# ASX Announcement

28 Jan 2022

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## Emyria secures $5m strategic investment from Tattarang; advances cannabinoid and MDMA analogue registration programs; adds experienced biopharma executive to board; boosts Real World Evidence analysis capabilities

**Emyria Limited (ASX: EMD)** (Emyria or the Company), a clinical stage biotech developing multiple treatments for unmet needs powered by real-world patient data, is pleased to report on the Company's activities for the quarter ending December 31, 2021.

**Highlights:**

- **Secured $5m strategic placement from Tattarang,** one of Australia's largest private investment groups owned by the Forrest family; further **$1.16m R&D cash refund** received
- **Appointed experienced, US-based biopharma executive** Dr. Karen Smith to Emyria's Board of Directors
- **Received positive animal data** on Emyria's first, ultra-pure cannabinoid formulation, EMD-RX5; results show high bioavailability when compared to Epidyolex, the only TGA and FDA approved CBD-only medicine
- **Received positive screening results** from first batch of MDMA analogues; first MDMA analogue patent family filed
- **Increased Real-World Data analytical capabilities** with invitation into Palantir's Foundry for Builders Program
- **Added unique wearable and patient monitoring technology** to Emyria's psychedelic-assisted therapy research programs

**Emyria's Managing Director, Dr. Michael Winlo,** said: "*Emyria's drug development and registration goals have gained significant momentum this quarter catalysed by a major strategic investment from Tattarang, one of Australia's largest private investment groups owned by the Forrest family. The Company continues to advance its data collection and analysis work into clinical stage biotech development with multiple programs.*

*Emyria also welcomed highly experienced US-based biopharma executive, Dr. Karen Smith, to our Board of Directors. Dr. Smith was previously the Chief Medical Officer and Global Head of Research and Development at Jazz Pharmaceuticals. Jazz is notable for having acquired GW Pharma for over $US7 billion in February 2021. GW Pharma commercialised Epidyolex, the only TGA and FDA approved cannabinoid medicine.*

*As Executive Director, Dr. Smith will help guide Emyria's US-focussed drug registration programs in addition to business development and strategic investment advice.*

*Emyria's leading proprietary, ultra-pure cannabinoid treatment - EMD-RX5 - demonstrated improved bioavailability in a gold-standard preclinical animal model when compared to the only TGA and FDA registered CBD-only medicine - Epidyolex.*

*These results give us confidence that EMD-RX5 has the potential to become a registered treatment, with both the TGA and FDA, for multiple drug indications as informed by Emyria's propriety Real-World Evidence. Phase 1 human clinical trials are scheduled to begin Q1 2022. Successful Phase 1 results will allow Emyria to trial EMD-RX5 for multiple indications. In parallel we are exploring additional cannabinoid formulations to expand our treatment portfolio.*

*Emyria's first drug registration program is targeting the symptoms of psychological distress (the "EMD-003 program"), a major unmet need affecting 15% of adults.*

*Our novel psychedelic treatment development program - in partnership with the University of Western Australia - made substantial progress during the quarter. We received positive screening results from our first batch of MDMA analogues. Initial results showed that a majority of compounds passed the preliminary safety screens and supported our first patent family filing. We are now expanding the MDMA analogue compound library, planning further screening tests, preparing for animal studies and filing additional patents. The company also continues to explore opportunities to develop additional novel psychedelic therapies which may complement its existing portfolio.*

*Each of our drug development programs is supported by Emyria's proprietary Real-World Evidence which is collected with patients receiving care at our clinical service subsidiary, Emerald Clinics. In the December quarter, we significantly boosted our Real-World Evidence capabilities after being selected to join Palantir's Foundry for Builders Program. Emyria now uses a powerful Big Data integration and analysis platform typically only available to much larger enterprises.*

*We also entered into a Letter of Intent with leading remote monitoring technology company, Cydelic - to incorporate a suite of biometric tracking technologies into our current and future clinical programs starting with our MDMA-assisted therapy trial. Biometric tracking can assist therapists monitor the safety and well-being of patients during psychedelic-assisted therapy sessions."*

**STRENGTHENED CASH POSITION**

**$5m strategic placement received from Tattarang**, one of Australia's largest private investment groups, owned by the Forrest family. Funds are being used to accelerate Emyria's ultra-pure cannabinoid registration programs with the TGA and FDA, and advance Emyria's novel MDMA-analogue development program with the University of Western Australia.

***Tattarang Chief Investment Officer John Hartman*** remarked on the investment saying, *"Emyria's investment in industry-leading data collection at the front-line of care will allow it to innovate faster and help bring new treatments to those who need them, faster and more cost effectively.*

*We believe evidence based, and properly registered, medicinal cannabis and novel psychedelic treatments have massive growth potential across global healthcare jurisdictions."*
*[See ASX announcement 22 Nov 2021]*

**Received a Research and Development (R&D) tax incentive refund of $1,162,134** for the financial year 2020/2021 based on eligible expenditure on R&D activities.
*[See ASX announcement 24 Nov 2021]*

## APPOINTED US-BASED, BIOPHARMA EXECUTIVE TO BOARD

**Dr. Karen Smith, M.D., Ph.D., M.B.A., L.L.M, appointed to Emyria's Board.**

Dr. Smith has overseen more than 100 clinical trials and more than 20 regulatory approvals.

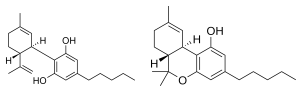
Karen's successful record of business development includes the acquisition of U.S. and international companies, divestitures and negotiating partnership deals between biotech and pharma.

In addition, Dr Smith has an established track record of driving shareholder value, including holding directorships in three companies which were acquired for over $1 billion USD each by major pharma - Acceleron Pharmaceuticals, Sucampo Pharma, and Forward Pharma.

Dr. Smith will lead Emyria's US-based pharmaceutical programs with a view to developing FDA-registered cannabinoid and psychedelic-assisted therapies.

*[See ASX announcement 29 Nov 2021]*

## ADVANCED EMYRIA'S DRUG REGISTRATION PROGRAMS

**Cannabinoid development progress** 

**Emyria received positive preliminary results from a pre-clinical canine study** comparing Emyria's proprietary, ultra-pure cannabidiol (CBD) formulation (**EMD-RX5**) to the only registered CBD product in Australia and the US (**Epidyolex *oil***).

The animal study results suggest Emyria has developed a novel, high performing and cost-effective CBD capsule that could be suitable to treat multiple clinical indications while also meeting the strict registration requirements for product quality and purity with both the TGA in Australia and the FDA in the USA.
*[See ASX announcement 15 Dec 2021]*

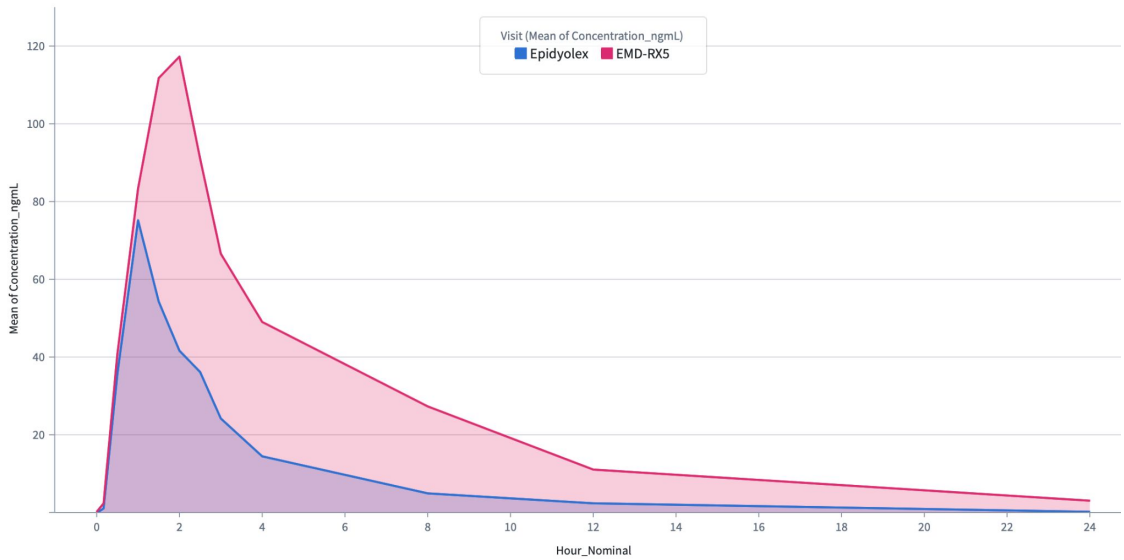
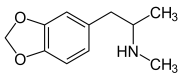



**Fig 1. Mean concentration (ng/ml) of CBD : Epidyolex vs EMD-RX5 over 24 hours**

**EMD-RX5 is now commencing Phase 1 clinical trials** in support of Emyria's leading drug registration programs:

- **EMD-003** - an over-the-counter, low-dose CBD medicine targeting the symptoms of psychological distress, affecting up to 15% of adults [1]
- **EMD-004** - a CBD medicine targeting the symptoms of Irritable Bowel Syndrome (IBS), affecting up to 11% of the population [2]

**MDMA analogue development progress**




**Positive in vitro receptor screening results received for the first batch of MDMA analogues.** Results highlighted a number of novel compounds with greater potency compared with MDMA for certain neuroreceptors at the test concentrations and have supported the successful filing of the first patent family. Further IP generation underway.

Notably, 66 of the 68 first-batch compounds screened demonstrated no interactions with the selected anti-targets (receptors and enzymes known to be involved in unwanted side effects).

A second batch of compounds from the original analogue library of > 100 compounds is now being prepared for initial screening and additional MDMA analogues are being created to expand the analogue library.

A collaboration between Emyria and Professor Iain McGregor (University of Sydney) was also formed to support follow-on screening assessments to help identify compounds with the greatest potential to help patients in need of registered therapeutics.

*[See ASX announcements 19 Oct 2021 and 08 Dec 2021]*

**BOOSTED EMYRIA'S DATA ANALYTICS AND RESEARCH TECHNOLOGY**

**Emyria was invited to join Palantir's Foundry for Builders Program** providing Emyria with access to the full Palantir Foundry stack, greatly enhancing Emyria's data infrastructure, security, integration, and analysis capabilities.

Palantir Technologies (NYSE:PLTR), co-founded by Peter Thiel (PayPal), is a world leader in data platforms for major organisations and institutions with complex and sensitive data environments including the FDA, National Institutes of Health and Sanofi.

Palantir Foundry will now form the backbone of Emyria's proprietary Real-World Evidence asset, as well as accelerate Emyria's data-guided drug development programs targeting FDA and TGA registrations.

*[See ASX announcement 07 Oct 2021]*

**Emyria to incorporate unique wearable technology into Emyria's MDMA-assisted therapy trials** via a letter of intent (LOI) with Cydelic - a private company based in Seattle developing tools and technologies that help track the wellbeing of patients before, during and after psychedelic-assisted therapy.

Emyria plans to work with Cydelic across all of its psychedelic-assisted therapy trials to capture unique biometric data that can assist with real-time patient safety and dose response analysis as well as the registration of psychedelic-assisted therapies.

Robust physiological measurements may assist with patient selection, safety monitoring during treatment, dose-response analysis as well as tracking long-term safety and durable changes to quality of life.

A validated system for tracking patient physiology alongside psychotherapy could help therapists monitor patient safety while also supporting the standardisation, scalability, registration and reimbursement of psychedelic-assisted therapies.

*[See ASX announcement 20 Dec 2021]*

**CORPORATE**

**Emyria has $8.7M cash** on hand as of 31 Dec 2021.

The Board of Directors, including Executive Directors, were paid $262,500 for the quarter ended 31 December 2021 (as disclosed in section 6 of the 4C quarterly report) and this comprised wages, fees and superannuation.

**Outlook**
Emyria is advancing towards registration of its proprietary, ultra-pure cannabinoid pharmaceutical - EMD-RX5.

Pivotal trials for EMD-RX5 as a potential treatment for the symptoms of psychological distress are expected to commence in early 2022.

EMD-RX5 is expected to be a multi-indication drug candidate and trials to obtain registration for additional clinical indications are in planning. In addition, Emyria is planning the development of other, proprietary ultra-pure cannabinoid formulations to address new indications as guided by Emyria's Real-World Evidence (RWE).

Emyria will continue to evaluate FDA pathways for both its current programs and additional indications using the Company's proprietary RWE for insights.

In parallel, the company continues to pursue an extensive screening and expansion program of an MDMA analogue library with partner the University of Western Australia. The goal of this program is to identify families of compounds with potential to become treatments for major mental health illnesses and neurological disorders.

Emyria also continues to evaluate extending its evidence-generating care model into the field of psychedelic-assisted therapy to help develop scalable and evidence-based psychedelic-assisted therapy programs targeting major mental health illnesses.

The Company will provide further updates to the market accordingly.

**PROMOTIONS DURING QUARTER**

**Presentation: South West Connect Event**
https://emyria.com/2021/10/27/presentation-south-west-connect-event/

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

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**REFERENCES:**


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

[2] Gralnek IM, Hays RD, Kilbourne AM, Chang L, Mayer EA. Racial differences in the impact of irritable bowel syndrome on health-related quality of life. J Clin Gastroenterol. 2004 Oct;38(9):782-9. doi: 10.1097/01.mcg.0000140190.65405.fb. PMID: 15365405.


## About Emyria (www.emyria.com)

Emyria Limited is a clinical stage biotech developing multiple treatments for unmet needs powered by real-world patient data. Emyria's model is aimed at accelerating treatment development and improving patient care.

**Emyria's Treatments** target unmet needs and are focused on obtaining approval from major global regulators. Emyria's drug development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au)

**Emyria Data** provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

## 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 | 31 December 2021 |

| **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 | 394 | 861 |
| 1.2 | Payments for | | |
| | (a) research and development | (554) | (868) |
| | (b) product manufacturing and operating costs | (586) | (1,213) |
| | (c) advertising and marketing | (102) | (221) |
| | (d) leased assets | (62) | (132) |
| | (e) staff costs | (345) | (856) |
| | (f) administration and corporate costs | (315) | (1,025) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 1 | 9 |
| 1.5 | Interest and other costs of finance paid | (3) | (5) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 1,162 | 1,162 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(410)** | **(2,288)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (6) | (29) |
| | (d) investments | - | - |
| | (e) intellectual property | (386) | (550) |
| | (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** | **(392)** | **(579)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | 5,032 | 5,032 |
| 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 | - | - |
| 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) | 1 |
| **3.10** | **Net cash from / (used in) financing activities** | **5,022** | **5,033** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 4,475 | 6,529 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (410) | (2,288) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (392) | (579) |

| 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) | 5,022 | 5,033 |
| 4.5 | Effect of movement in exchange rates on cash held | 1 | 1 |
| **4.6** | **Cash and cash equivalents at end of period** | **8,696** | **8,696** |

| 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 | 8,696 | 4,475 |
| 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)** | **8,696** | **4,475** |

| 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 | 263 |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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 | - | - |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | - | - |
| 7.4 | **Total financing facilities** | - | - |

| | | |
|---|---|---|
| 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.

| |
|---|
| |

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | (410) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 8,696 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 8,696 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 21.2 |

*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 January 2022

Authorised by: Simon Robertson (Company Secretary)
(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.