ASX Announcement

19/01/2021

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myriad data.
individual care.

Emyria launches drug development programs, forms strategic partnerships with Mind Medicine Australia and Sapphire Medical

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development company, is pleased to share this report on the Company's activities for the quarter ending December 31, 2020.

Highlights:

- Launched first drug development programs backed by **Emyria Data** and **filed IP**:
  - **EMD-003**, targeting mental health
  - **EMD-004**, targeting irritable bowel syndrome
  - Commenced expansion of analytical team to identify **new cannabinoid drug indications** for Emyria's growing drug development portfolio
- Welcomed **TGA announcement** rescheduling low-dose CBD to Schedule 3
- Formed partnership with **Sapphire Medical**, to obtain **UK patient data**
- Launched observational studies into **Autism Spectrum Disorder** (ASD) and **Insomnia** with **Zelira**
- Continued **surging clinical demand for patient services** across quarter
- Formed partnership with **Mind Medicine Australia** to develop an evidence-generating care model for **psychedelic-assisted therapy**
- **Grew revenues** - 200% increase from June '20 quarter and Sep '20 quarter
- A continuation of **cash receipts exceeding $500k** in the Dec 20 quarter
- **Consistent gross operational expenditure** since listing of $1.5m per quarter
- Investment and potential of our R&D demonstrated by **$950k R&D refund**
- Strengthened cash position with strategic placement from **Sixty Two Capital**

Emyria's Managing Director, Dr Michael Winlo, said: "*Emyria ends a challenging and unprecedented 2020 with a strong quarter full of highlights. We have increasing demand from patients for our independent and personalised model of care at Emerald Clinics. This allows us to enrich and grow our proprietary data asset which we use to improve care, create IP and generate robust evidence to support our own drug development programs. As an example, EMD-003, launched in the December quarter, will use this evidence-based data to seek registration with the TGA for the rescheduled OTC market. EMD-003 will target the growing global mental health burden with a focus on the symptoms of anxiety, depression and stress. In the December quarter we also formed new partnerships that will expand our therapeutic options and patient data which positions us well for 2021.*"

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Emyria | Treatments

Emyria launched its first two drug development programs in the December quarter of 2020. Each program is guided by **Emyria Data**, which is gathered from Emyria's clinical subsidiary - **Emerald Clinics**. Comprehensive analysis has revealed a number of significant dose-response insights for specific patient groups. These insights are now guiding the design of pivotal clinical trials which, if successful, will support applications to register Emyria's treatments with Australia's Therapeutic Goods Administration (TGA) and other global regulators.

The first two data-, and IP-backed, programs are cannabinoid-based medicines targeting large unmet needs. **EMD-003**, focussed on alleviating mental health symptoms and **EMD-004**, focussed on irritable bowel syndrome.

EMD-003 - a cannabinoid treatment for mental health

EMD-003 is Emyria's leading cannabinoid drug program. EMD-003 is focussed on unmet needs within mental health. Specifically, EMD-003 will target the treatment of psychological distress and the symptoms of anxiety, depression and stress for certain patient populations.

Analysis of Emyria's data has identified specific patient populations that appear to have a safe and effective response to regulated doses of CBD. Patents, covering these insights and intellectual property, have been filed. The Company believes a strong IP portfolio will be important in cannabinoid medicine development since neither of the two main ingredients in medicinal cannabis - CBD or THC - can be patented as chemical entities. Therefore, IP is restricted to dose formulations and "methods of use" which describe how the treatments may be effectively and safely administered to specific patients to treat specific conditions.

Mental health is also a rising global health challenge, particularly in the last 12 months. In the 2017-2018 National Health survey, mental health topped the list of chronic health conditions in Australia affected 4.8 million people, or 20.1% of all Australians [1]. In any one year over 2 million Australians suffer from anxiety alone [2]. Psychological distress, in particular, has been increasing in incidence [3].

[See ASX announcement 25 NOV 2020]

EMD-004 - a cannabinoid treatment for irritable bowel syndrome

EMD-004 is a cannabinoid-based medicine focussed on treating symptoms associated with irritable bowel syndrome - a large unmet need.

IBS is common and affects around 3 out of every 10 people. In Australia there are no medicines designed specifically for IBS [4]. Emyria's observational trial on IBS has ethics approval and **recruiting is underway**.

[See ASX announcement 03 DEC 2020]

TGA rescheduling for low-dose CBD

On December 15, 2020, the TGA announced a final ruling that would allow **low-dose CBD (<150mg) to be registered as a Schedule 3 medication**. The TGA emphasised that all *"applications to register a Schedule 3 low-dose CBD preparation on the ARTG would involve assessment of safety and efficacy data to support the proposed dose and indication."* (See page 11 of Final Decision document).

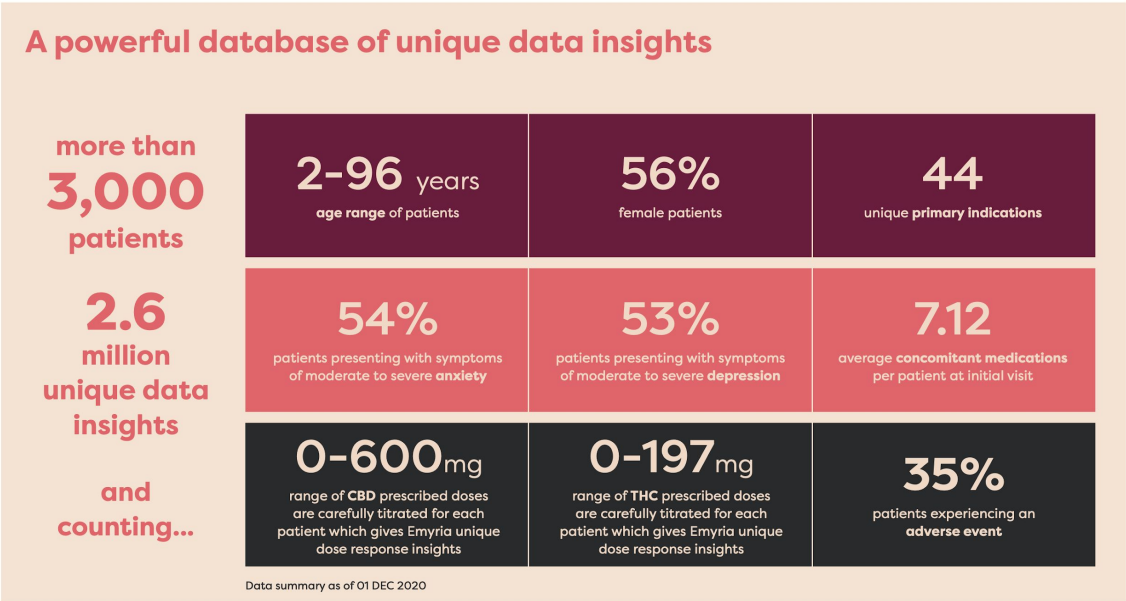
In anticipation of the TGA ruling, Emyria conducted an in-depth analysis of its own data, published literature and patent landscape and filed unique IP which covers the use of specific doses of CBD at or below the 150mg dose for a set of medical indications and patient cohorts. The IP specifically supports **EMD-003**.

[See ASX announcement 16 DEC 2020]

Emyria Data

Emyria's strategy has been to invest in technology and processes to both improve care and learn from every patient. As a result, Emyria has now built one of the largest, trial-grade clinical data sets on pharmaceutical cannabinoid medicines. **Emyria Data** covers safety and efficacy insights for a diverse set of patients receiving a wide range of treatments (*see infographic below*).

Emyria Data now contains detailed, anonymous, long-term, clinical data for over 3,000 consenting patients. **Emyria Data** improves our care model, is proprietary and a valuable source of IP.



Expanding analytical team

In the December quarter, Emyria expanded our in-house analytics team by adding **PhD level expertise** in **biostats** and **behavioural economics**. Emyria also engaged **Bayesian Intelligence [BI]** - experts in Bayesian network modelling and real-world problem solving - to commence design and development of a proprietary clinical decision support system.

Autism clinical trial with partner Zelira

Emyria continued to support sponsored clinical research and complete data deals with fee-paying, research-focussed commercial partners.

In November, Emyria entered into a data deal with Zelira to support one of the largest medicinal cannabis studies ever undertaken in Autism spectrum disorder (ASD). Emyria will support a study for ~200 patients across Emyria's national Emerald Clinics network. Emyria will provide real-world data to help accelerate and inform drug development and pharmaceutical registration.

[See ASX announcement 19 NOV 2020]

Growing clinical engagement across Australia

Emerald Clinics' doctors provide in-depth, long-term, individualised care for unresolved patient conditions. The average face-to-face time with our clinicians is more than 30mins. Initial consultations can be more than one hour. Our model ensures each patient receives attentive, personalised care and ensures we gather comprehensive, validated, clinical assessments for our **Emyria Data** asset.

New clinical hires to meet demand

During the quarter, Emerald Clinics hired additional clinical staff to help meet increasing patient demand for our clinical services.

UK clinical partner - Sapphire Medical (https://www.sapphireclinics.com)

In October, Emyria entered into an agreement with Sapphire Medical Clinics, based in London, UK and led by several prominent clinicians. Sapphire's Harley Street clinic was the first medicinal cannabis clinic registered by the UK's Care Quality Commission (CQC) in 2019 and is the most recognised medicinal cannabis clinic in the UK.

Under the partnership, Sapphire will provide UK-centric, anonymised, clinical data to Emyria - further enhancing the global scope of **Emyria Data.** The UK medicinal cannabis market is also predicted to be worth nearly £1bn (AUS$1.8bn) servicing nearly 340,000 patients.

[See ASX announcement 21 OCT 2020]

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MIND MEDICINE AUSTRALIA

New care model development : psychedelic-assisted therapy for major mental health concerns with partner Mind Medicine Australia (https://mindmedicineaustralia.org.au)

In November 2020, **Emyria** and **Mind Medicine Australia** announced a partnership to co-develop a scalable, evidence-generating care model for Australian-based **psychedelic-assisted therapy** for patients with **major mental health concerns**.

Emyria will use its expertise in building evidence-generating care models and real-world clinical data registries. The goal is to develop safe and clinically-supervised care models that can help evaluate the most promising psychedelic medications and psychotherapies. The initial programs will focus on major mental health concerns - **post-traumatic stress disorder (PTSD)** and **treatment resistant depression** utilising pivotal research conducted recently in North America and Europe with **MDMA-** and **psilocybin-assisted psychotherapies** respectively.

The partnership is also aiming to **create a world-class data registry** that will contain data on diagnoses, concomitant medications, dosing information and patient responses to psychedelic-assisted treatments as measured using validated clinical and patient-reported assessments. The data will support ongoing research into the **safety**, **effectiveness** and **cost benefits** of psychedelic-assisted therapies and is expected to support further drug and care model development.

Unlike traditional drug treatment, psychedelic-assisted therapies require close clinical oversight before, during and after drug administration. The **clinical care model is tightly interlinked to therapy administration** and requires careful development. Emyria believes both high quality clinical evidence and carefully developed, evidence-based, care delivery models will be vital to improving patient access to these treatments.

Under the TGA, psychedelic medications such as psilocybin and MDMA are currently Schedule 9 of the Uniform Scheduling of Medicines and Poisons (which deals with Prohibited Substances). Despite approvals being given by the TGA under the Special Access Scheme, in most States of Australia these treatments are only available via approved clinical trials which require oversign by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes.

Mind Medicine Australia is currently leading an internationally-supported rescheduling proposal for psilocybin and MDMA with the TGA. Successful rescheduling would allow these treatments to be more easily used as clinical therapies in medically controlled environments for key mental illnesses. The rescheduling would move these medicines to Schedule 8 (which deals with Controlled Medicines), the same category as THC-containing cannabinoid medicines [7].

[See ASX Announcement 19 NOV 2020]

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Emyria | Digital Health

Openly

Openly - further development, TGA registration and partnerships

Emyria continues to support strategic development into its remote monitoring platform - **Openly.** After obtaining Class I registration with the TGA, in December, Emyria commenced an application for **Class II TGA registration** for the platform's smartphone-led **heart rate** and **heart rate variability** measurement technologies. These vital sign measures correlate to **psychological distress** - which can be an early sign of clinical deterioration or mental health changes. The Company believes these measures will be important to the development of **EMD-003.**

The company continues to work with **Mt Sinai hospital (NY)** on the development of this technology and has **applied for a number of grants** to further develop Openly and its application to **mental health**.

CORPORATE

$1.2m placement

During the quarter Emyria issued 14.12 million new shares at $0.085 with a 1 for 3 attaching option (strike price $0.20, 2 year expiry) to new strategic and sophisticated investors. This placement was conducted and cornerstoned by Sixty Two Capital.

[See ASX announcement 16 DEC 2020]

R&D refund

Emyria received R&D refund of $954,000.

[See ASX announcement 02 NOV 2020]

Cash

Emyria has $4.8M cash as of 30 December 2020.

The board of directors were paid $221,000 for the quarter ended 31 December 2020 (as disclosed in section 6 of the 4C quarterly report) and this comprised wages, fees and superannuation.

Outlook

Emriya will continue its focus on the registration of **EMD-003**, a cannabinoid-based medicine to reduce symptoms of anxiety, depression and stress.

Emyria is now analysing its data to refine the pivotal registration clinical trials which are expected to commence in H1, 2021. The company will provide further updates to the market accordingly.

USE OF FUNDS AS AT 31 DECEMBER 2020

	Use of Funds reported in Prospectus on 11 Dec 19	Expenditure period 11 Dec 19 to 31 Dec 20
	$'000s	**$'000s**
Clinic Operations - Existing	2,500	1,276
Develop Data Platform*	800	861
Clinical Trials	800	-
Clinics Development - New and Existing	800	-
Corporate Overheads	1,600	2,204
Business Development	-	284
Cost of the Offers	682	926
Working Capital	518	590
Total Expenditure	**7,700**	**6,142**

Please note that the "Use of Funds" for the 12-month period post admission, disclosed above, was prepared prior to the international spread of COVID-19. This significant external event, which is continuing to affect the operations of many companies and other organisations with which the Company engages, may potentially impact on future allocation of expenditure for the Company. At this point in time, the pandemic's human health and economic impacts are unknown. Ongoing national and international travel restrictions and lockdowns, quarantine and social distancing measures and other interventions undertaken in response to COVID-19 may impact on the Company's operations and allocation of funds in the future. In light of this, the Company will continuously monitor its capital investment opportunities and review its operations and update the market accordingly.

*During the quarter ended 31 December 2020, the Company received an R&D refund of A$954,000 for the financial year ended 30 June 2020.

COMPANY PRESENTATIONS DURING DECEMBER QUARTER

TechKnow
https://vimeo.com/489201557

Webinar on Sapphire UK deal
https://vimeo.com/472018026

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

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About Emyria (www.emyria.com)

Emyria Limited is a data-backed, drug development company. **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	
EMRYIA LIMITED	
ABN	**Quarter ended ("current quarter")**
96 625 085 734	31 December 2020

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	503	1,150
1.2	Payments for		
	(a) research and development (includes allocated salaries)	(681)	(1,613)
	(b) clinic operating costs (includes allocated salaries)	(593)	(1,179)
	(c) advertising and marketing	(79)	(205)
	(d) leased assets	(19)	(39)
	(e) staff costs (unallocated salaries)	(208)	(494)
	(f) administration and corporate costs	(128)	(319)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	14
1.5	Interest and other costs of finance paid	(4)	(11)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	954	954
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(248)**	**(1,742)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(44)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**-**	**(44)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,200	3,400
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	(74)	(198)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(259)	(259)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – net payments from cash backed guarantees	50	37
3.10	**Net cash from / (used in) financing activities**	**917**	**2,980**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,206	3,686
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(248)	(1,741)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(44)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	917	2,980
4.5	Effect of movement in exchange rates on cash held	(5)	(10)
4.6	**Cash and cash equivalents at end of period**	**4,870**	**4,870**

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	4,870	3,206
5.2	Call deposits	-	1,000
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)**	**4,870**	**4,206**

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	221
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)	(248)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	4,870
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	4,870
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	19.6

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: 19/1/2021 .....

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.