3, over-the-counter (OTC) treatment for the symptoms of psychological distress.

The study's primary endpoints are changes in validated psychological distress symptom scores. Secondary endpoints include validated measures of sleep, pain and other quality of life scores.

The Phase 3 trial is a multi-center, double-blind, randomised, placebo-controlled trial and will be conducted under Australia's Clinical Trials Notification (CTN) Scheme.

Phase 3 site expansion to multiple states

Emyria qualified 8 sites to support the pivotal Phase 3 trial. Qualified sites have successfully passed extensive feasibility and suitability screens with an independent monitor and are formally approved to participate in core trial activities such as patient recruitment, treatment dosing and clinical assessments.

Emyria's Phase 3 clinical trial is now available to patients across Western Australia, Queensland, New South Wales, South Australia and the Australian Capital Territory.

Emyria's clinical service subsidiary - Emerald Clinics - will begin accepting expressions of interest for these new sites from September 28th 2022 to support patient recruitment

EMD-RX5 - a unique, Ultra-Pure CBD capsule

EMD-RX5 was developed to overcome many of the limitations with commonly available cannabinoid medicines and has been clinically demonstrated to have excellent safety, tolerability, bioavailability and low patient variability in a head-to-head comparison with the only registered CBD medicine in the world - Epidyolex [1].

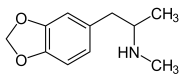
EMD-RX5 is a proprietary capsule formulation of Ultra-Pure CBD with the potential to address multiple clinical indications and with the required purity to pursue registration opportunities across multiple major global markets.

Target indication - Psychological distress:

Psychological distress describes a set of mental and physical symptoms such as anxiety, stress, depression, sleep disturbance and gastrointestinal upset that, at any one time, can affect up to 15% of the adult population [2].

Psychological distress has a higher incidence rate in rural patients [3] and patients with chronic disease [2]. Overall the incidence of psychological distress is believed to be increasing. There is currently no over-the-counter treatment for psychological distress.

MDMA-INSPIRED DRUG DISCOVERY PROGRAM



Expanded and screened novel analogue library

A third batch comprising 19 novel MDMA analogues was created, characterised and successfully passed initial safety screening with Eurofins. The design of this third batch was led by Professor Matt Piggott and his expert team at UWA and guided by the successful results received from the screening of the first two batches. The growing library of novel, neurological active entities is now over 100 compounds and exclusively optioned to Emyria.

Innovative preclinical program commenced

Institute of Respiratory Health

Emyria's first preclinical program will explore the antifibrotic potential of a priority set of novel MDMA analogues. Some compounds structurally related to MDMA are known to increase the risk of developing heart valvulopathy (a fibrotic disorder). As a result, initial safety tests are conducted on each new MDMA-like analogue in order to screen out compounds that pose the greatest risk of inducing fibrosis.

To evaluate the therapeutic potential of these compounds, Emyria has engaged the Institute of Respiratory Health (IRH) in Western Australia to conduct a series of human cell line assays under the leadership of Associate Professors Steven Mutsaers and Cecilia Prêle.

PsychoGenics

US-based Neuroscience CRO PsychoGenics will use its proprietary SmartCube(™) platform to study novel compounds from the MDMA-inspired drug discovery program. Study results are expected to help Emyria select promising drug candidates for clinical studies and help both parties evaluate the potential for a partnership to accelerate development and commercialisation of the broader MDMA-inspired library.

PsychoGenics's specialist drug screening platforms have been used in shared-risk partnerships with major pharmaceutical companies, including Sunovion and Roche, resulting in the discovery of several novel compounds now in clinical trials.

CORPORATE

Emyria had $2.2m cash available on hand as of 30 September 2022. The Company completed a placement in October for **$3m** (gross) with funds receivable in November, and is also expecting to receive its R&D refund of at least **$2m** in the December quarter for the 2022 financial year.

The board of directors were paid $310,000 for the quarter ended 30 September 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.

Logistics and recruitment for the Phase 3 clinical trial of EMD-RX5 are underway and will be the major focus for the company over the coming months. 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 across Australia.

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, EMD-RX5 has been uniquely formulated to have the potential to become a registered treatment in other global markets as well as for other indications. Therefore, we believe EMD-RX5 has the potential to address large unmet needs globally and represents a significant commercial opportunity for Emyria.

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 patient data for insights.

In parallel, the company will use its preclinical screening results developed with its collaborators 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 potential to become next generation psychedelic-assisted therapies as well as treatments for major mental health illnesses and neurological disorders.

This release has been approved by the Managing Director of Emyria

FOR FURTHER INFORMATION

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REFERENCES:

[1] See *ASX release 25 May 2022*
[2] National Study of Mental Health and Wellbeing 2020-21 series, Australian Bureau of Statistics
[3] Kilkkinen et al. Prevalence of psychological distress, anxiety and depression in rural communities in Australia. Aust J Rural Health. 2007 Apr;15(2):114-9. doi: 10.1111/j.1440-1584.2007.00863.x.

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UPCOMING DRUG DEVELOPMENT MILESTONES

DRUG DEVELOPMENT

CLINICAL PROGRAMS
Ultra-Pure cannabinoid delivery platform

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

NEW DRUG DISCOVERY

PRE-CLINICAL PROGRAM
MDMA-like analogues

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 has developed an Ultra-Pure cannabinoid platform that can support the registration of multiple proprietary dose forms. 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 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 INTERACTIVE INVESTOR HUB
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.

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 September 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	380	380
1.2	Payments for		
	(a) research and development	(357)	(357)
	(b) product manufacturing and operating costs	(565)	(565)
	(c) advertising and marketing	(66)	(66)
	(d) leased assets	(108)	(108)
	(e) staff costs	(470)	(470)
	(f) administration and corporate costs	(595)	(595)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	3
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**	**(1,778)**	**(1,778)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(9)	(9)
	(d) investments	-	-
	(e) intellectual property	(691)	(691)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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**	**(700)**	**(700)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
3.5	Proceeds from borrowings	800	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**	**800**	**800**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,879	3,879
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,778)	(1,778)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(700)	(700)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	800	800
4.5	Effect of movement in exchange rates on cash held	1	1
4.6	**Cash and cash equivalents at end of period**	**2,202**	**2,202**

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	2,202	3,881
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)**	**2,202**	**3,881**

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	310
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	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 and maturity date of 31 December 2022. The facility was fully utilised at 30 September.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,772)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,202
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	2,202
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.24

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: Yes, 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 secured a placement of $3m with funds receivable in November and is also expecting its R&D Tax refund in excess of $1.2m net (after repayment of the Radium facility – see section 7.6).

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 the capital raise and expected net R&D Tax refund.

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: 31 October 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.