ASX Announcement

26/10/2021

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Emyria advances multiple drug registration programs; establishes pure cannabinoid delivery platform; secures exclusive rights to major MDMA-analogue library; clinical advisory strengthened

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

Highlights:

- **Launched** development of a unique **TGA- and FDA-compliant cannabinoid dose form** with major US contract research organisation, Altasciences
- **Obtained exclusive access to a library of more than 100 novel MDMA analogues** developed at the University of Western Australia (UWA); potential to develop multiple treatments targeting major psychiatric and neurological disorders; pre-clinical data of one MDMA analogue class shows potential in reducing symptoms associated with Parkinson's disease treatment
- **Boosted drug development and clinical advisory** with addition of renowned **neuropharmacologist**, Dr. Mat Martin-Iverson and **Consultant Psychiatrist** and **Pain Medicine Fellow-in-training**, Dr. Jeremy Tannenbaum
- Emyria well funded to accelerate drug development programs with **$4.5M** cash as of 30 Sep 2021, and a further **$1.1M R&D tax incentive** expected in Q2, FY21/22

Emyria's Managing Director, Dr. Michael Winlo, said: "*Emyria has made significant strategic progress this quarter.*

Firstly, we engaged a leading US-based contract research organisation, Altasciences, to develop a range of bespoke pharmaceutical medicines. These dose forms will form the backbone of Emyria's cannabinoid drug development and registration programs, (such as EMD-003 and EMD-004) and are 100%-Emyria-owned. Our dose forms comprise pure cannabinoids, providing purity, reliability and cost advantages to botanicals.

In addition, we engaged Calvert Labs, an Altasciences company, to perform a range of preclinical and animal pharmacokinetic, bioavailability and toxicology studies on Emyria's unique cannabinoid medicines.

Secondly, we boosted our drug development pipeline through an exclusive deal with the University of Western Australia (UWA) which provides Emyria with access to a library of over 100 MDMA-like compounds. Emyria is now leading a screening and patent strategy program to develop treatments for a range of major psychiatric and neurological conditions. Some of these novel compounds have already shown promise in the management of Parkinson's disease.

Finally, we boosted our neuropharmacology and psychiatry expertise by welcoming renowned neuropharmacologist, Dr. Mat Martin-Iverson to our team as well as Consultant Psychiatrist and Pain Medicine Fellow-in-training, Dr. Jeremy Tannenbaum."

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ADVANCING EMYRIA'S DRUG REGISTRATION PROGRAMS

Data-backed cannabinoid-based pharmaceutical development and registration

Emyria is developing a number of unique cannabinoid-based pharmaceuticals for registration with major global regulators such as the TGA in Australia and the FDA in the US.

Each of Emyria's drug development programs is guided by Emyria's proprietary Real-World Evidence (RWE) data, which is gathered with patients across Emyria's national clinical network, provides helpful dose-response insights, helps inform care and is also a source of intellectual property.

Consequently, Emyria has a strong and growing patent portfolio related to it's cannabinoid-based pharmaceutical development programs and their target clinical indications.

Two drug development programs have been announced to date. Each program targets a large, unmet patient population:

- **EMD-003** - an over-the-counter, low-dose CBD medicine targeting the symptoms of psychological distress
- **EMD-004** - a CBD +/- THC medicine for Irritable Bowel Syndrome (IBS)

A unique, synthetic cannabinoid dose platform

This quarter, Emyria bolstered its drug development programs by engaging North American pharmaceutical manufacturer, **Altasciences**, to deliver a proprietary, ultra-pure, cannabinoid-based medicine platform.

Emyria's medicine platform is intended to meet the quality and reliability requirements of both the Australian and US drug regulation agencies. The platform will provide the backbone for both **EMD-003** and **EMD-004**.

The major advantages of Emyria developing its own, novel cannabinoid platform are:

- **Accelerated US FDA registration** - By using synthetic ("ultra-pure") cannabinoid Active Pharmaceutical Ingredients (APIs), Australian clinical development and trials can support US/FDA registration, accelerating timelines for FDA registration
- **Ownership** - Emyria retains 100% ownership of the platform, including all commercialisation rights and revenues
- **Cost effective** - Synthetic cannabinoids currently have lower manufacturing costs compared to plant-derived options, substantially improving affordability, patient access and providing Emyria with a competitive cost advantage

[See ASX announcement 13 AUG 2021]

Also this quarter, Emyria engaged **Calvert Labs**, an Altasciences company, to conduct a range of preclinical and animal pharmacokinetic, bioavailability and toxicology studies on Emyria's novel formulations. These studies are ongoing.

[See ASX announcement 27 AUG 2021]

MDMA-based treatment development

Alongside bespoke cannabinoid-based pharmaceutical development, Emyria is also preparing its national clinical site network, data infrastructure and clinical expertise working with unregistered treatments, to support psychedelic-assisted therapy for patients with major mental health concerns.

MDMA-assisted therapy for patients with Post-Traumatic Stress Disorder (PTSD)

A clinical trial in MDMA-assisted therapy for patients with Post-Traumatic Stress Disorder (PTSD). This program - **EMDMA-001** - is progressing towards ethics submission.

This quarter, to support Emyria's psychedelic-assisted research and related drug development programs, Consultant Psychiatrist, Dr. Jeremy Tannenbaum was appointed to Emyria's clinical advisory.

Dr. Jeremy Tannenbaum is a Consultant Psychiatrist and Pain Medicine Fellow-in-training. Dr. Tannenbaum's interests cover the emerging use of psychedelic-assisted psychotherapy and other potential uses of psychedelics as well as the holistic treatment of complex pain conditions.

Dr. Tannenbaum also completed a clinical observership with leading psychedelic-assisted therapy pioneers, Professor David Nutt (Imperial College, UK) and Dr Robin Carhart-Harris in the early stages of their research into the therapeutic role of psilocybin.

[See ASX announcement 16 SEP 2021]

Unique MDMA analogues expand Emyria's drug discovery pipeline

Also this quarter, Emyria secured exclusive rights to a library of **more than 100 novel MDMA analogues** from the University of Western Australia.

The library of compounds has been developed by the highly regarded research group of medicinal chemist, Dr. Matt Piggott, who has been working with MDMA analogues, and exploring their therapeutic potential, for more than 10 years.

The agreement with UWA provides Emyria with a unique drug discovery pipeline, which will assist the company in becoming a leader in the development of psychedelic-assisted therapies and treatments for major neurological disorders.

The existing library will be screened and expanded in order to identify families of patentable compounds which show the greatest potential to become new, registered psychedelic-assisted therapies and treatments for major neurological disorders.

Emyria will lead the global patent strategy, already underway, of this unexplored research space.

[See ASX announcement 05 AUG 2021]

To advise over the screening and expansion of Emyria's MDMA-analogue program, this quarter, Emyria appointed renowned neuropharmacologist, **Dr. Mathew Martin-Iverson** to Emyria's clinical advisory.

Dr. Martin-Iverson has over 35 years of experience studying and researching the effects of amphetamines and other psychostimulants. Dr. Martin-Iverson has authored over 160 publications with a particular focus on dopamine-related effects including its role in drug addiction, schizophrenia, Parkinson's disease, attention and motivation.

[See ASX announcement 28 AUG 2021]

MDMA-analogues show early promise in Parkinson's Disease

Also highlighted this quarter were the results of a study involving a gold standard model of Parkinson's disease (PD) in which MDMA was shown to enhance the beneficial effects of the most common PD treatment, L-DOPA whereas MDMA-analogue UWA-101 maintained beneficial effects but was predicted to be non-psychoactive.

UWA-101 is just one of over 100 MDMA-like compounds that have been synthesised by Dr. Matt Piggott and his research team at UWA and exclusively optioned to Emyria.

These results highlight the potential of uniquely designed MDMA-analogues to elicit different neurological effects, which may lead to new treatments for psychiatric and neurological disorders such as Parkinson's disease.

[For more on this study, please see ASX announcement 01 SEP 2021]

CORPORATE

Outlook

Emyria continues to pursue drug registration for its pure cannabinoid-based pharmaceutical development programs.

Upon completion of key preclinical evaluation, pivotal trials are expected to commence. 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, Emyria 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 continues to pursue the extensive screening and expansion program on an MDMA-analogue library in partnership with UWA in order to recognise compounds with promise to become treatments for major mental health illnesses and neurological disorders.

The Company will provide further updates to the market accordingly.

Cash

Emyria has **$4.5M** cash on hand as of 30 Sep 2021.

Emyria has also made a submission for an **R&D cash refund** estimated at **$1.1M** and expected to arrive in Q2, FY21/22 pending successful review by the Australian Tax Office.

The board of directors were paid $262,500 for the quarter ended 30 September 2021 (as disclosed in section 6 of the 4C quarterly report) and this comprised wages, fees and superannuation.

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 clinical drug development and care delivery company focused on 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	30 September 2021

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	467	467
1.2	Payments for		
	(a) research and development (includes allocated salaries)	(314)	(314)
	(b) clinic operating costs (includes allocated salaries)	(627)	(627)
	(c) advertising and marketing	(120)	(120)
	(d) leased assets	(70)	(70)
	(e) staff costs (unallocated salaries)	(510)	(510)
	(f) administration and corporate costs	(710)	(710)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	8
1.5	Interest and other costs of finance paid	(2)	(2)
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**	**(1,878)**	**(1,878)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(23)	(23)
	(d) investments	-	-
	(e) intellectual property	(164)	(164)

	(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**	**(187)**	**(187)**

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	-	-
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	11	11
3.10	**Net cash from / (used in) financing activities**	**11**	**11**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,529	6,529
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,878)	(1,878)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(187)	(187)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	11	11

4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**4,475**	**4,475**

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	4,475	6,529
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)**	**4,475**	**6,529**

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)	(1,878)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	4,475
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	4,475
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	2.4

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: 26 October 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.