ASX Announcement

28/07/2021

emyria
myriad data.
individual care.

Emyria advances drug registration programs, launches EMDMA-001; validates data platform; obtains TGA 'Class IIa' registration

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical drug development and care delivery company, is proud to report on the Company's activities for the quarter ending June 30, 2021.

Highlights:

- Substantial progress made on the registration of **EMD-003** - Emyria's first Schedule 3 product candidate
- **Announced MDMA-assisted therapy trial for PTSD** (EMDMA-001) and appointed a Principal Investigator
- **Validated Emyria's clinical data platform** and opioid-reduction care model with **IQVIA (NYSE: IQV)**
- **Registered Openly as a "Class IIa medical device"** with the **TGA**
- **Expanded IP portfolio** with new patents filed for EMD-003 and EMD-004
- **Strengthened cash position** with well-supported **$5m placement**.

Emyria's Managing Director, Dr. Michael Winlo, said: "*Emyria has made great progress on a number of strategic fronts this quarter.*

We have advanced our lead drug registration programs, EMD-003 and EMD-004 and filed additional patents to protect our use of cannabinoids for our target indications.

A Real World Evidence study with IQVIA helped validate Emyria's proprietary clinical data and reveal that our care models significantly reduce opioid use amongst our most opioid-dependent patients.

Our remote monitoring smartphone application - OPENLY - achieved a Class IIa medical device registration with the TGA demonstrating our commitment to registered products and treatments with major regulators.

We revealed how we are applying our evidence-generating care model to the emerging field of psychedelic-assisted therapy by Sponsoring an MDMA-assisted psychotherapy clinical trial for severe Post-Traumatic Stress Disorder. The study will run with partners Mind Medicine Australia and help us develop an evidence-based and scalable care model for the Australian context."

Emyria Treatments

EMD-003 - a unique cannabinoid targeting psychological distress

Emyria's EMD-003 drug development program remains on track to deliver one of the first registered Schedule 3, over-the-counter medicines in Australia:

- TGA engaged and feedback received regarding the proposed indication
- Pivotal clinical trial protocols completed
- Multi-site trial commencement planned for Q4, 2021
- Costs budgeted within current cash position

[See ASX announcement 07 APR 2021]

EMD-004 - a unique cannabinoid targeting Irritable Bowel Syndrome (IBS)

Emyria's EMD-004 drug development program strengthened after filing of additional patents supporting the use of cannabinoid medicines to treat Irritable Bowel Syndrome (IBS). The new patents were filed after analysis of Emyria's clinical data and an extensive review of the global literature and patent landscape.

Emyria's EMD-004 patents cover unique dose strengths and formulations, believed to be most effective in treating a range of IBS-related symptoms including:

- **CBD-only formulations** which could support a Schedule 3, over-the-counter registration program in Australia and;
- **CBD and THC** containing formulations which could support higher Schedule applications and position the product to pursue global registrations

[See ASX announcement 15 JUN 2021]

EMDMA-001 - MDMA-assisted psychotherapy for Post Traumatic Stress Disorder

Emyria and Mind Medicine Australia announced a Phase II, open-label clinical trial of **MDMA-assisted psychotherapy for severe Post-Traumatic Stress Disorder (PTSD)** - **EMDMA-001**. The trial will be fully sponsored by Emyria and will be run out of Emyria's fit-for-purpose clinic in Melbourne before expanding to other sites. The trial will utilise psychotherapists graduating from Mind Medicine Australia's first Certificate in Psychedelic-Assisted Therapy (CPAT) training program.

EMDMA-001 will leverage Emyria's established clinical infrastructure and data capture technology to provide safe patient access while also generating high quality, Real-World Evidence to inform future development

[See ASX announcement 05 MAY 2021]

Psychiatrist, Dr. Kotler, appointed as Principal Investigator for EMDMA-001

Consultant Psychiatrist, Dr. Eli Kotler was appointed as the Principal Investigator for EMDMA-001 and will oversee the clinical governance for the clinical trial.

[See ASX announcement 29 JUN 2021]

Emyria | Care

Data validation - Emyria's care model reduces opioid use

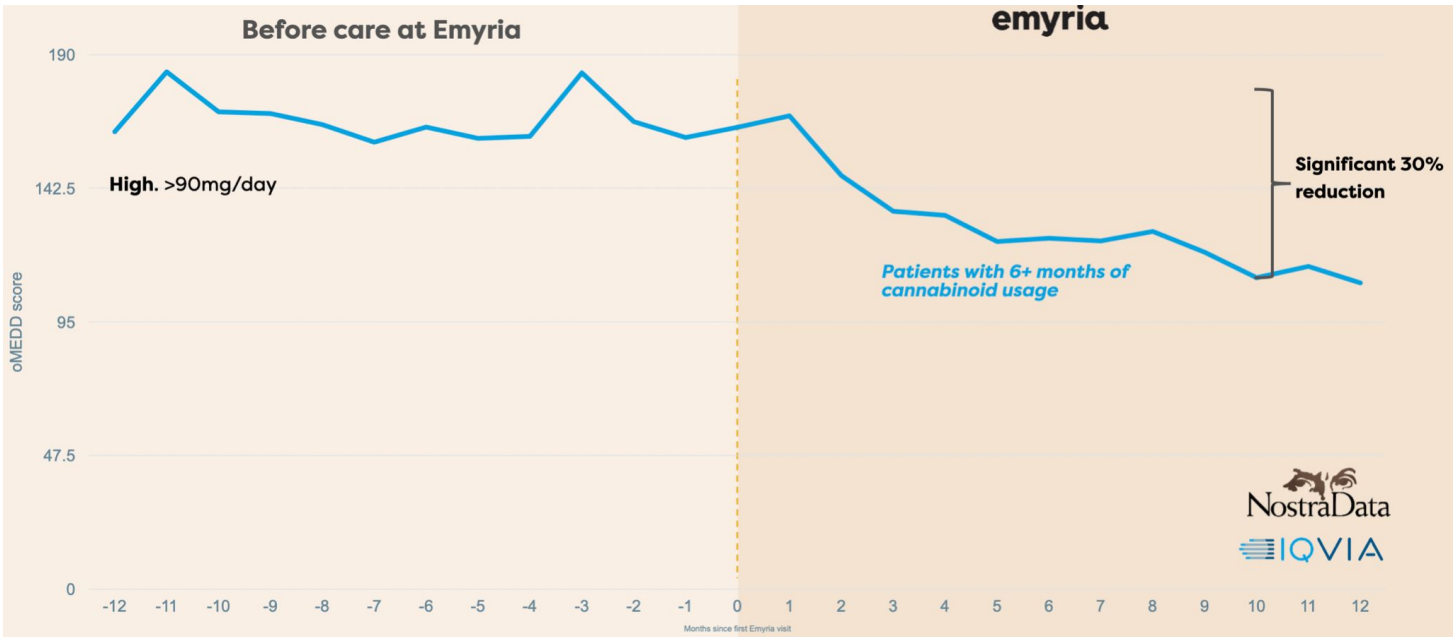
An analysis of community pharmacy dispensing data anonymously linked to Emyria's robust patient data, and led by IQVIA (NYSE: IQV), revealed that Emyria's care model leads to a significant reduction in opioid use amongst the most highly dependent opioid patients. (See chart below)

This analysis showed that the most opioid-dependent patients significantly reduced their average daily opioid usage (>30%) while also gaining improvements in pain symptoms and quality of life measures.

The project highlighted the validity, utility, reach and richness of Emyria's proprietary Data as well as the effectiveness of Emyria's Care programs.

Emyria continues to deeply analyse the data to assess potential for new registered treatments with the FDA for opioid-sparing.

Average Oral Morphine Equivalent Daily Dose (OMEDD) trend pre and post Emyria



The chart above shows the oral morphine equivalent daily dose ("OMEDD") for a cohort of 220 patients presenting at Emyria's Emerald Clinics with a high average daily opioid consumption rating (>90mg of opioid equivalent medicine per day).

OMEDD scores were derived by examining linked community pharmacy dispensing data from NostraData/IQVIA in the 12 months *before* and 12 months *after* starting care at Emerald Clinics.

[See ASX announcement 07 JUN 2021]

emyria

Emyria Digital Health

Openly

Openly - successful Class IIa registration with the Therapeutic Goods Administration

Emyria received an **Australian-first**, **Class IIa "software-as-a-medical-device"** (SaMD) registration with the Therapeutic Goods Administration (TGA) for the Openly smartphone application. (ARTG #: 343533)

Openly is now recognised as capable of providing **medical-grade heart rate (HR), heart rate variability (HRV)** and **atrial fibrillation (AF)** remote monitoring using only a smartphone camera enabling medical- grade monitoring and opening up further opportunities for Emyria in both telemedicine and consumer healthcare markets.

[See ASX announcement 12 MAY 2021]

CORPORATE

Cash

Emyria has $6.5M cash as of 30 June 2021.

The board of directors were paid $263,000 for the quarter ended 30 June 2021 (as disclosed in section 6 of the 4C quarterly report) and this comprised wages, fees and superannuation.

Outlook

Emyria continues to pursue drug registration for its cannabinoid-based drug development programs **EMD-003** (psychological distress) and **EMD-004** (Irritable Bowel Syndrome). This will involve commencing pivotal clinical trials using unique dose forms for the target indications. Emyria will continue to evaluate FDA pathways for other unique cannabinoid medicines

In parallel, Emyria continues to extend its evidence-generating care model into psychedelic-assisted therapies to help develop scalable and evidence-based psychedelic-assisted therapy programs to treat major mental health illnesses.

The company will provide further updates to the market accordingly.

PROMOTIONS DURING QUARTER

Investor Webinar: Emyria Data Validated, Care Model Reduces Opioids

https://vimeo.com/560720397

MarketLit Investment Conference

https://www.youtube.com/watch?v=YQV6WZ-vzDc&ab_channel=TCNTV

ShareCafe Hidden Gems - Medicinal Cannabis Special

https://www.youtube.com/watch?v=ZmO93H5-ntc&ab_channel=ShareCafe

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

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About Emyria (www.emyria.com)

Emyria Limited is a data-backed, care model and treatment development company. **Emyria's Treatments** target large unmet needs and are focused on obtaining approval ("registration") from major global regulators. Emyria's treatment 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	
EMRYIA LIMITED	
ABN	**Quarter ended ("current quarter")**
96 625 085 734	30 June 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	409	1,939
1.2	Payments for		
	(a) research and development (includes allocated salaries)	(549)	(2,896)
	(b) clinic operating costs (includes allocated salaries)	(587)	(2,123)
	(c) advertising and marketing	(82)	(406)
	(d) leased assets	(41)	(151)
	(e) staff costs (unallocated salaries)	(343)	(1,043)
	(f) administration and corporate costs	(244)	(748)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	23
1.5	Interest and other costs of finance paid	(4)	(18)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	954
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,437)**	**(4,469)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(51)
	(d) investments	-	-
	(e) intellectual property	(241)	(241)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(f) other non-current assets	-	-
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**	**(241)**	**(292)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,000	8,400
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	(323)	(528)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(259)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – net payments from cash backed guarantees	(18)	(12)
3.10	**Net cash from / (used in) financing activities**	**4,659**	**7,601**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,540	3,686
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,437)	(4,469)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(241)	(292)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4,659	7,601
4.5	Effect of movement in exchange rates on cash held	9	4
4.6	**Cash and cash equivalents at end of period**	**6,530**	**6,530**

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	6,530	3,540
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)**	**6,530**	**3,540**

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** *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	-	-
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.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,437)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	6,530
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	6,530
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	4.5

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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

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

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

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 2021.....

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.