ASX Announcement

23/08/21

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Emyria Drug Development Webinar

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed treatment development and clinical services company, is pleased to invite shareholders to an overview of Emyria's novel cannabinoid and MDMA drug development programs to be held on the:
24 August at 12:30 pm AEST.

Emyria's Managing Director and CEO, Dr, Michael Winlo will present the attached presentation and cover the recently announced 'pure CBD agreement with Altasciences to accelerate FDA and TGA cannabinoid registration programs', Emyria's novel MDMA-analogue drug discovery pipeline, and the imminent independent report to inform the possible re-scheduling of MDMA and psilocybin with the TGA.

Details of the event are as follows:

- **Event:** Emyria Drug Development Webinar
- **Webinar Presenter:** Emyria's Managing Director, Dr, Michael Winlo
- **Date and Time:** Tuesday 24 August 2021, 12:30pm AEST
- **Where**: Zoom Webinar - details to be provided upon registration

To register your interest in the webinar please click through to the link below.

Registration Link:
https://janemorganmanagement-au.zoom.us/webinar/register/WN_zBsUQCCqQHavOCeJ_WIagw

After registering your interest, you will receive a confirmation email with information about joining the webinar. Participants will be able to submit questions via the panel throughout the presentation, however, we encourage shareholders and investors to send through questions via email beforehand to Lexi O'Halloran at: lexi@janemorganmanagement.com.au

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

For further information on **Emyria**:

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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.

Emyria's first drug development program, **EMD-003** is targeting unmet needs in mental health. Specifically psychological distress and the symptoms of anxiety, depression and stress.

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.

ADVANCING NOVEL CANNABINOID and PSYCHEDELIC THERAPIES

August 2021

Dr Michael Winlo, CEO

ASX: EMD

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Disclaimer

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This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of Emyria and certain of the plans and objectives of Emyria with respect to these items. These forward-looking statements are not historical facts but rather are based on Emyria's current expectations, estimates and projections about the industry in which Emyria operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Emyria, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Emyria cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Emyria only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. Emyria will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

Presentation release authorised by Michael Winlo, CEO and Managing Director

Corporate snapshot

Key Metrics	Value
Shares on issue	254m
(Escrowed component)	*100m*
Last close (20 Aug 2021)	A$0.175
Market Capitalisation (20 Aug 2021)	**A$44.5m**
Cash (30 June 2021)	A$6.5m
Debt (30 June 2021)	-
Enterprise value	**A$38m**
Total options (exercise price $0.114-0.45) *expiring. 2022-24*	63m

Top 20 = 60.48%
Director ownership = 27.17%

Share Price Chart



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Board with deep clinical and commercial expertise

Key Person	Role	Experience	Affiliations
	**Dr Stewart Washer** Chairman & Founder	**Cynata** (ASX:CYP) – stem cells **Orthocell** (ASX:OCC) – regenerative medicine **Botanix** (ASX:BOT) – synthetic CBD	ortho·cell advancing tissue repair & regeneration; botanix PHARMACEUTICALS; cynata therapeutics
	**Dr Michael Winlo** Managing Director	**Medical doctor** Director at **Linear Clinical Research** - Phase 1 clinical trials Health Lead at **Palantir** (NYSE:PLTR) - Big Data analytics MBA from **Stanford University**	linear; Palantir; Stanford University
	**Dr Alistair Vickery** Medical Director	Specialist **general practitioner** Chair of **Black Swan Health** - mental health Associate **Professor of Primary Health Care**	BLACK SWAN HEALTH LTD; THE UNIVERSITY OF WESTERN AUSTRALIA
	**Matt Callahan** NED & Founder	Founder **Botanix** (ASX:BOT) - synthetic CBD Founder **Orthocell** (ASX:OCC) - regenerative medicine 4 products through **FDA approval** More than 20 years' **legal and IP experience**	ortho·cell advancing tissue repair & regeneration; botanix PHARMACEUTICALS; iCeutica Making Drugs Better
	**Professor Sir John Tooke** Independent NED	**Knighted** in the UK for Services to Medicine Senior Independent Director, **BUPA Chile** Head of Medical Sciences, **University College London** Review board, **Google DeepMind** Immediate past **President Academy of Medical Sciences**	Bupa; UCL; DeepMind; The Academy of Medical Sciences

Recently appointed Key Advisors

Key Person	Role	Experience	Affiliations
	**Dr Karen Smith, MD, PhD, MBA, LLM** Chair of Strategic Advisory	**Multiple Directorships** with innovative pharmaceutical companies **Ex-Chief Medical Officer** and **Global Head of R&D** at **Jazz Pharmaceuticals** Overseen more than 100 clinical trials and **20 regulatory approvals**	Jazz Pharmaceuticals
	**Dr Richard Magtengaard, MBBS, BSc , RAN , RTD , FRANZCP** Consultant Psychiatrist	**Director of Military Trauma Recovery Program**, Salvado Former Commissioned Officer within the **Royal Australian Navy** Member of Australasian Military Medical Association; affiliations with the ADF Joint Health Command, St John's Ambulance and WAPOL	Salvado. NAVY
	**Dr Eli Kotler, MBBS, MPM, FRANZCP, AFRACMA** Consultant Psychiatrist	**Medical Director** at **Malvern Private Hospital**, specialising in drug & alcohol addication recovery Strong **research background** Board Member, **Mind Medicine Australia**	MALVERN PRIVATE HOSPITAL MACQUARIE HEALTH CORPORATION MIND MEDICINE AUSTRALIA
	**Assoc. Prof. Matthew Pigott, Dr, BSc PhD** Medicinal Chemist, MDMA Analogues	Worked on **antibiotic drug discovery** in collaboration with **GlaxoSmithKline** Has spent the past 10 years developing **MDMA analogues** for Parkinson's disease and other **neurological conditions**	THE UNIVERSITY OF WESTERN AUSTRALIA
	**Prof. Mathew Martin-Iverson, BSc Alta., PhD Br.Col.** Neuropharmacologist	**Head of Psychopharmacology, UWA** Over **35 years** of experience studying **amphetamines** and other **psychostimulants**	THE UNIVERSITY OF WESTERN AUSTRALIA

Emyria's accelerated drug development programs

Proprietary Assets

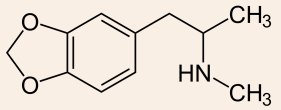
- One of the world's largest, **real-world evidence** (RWE) patient registries tracking dose responses to pharmaceutical-grade cannabinoid medicines
- Growing **patent portfolio** covering novel treatment methods and **new chemical entities**
- Proprietary **MDMA-analogue** drug discovery pipeline (>100 entities)
- Novel **synthetic cannabinoid** delivery platform (FDA-compliant)
- **Clinical service delivery** footprint across Australia (7 sites)
- **TGA approved** remote patient monitoring tech (Class IIa)

Company Highlights

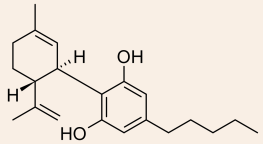
- **Two active cannabinoid drug development programs** targeting unmet needs in **Mental Health** and **Irritable Bowel Syndrome.** Seeking registration with the TGA and FDA
- Partnership with **Mind Medicine Australia** to deliver scalable MDMA-assisted psychotherapy trial targeting PTSD (starting with Phase II trial)
- Exclusive agreement with UWA to **screen** and **expand** library of **>100 novel MDMA analogues,** aiming to develop multiple psychiatric and neurological treatments

Treatment Programs

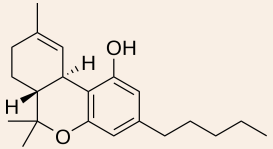
3,4-Methylenedioxymethamphetamine (MDMA + psychotherapy / analogues**)**



Pure Cannabidiol (CBD)



Pure Tetrahydrocannabinol (THC)



Presentation overview

1.

How Emyria accelerates treatment development

Overview of Emyria's unique drug development assets:

- A **clinical service** that cares for thousands of patients
- Robust **clinical data** and analysis systems
- Experienced **drug development team**

2.

Emyria's leading treatment programs

Overview of Emyria's leading drug development programs:

- **Synthetic cannabinoid** delivery
- **MDMA-assisted psychotherapy**
- Novel **MDMA-analogue** development

3.

Emyria's upcoming milestones

Overview of Emyria's drug development milestones for the next 3 quarters



1

How Emyria accelerates treatment development



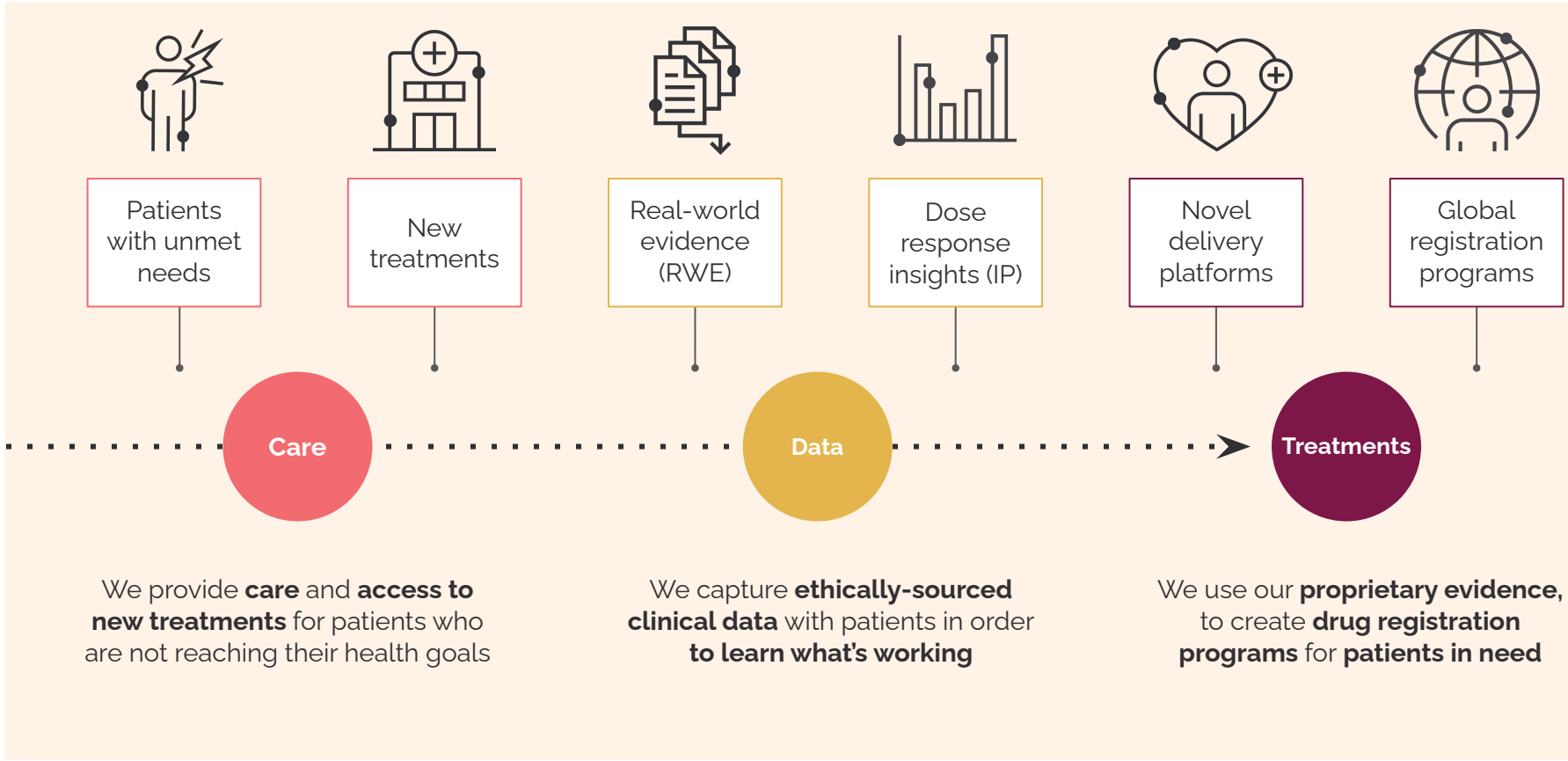
At Emyria, we believe...

There are better ways to get better.
Everyday we care for patients with complex and challenging conditions who are not reaching their health goals. We believe that by providing a safe place for our patients to access promising new treatments, we may improve their lives. By paying attention to what's happening with rich data collection, we can also lead the discovery of the next generation of treatments and care models to help the lives of patients beyond our clinics.

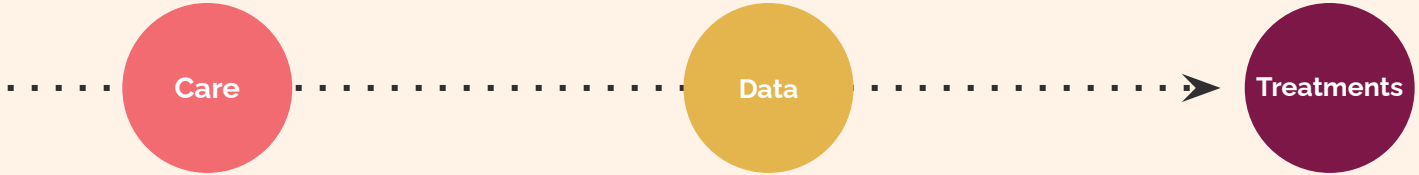
Drug development can be faster.
Treatment development can take so long. We believe that by investing in better data collection at the front-line of care we can innovate faster, personalise care and protect our insights. We can also reduce the risk of our drug development programs. Helping bring new treatments to those that need them, faster and more cost effectively.

Registration matters.
Registered products (both treatments and technologies) must demonstrate the highest standards of quality, safety and efficacy. They have earned the trust of patients and clinicians, may be eligible for reimbursement, and can therefore reach larger patient populations. Registration is our goal for all our programs.

An accelerated treatment development model



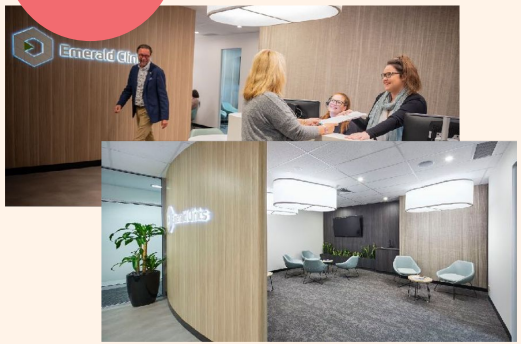
An accelerated treatment development model (cont.)



What we do	We provide **front-line care,** and **access to new treatments,** for patients who are not reaching their health goals.	We collect **robust & ethically-sourced evidence** with patients. We analyse this data for dose response insights & novel IP.	We use our proprietary evidence and in-house team to create global **drug development** and registration programs
How this creates value	Each of **our patients** have unmet clinical needs and therefore **represent a global opportunity** for a better treatment option. Our clinics are a source of patients and can support clinical trials.	Reliable, **clinical-trial-grade data** guides our care delivery models, novel drug development programs and also helps generate intellectual property.	**Registered treatments** have proven quality, safety and efficacy. They **can reach large patient populations** via routine prescription and **reimbursement**.

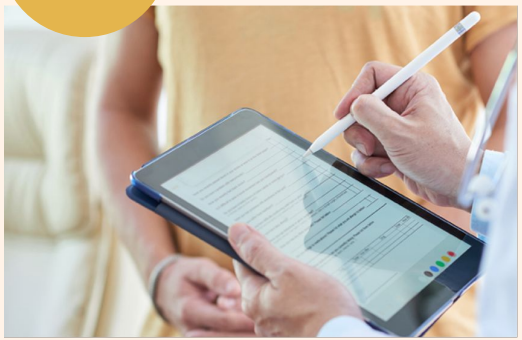
Emyria's successes to date

Care



- **7 sites** around Australia
- **4,500 patients** and growing
- Patients aged **2-98 years**
- **40+** clinical indications

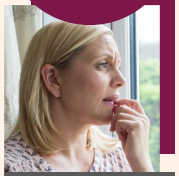
Data



- **Millions** of data points
- **Validated** assessments
- Unique **dose response** insights
- **TGA class IIa** data platform

Treatments

Current drug development programs



EMD-003

CBD medicine targeting **psychological distress**



EMD-004

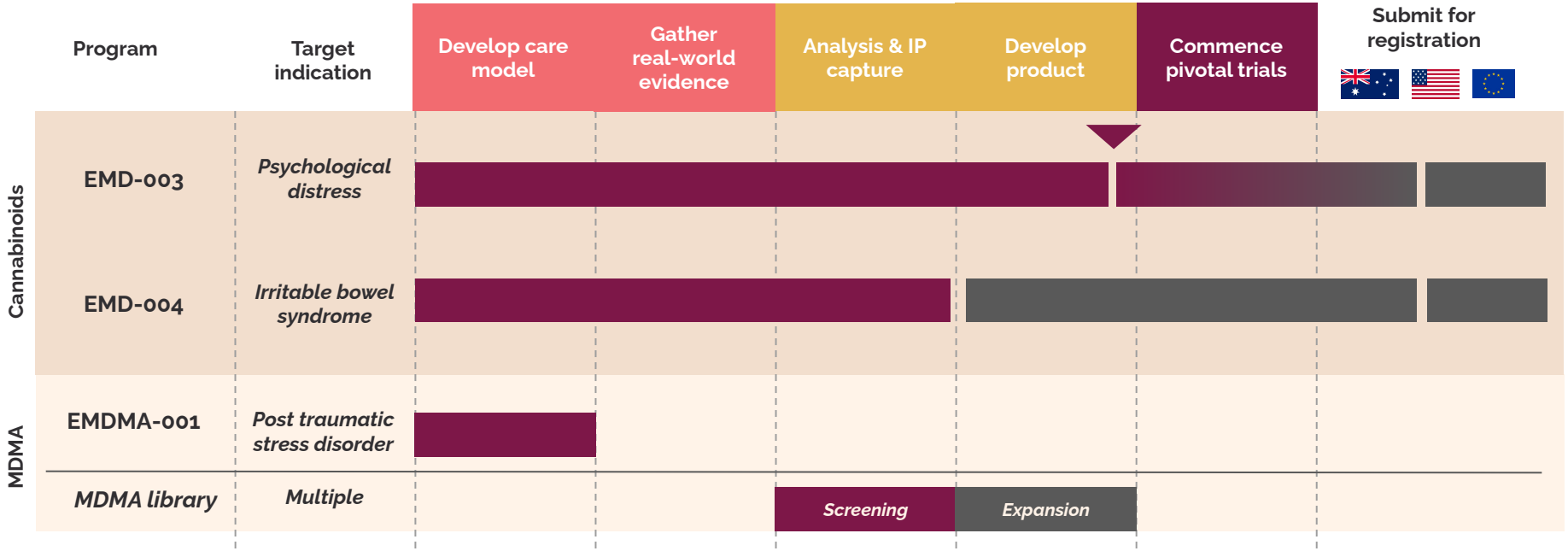
CBD +/- THC for **Irritable Bowel Syndrome (IBS)**



EMDMA-001

MDMA-assisted psychotherapy for **Post-Traumatic Stress Disorder (PTSD)**

Emyria's active treatment pipeline + global registration plans



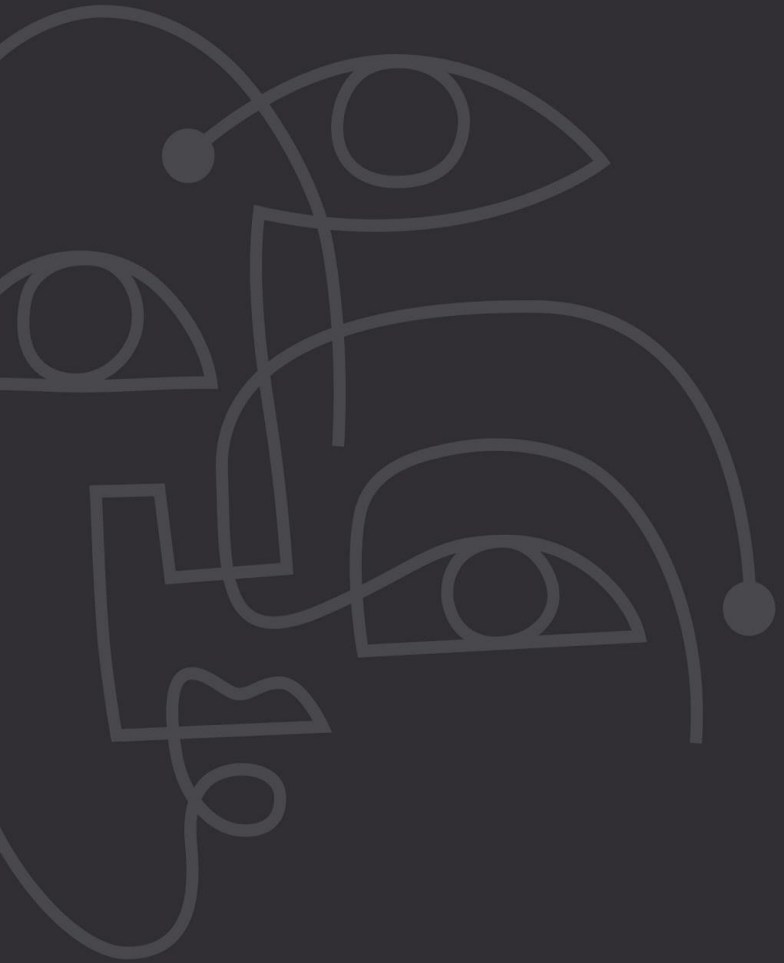
40+ other indications

Current status

In planning

Where we are now

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Emyria focusses on major unmet needs



Emyria has a special focus on major mental health concerns

Mental illness is a primary presentation for ~15% of Emyria patients
More than 60% of Emyria patients suffer from mental health symptoms (regardless of primary indication)
Mental health is one of the largest global healthcare challenges with an urgent need for innovative approaches

SIGNIFICANT GLOBAL BURDEN

~1bn — **Affected people**
Global population with mental health disorders [1]

~$16tn — **Global economic impact**
Estimated global economic costs of mental health disorders by 2030 [2]

~2X — **Increase in prevalence of anxiety and depression**
From March 2020 as a result of the COVID-19 pandemic [3]

URGENT NEED FOR INNOVATION

~33% — **Respond inadequately**
A third of patients with depression respond inadequately or relapse with current treatments within certain indications [4]

Up to 12 wks — **Slow onset of treatment effect**
Frontline treatments for depression and anxiety have slow onset (4-12 weeks) [5]

7 — **Psychiatry approvals since 2015**
Only 7 new drugs approved by the FDA for psychiatry disorders since 2015 – less than 10% relative to oncology (N=83) [6]

1. Ritchie, "Global mental health: five key insights which emerge from the data", Our World In Data (2018)
2. Patel et al., "The Lancet Commission on global mental health and sustainable development", The Lancet (2018).
3. OECD, Tackling the Mental Health Impact of the COVID-19 Crisis: An Integrated, Whole-of-Society Response, OECD 2021
4. Salzer, "National Estimates of Recovery-Remission From Serious Mental Illness", Psychiatry Online (2018)
5. Tew et al., "Impact of prior treatment exposure on response to antidepressant treatment in late life" Am J Geriatr Psychiatry (2006)
6. EvaluatePharma (as of 19.03.2021). New drugs include new molecular entities or new active ingredients.

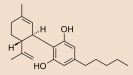
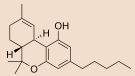
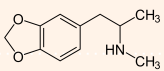


2

Emyria's leading treatment programs



Emyria's unique treatment discovery & development engines

	Proprietary *assets*	Proprietary *insights*	Proprietary *delivery platform*	Proprietary *programs*	Target clinical indication	Stage of development
 **Cannabinoid-based treatments** 	**Real-world data** on 4,500+ patients receiving cannabinoid-based treatments for 40+ clinical indications	What dose works for what indication. Dose-response insights support "methods of use" patents.	Novel, FDA-compliant, highly purified formulation of synthetic cannabinoids [3]	**EMD-003 [4]**	Symptoms of psychological distress	Preparing for registration trials
				EMD-004 [5]	Irritable Bowel Syndrome (IBS) and symptoms	Gathering real-world data
				EMD-00X (future programs)	*In development*	*Continuous analysis*
MDMA-based treatments 	**Exclusive MDMA-analogue compound library** developed over 10 yrs [1]	Neurological receptor activity for unique chemical structures	Novel MDMA-analogues	*EMDMA-00X (future programs*	*Mental health and neurological disorders*	Screening program and multi-patent filing strategy underway
MDMA-assisted therapy	Psychedelic-assisted therapy model delivered with partners [2]	Expanding patient access to MDMA therapy	MDMA-assisted psychotherapy	**EMDMA-001 [6]**	Post-Traumatic Stress Disorder (PTSD)	Preparing Phase II clinical trials

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1. ASX Announcement 05 August 2021
2. ASX Announcement 19 November 2020
3. ASX Announcement 13 August 2021
4. ASX Announcement 05 January 2021
5. ASX Announcement 15 June 2021
6. ASX Announcement 05 May 2021

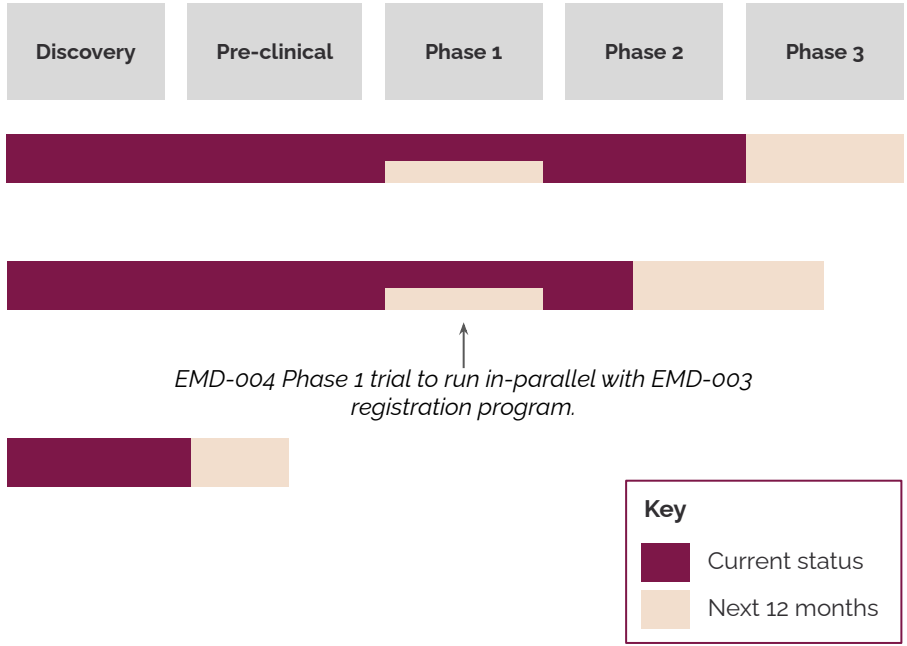
Emyria's cannabinoid pipeline

A novel cannabinoid delivery platform suitable for TGA and FDA registration



Emyria's cannabinoid product pipeline

Drug program	Target indication	Treatment platform	Delivery
EMD-003	Psychological distress	Synthetic cannabidiol (CBD)	Liquid-filled hard capsule
EMD-004	Irritable bowel syndrome	Synthetic cannabinoids (CBD +/- THC)	*In development*
EMD-00X	*Next indications are in development. Emyria has dose-response insights for cannabinoids across more than 40 clinical indications*	*Synthetic cannabinoids targeting additional FDA and TGA registration*	*In development*





Emyria's cannabinoid patent portfolio

	Title	Official No.	Status
Emyria's cannabinoid patents cover unique formulations, delivery approaches and "method of use"	Use of Cannabidiol for the Treatment of Psychological Distress	2020904152	Provisional filed
	Use Of Cannabidiol for the Treatment of Psychological Distress	2021901086	Provisional filed
	Use Of Cannabidiol for the Treatment of Irritable Bowel Syndrome-Related Psychological Distress	2021901672	Provisional filed
	Use Of Cannabinoid Combination for the Treatment of Irritable Bowel Syndrome-Related Psychological Distress	2021901674	Provisional filed
	Cannabidiol Dosing Regime	2021902001	Provisional filed
	Others in development covering unique delivery platforms, dose responses and clinical indications	*Multiple provisionals expected 2021*	

Emyria's advantages in cannabinoid treatment development

ADVANTAGE 1: One of the world's largest Real-World Data assets

At Emerald Clinics, Emyria has gathered clinical-trial grade, **real-world data on over 4,500 patients** providing unique insights, and IP, into what treatments work best and in whom.



ADVANTAGE 2: A unique cannabinoid delivery technology

With partner Altasciences, Emyria is developing a novel, FDA-compliant, ultra pure, cannabinoid delivery platform in patient-preferred forms.



ADVANTAGE 3: Experienced team to accelerate registration process

Our in-house team of clinical trial and drug registration experts have overseen multiple, successful FDA registrations.





1. Emyria's cannabinoid Real-World Data (RWD)

Our proprietary, robust and ethically-sourced clinical data covers dose-response insights across a diverse set of more than 4,500 patients, including clinical indications and treatment programs. We analyse for insights and IP which de-risks our unique drug development programs

2 - 98 years **age range** of patients	**56%** **female** patients	**44** Unique **primary indication**s
54% Patients presenting with symptoms of moderate to severe **anxiety**	**53%** Patients presenting with symptoms of **depression**	**7.12** Average **concomitant medications** per patient at initial visit
0-600 mg Range of **CBD** prescribed doses are carefully titrated for each patient which gives Emyria unique dose response insights	**0-197** mg Range of **THC** prescribed doses are carefully titrated for each patient which gives Emyria unique dose response insights	**35%** Patients experiencing an **adverse event**

Data summary as of 01 DEC 2020

2. Emyria's unique synthetic cannabinoid platform



ALTASCIENCES

Emyria is developing a novel cannabinoid delivery platform with leading North American contract drug manufacturer Altasciences (See ASX Announcement 13 August 2021)

Feature	Emyria's Synthetic Platform	Botanical alternatives
Safety	*Synthetic CBD has been shown to have equivalent physiological effects to plant derived options [1]*	
Reliability	Synthetically manufactured cannabinoids ensure tight batch-to-batch consistency	Botanical CBD can have high batch-to-batch variability (see TGA audit results https://www.tga.gov.au/testing-medicinal-cannabis-products-being-supplied-sas-australia)
Regulatory	Consistent purity ensures acceptability from all major global regulators	Plant-extracted cannabinoid acceptable by some regulatory agencies only
Cost	Far more cost effective over long-term	Currently expensive ($250-800/month for 150mg/day CBD)

1. Maguire R, F, Wilkinson D, J, England T, J, O'Sullivan S, E: The Pharmacological Effects of Plant-Derived versus Synthetic Cannabidiol in Human Cell Lines. Med Cannabis Cannabinoids 2021. doi: 10.1159/000517120



3. Emyria's accelerated registration strategy

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✔ ***Real-world data on safety & efficacy at target dose***

- Longitudinal clinical data on over 4,500 patients and growing
- Each target indication already has 1,000's of prescriptions at target dose strengths

✔ ***IP on "method of use"***

- Unique insights support a strong and growing patent portfolio
- Emyria's patents cover dose ranges for target indications

✔ ***Streamlined access to patients & clinical trial infrastructure***

- We operate 7 clinical sites in Australia
- All GPs are GCP-trained
- Clinical trial-grade data capture platform in place

✔ ***Protocols developed***

- Patient inclusion criteria and trial endpoints developed using Emyria's data and in-house clinical trial team

✔ ***Regulatory strategy***

- Emyria partnered with experienced regulatory consultant with prior registration successes

✔ ***Experienced drug development team***

- Emyria's team has overseen over 100 clinical trials and 25 drug approvals

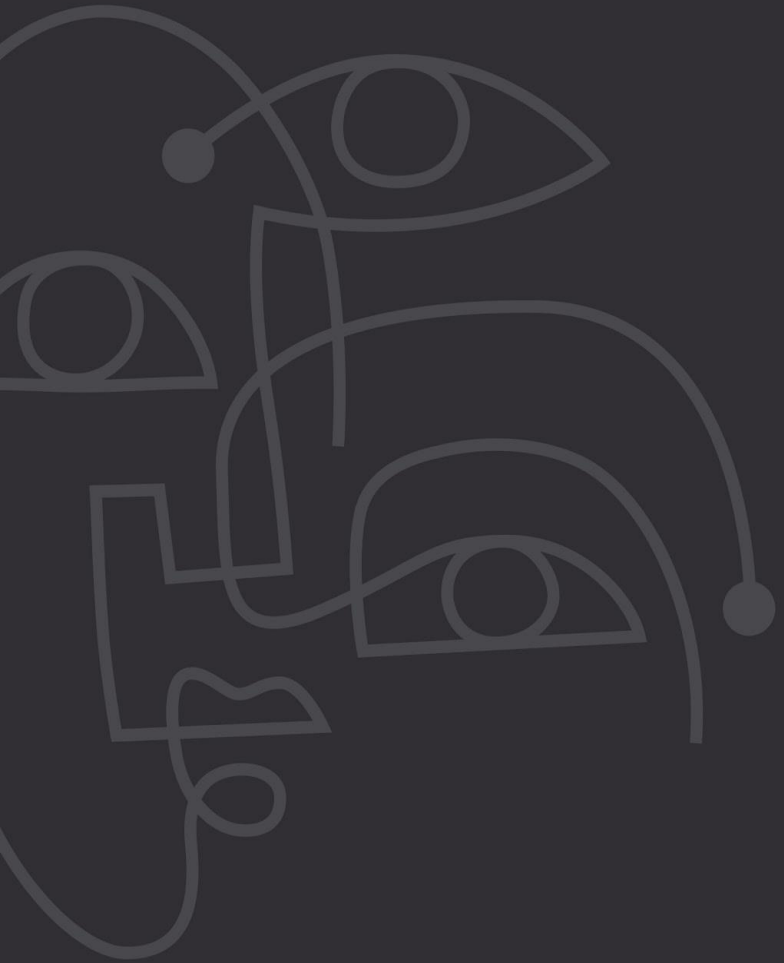
Drug delivery platform

✔ ***Unique dose form and formulation***

✔ ***Large scale, GMP manufacturing***

✔ ***Low cost of goods***

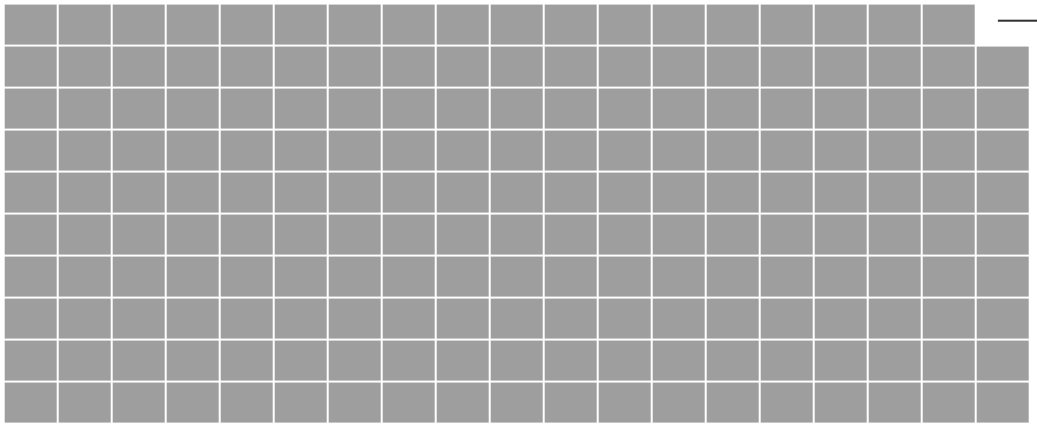
✔ ***Synthetic API also suitable for FDA and other major regulators***



How drug registration creates value



There are 190 unregistered cannabinoids in Australia[1]...



$100m

Total Australian sales in 2020

...and only 1 registered product
(Epidyolex by GW Pharma)

$686m

Total Global sales in 2020[2]

03 Feb 21, GW acquired by Jazz Pharmaceuticals (USD$7.2B)



*Emyria has appointed **Dr Karen Smith**, Ex-Chief Medical Officer and **Global Head of R&D at Jazz Pharmaceuticals** to Chair Emyria's Strategic Advisory (ASX Announcement 22 Feb 21)*

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1. https://freshleafanalytics.com.au/wp-content/uploads/2021/03/FreshLeaf-Analytics-H1-2021.pdf
2. https://www.globenewswire.com/news-release/2021/02/16/2175953/0/en/GW-Pharmaceuticals-plc-Reports-Fourth-Quarter-and-Year-End-2020-Financial-Results-and-Operational-Progress.html



Special Access Scheme vs Routine Prescription

80,417

Count of **Special Access Scheme** applications for ***unregistered*** **cannabinoids**, for **all indications**, in **12 months**

(Only 0.28% of antidepressant prescription count shown to scale on the right)

29,112,803

Count of **routine prescriptions**, for ***registered*** **antidepressants** only, in **12 months**

Registered treatments have a far greater ability to reach patients and attract reimbursement

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Sources:
https://freshleafanalytics.com.au/wp-content/uploads/2021/03/FreshLeaf-Analytics-H1-2021
https://www.pbs.gov.au/info/browse/statistics (data from 01 Jul 2018 to 30 Jun 2019

EMD-003/004



EMD-003: *over-the-counter medicine for psychological distress*

On November 2020 the **TGA allowed low-dose CBD** to be registered as an "over-the-counter", pharmacist-only, Schedule 3 (S3) medicine. [1]

Registered S3 treatments do not require a doctor's prescription. The **OTC market in Australia** is estimated at over **$20B/year** [2]

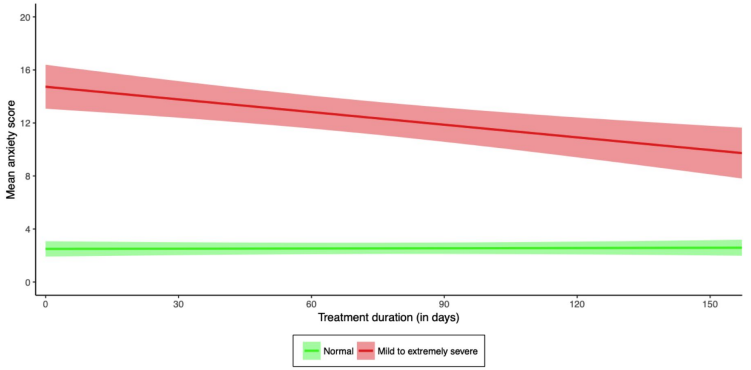
Analysis of Emyria's clinical data showed an improvement in the symptoms of psychological distress for a specific group of patients (see chart). Emyria filed multiple 'methods of use' patents to cover use of low-dose CBD across a range of appropriate indications.

Emyria's **EMD-003** drug registration program is guided by these insights.



Up to 15% of Australian adults experience high or very high levels of psychological distress [1]

At August 2021 alone, Emyria has treated psychological distress symptoms in more than 400 patients with low-dose CBD for > 6 months.



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1. See ASX announcement 16 December 2021
2. https://insights10.com/product/australia-otc-market-analysis/
2. Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW.

EMD-003: Registration trial approach

Phase 1 - Bioavailability

Randomised Controlled Crossover Bioavailability Trial

Phase 3 - Efficacy and Safety

Randomised Placebo Controlled Double Blind Trial

EMD-003: n = 110 | Placebo: n = 110

Patients with Pain & Stress
Study time/patient ~ 8 wks
Total study time = 4-5 mths



All studies designed to aid in submissions to TGA (Australia) and FDA (USA)

Australian Government
Department of Health
Therapeutic Goods Administration

FDA

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EMD-004: *targeting irritable bowel syndrome*



IBS affects around 11% of the population globally and there is currently no approved medication [1]

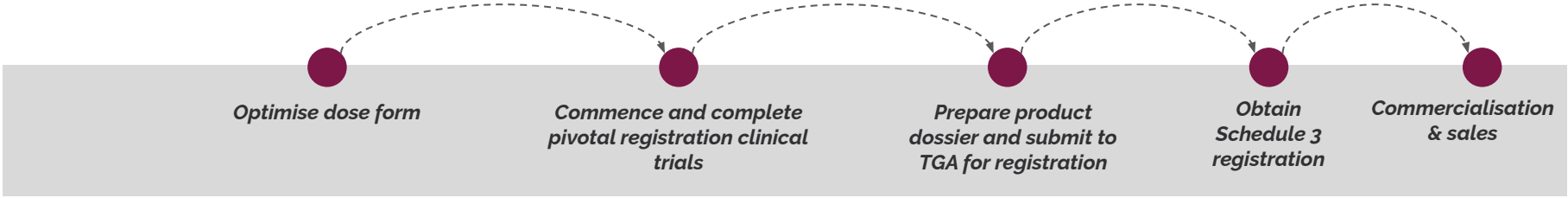
Analysis of Emyria's RWD has revealed an **improvement in symptoms** related to Irritable Bowel Syndrome (**IBS**) for a specific group of patients.

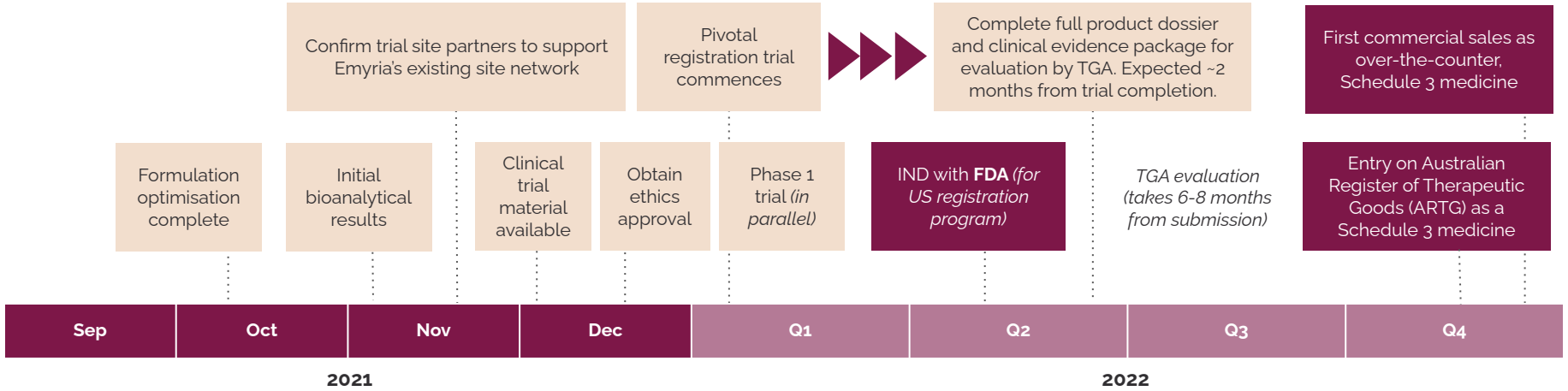
In order, to evaluate this benefit more thoroughly, Emyria' initiated a stand-alone, ethics-approved clinical trial (**CALM-GUT**) to increase the count of patients and expand the clinical evaluations and data collected on this group of patients.

Emyria has since **filed multiple 'methods of use' patents** to cover combination cannabinoid treatments for symptoms related to IBS and launched, **EMD-004**, a drug registration program guided by these insights.

1. Canavan, C., West, J., & Card, T. (2014). The epidemiology of irritable bowel syndrome. Clinical epidemiology, 6, 71–80. https://doi.org/10.2147/CLEP.S40245

Cannabinoid development milestones





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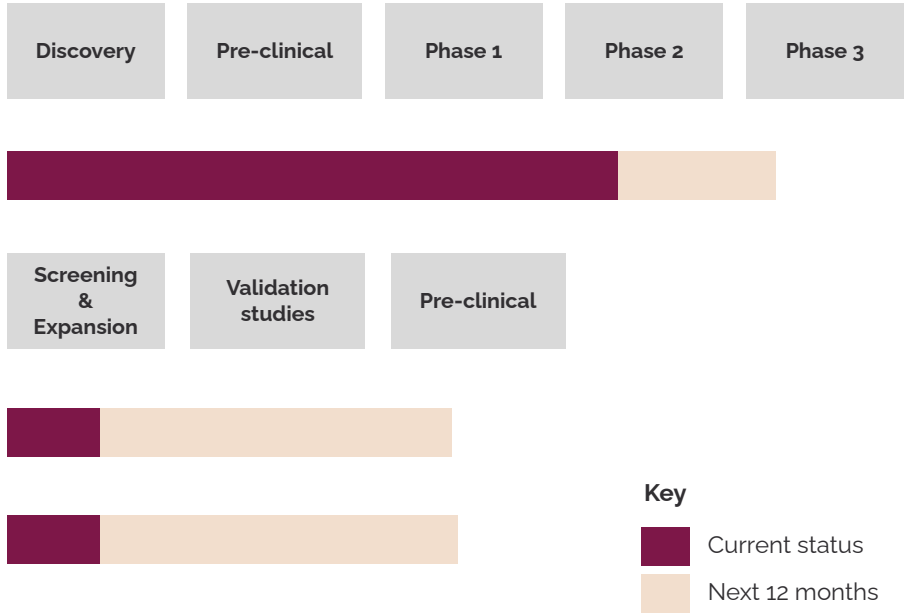
Emyria's MDMA programs



Emyria's MDMA-based treatment development pipeline

Psychotherapy program	Indication	Treatment Platform + Delivery
EMDMA-001	Post traumatic stress disorder	MDMA-assisted psychotherapy with trained therapists

Drug development program	Indication	Treatment Platform + Delivery
EMDMA-00X-PSY	Major mental health disorders	Novel MDMA-analogue psychedelics to support psychotherapy for major mental health disorders
EMDMA-00X-NEU	Major neurological disorders	Novel MDMA-analogues as unique prescription treatments for neurological disorders



The market opportunity for psychedelic-assisted psychotherapy

$100b
Estimated market for psychedelic medicines

Canaccord Genuity

264m
Number of people who suffer depression globally

World Health Organization

$10.2b (AUD)
Aggregate market cap of psychedelic drug companies

yahoo! finance

2 in 3
Veterans suffer from PTSD

Cohen Veterans Network

1 in 4
People in the world are affected by mental health disorders

World Health Organization



*Emyria can leverage an **established clinical site** and **provider network**, an **experienced in-house drug development team** and also has access to **unique treatment assets***



Psychedelic competitive landscape (top 15 by market cap)

Symbol	Company	Market Cap (AUD)	
ATAI	ATAI Life Sciences N.V.	$3,216,535,666	Multiple psychedelics R+D targeting depression, anxiety, substance use,, TBI, Schizophrenia
CMPS	COMPASS Pathways Plc	$1,789,730,559	Testing synthesized psilocybin, administered with support from a trained therapist, to treat depression
GHRS	GH Research PLC	$1,464,094,233	(5-MeO-DMT) for depression
MNMD	Mind Medicine (MindMed) Inc.	$1,145,502,960	LSD experiential therapy for anxiety, 18-MC for substance abuse, LSD microdosing
CYBN:AQL	CYBIN INC.	$501,142,795	Psilocybin for MDD, deuterated tryptamine for anxiety and alcohol, phenethylamines
FTRP:CA	Field Trip Health Ltd.	$492,435,180	Ketamine-assisted psychotherapy clinical service
IHL:ASX	Inncannex Healthcare Ltd	$341,789,028	Commencing phase 2b trial for Psi-GAD psilocybin, targeting Generalised Anxiety Disorder
SEEL	Seelos Therapeutics Inc.	$272,158,453	Ketamine for major depressive disorder (MDD)
NUMI:CA	Numinus Wellness Inc.	$250,081,619	Ketamine clinics and clinical trials in MDMA-assisted therapy for PTSD & psilocybin for substance abuse
CBDT:CNX	Empower Clinics Inc.	$182,037,779	Launched subsidiary to focus on psilocybin research for mental health treatments
MYCO:AQL	MYDECINE INNOVATIONS GROUP INC.	$161,289,955	Psilocybin and entactogenic compounds for PTSD, anxiety, substance abuse
COPHF	Creso Pharma Limited	$135,690,356	Developing synthetic psilocybin for treatment resistant depression
ALID	Allied Corp	$127,048,628	Psilocybin and cannabis for depression and anxiety
TRIP:CNX	Red Light Holland Corp.	$123,501,731	Microdose psilocybin
RVV:CNX	Revive Therapeutics Ltd	$107,394,777	Psilocybin and cannabidiol for multiple indications
EMD:ASX	**Emyria Limited**	**$44,466,075**	**Commencing phase IIb MDMA-assisted therapy trial for PTSD, Developing range of novel MDMA-analogues from library of >100 compounds, real-world data generation**

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Source: https://psychedelicinvest.com/index/(accessed August 22nd)



MDMA-assisted therapy (EMDMA-001)



Developing a scalable MDMA-assisted therapy program

MIND MEDICINE AUSTRALIA is a leading charity that spurred the TGA to consider descheduling MDMA and psilocybin.

An independent panel of experts is due to provide the TGA with a recommendation on **September 30th, 2021.**

Mind Medicine Australia is also providing the first **Certificate in Psychedelic-Assisted Therapy (CPAT**) to clinicians in Australia.

Emyria has partnered with **Mind Medicine Australia** [1] and their trained therapists, to deliver scalable, evidence-based psychedelic assisted therapy for sufferers of severe Post Traumatic Stress Disorder (PTSD)

PTSD is a massive contributor to the global burden of disease, affecting almost 4% of the world's population [2].

A recent study by the Multidisciplinary Association for Psychedelic Studies (MAPS) found that 67% of participants with severe PTSD no longer met diagnostic criteria for PTSD following three sessions of MDMA-assisted psychotherapy, and 33% met the criteria for remission [3]

Emyria's expertise in complex patients, focus on mental health and evidence-generating care model is uniquely placed to lead this emerging new field of healthcare.

1. ASX Announcement 19 November 2020
2. Koenen KC, Ratanatharathorn A, Ng L, McLaughlin KA, Bromet EJ, Stein DJ, et al. Posttraumatic stress disorder in the World Mental Health Surveys. Psychological medicine. 2017;47(13):2260–74. Epub 2017/04/08. pmid:28385165; PubMed Central PMCID: PMC6034513.
3. Mitchell, J.M., Bogenschutz, M., Lilienstein, A. et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 27, 1025–1033 (2021). https://doi.org/10.1038/s41591-021-01336-3

EMDMA-001: a Phase IIa Clinical Trial for PTSD

Open-label interventional study
Proof of Concept for n= 12

Screening | Preparation | Drug treatment + non-drug psychotherapy: Cycle 1, Cycle 2, Cycle 3 | Follow-Up

Duration = 18 months

EMDMA-001 will follow a similar design to the promising Phase III trials concluded in the US but with a **broader inclusion criteria** to evaluate the potential to extend MDMA-assisted therapy to additional patient populations.



*The study will be led by consultant psychiatrist **Dr Eli Kotler** (left), and will be run out of the Victorian Counselling and Psychology Services in **Melbourne** (below)*



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Emyria poised to lead psychedelic-assisted therapy in Australia

MMA submits application to TGA to have **MDMA downgraded** from **S9 to S8**

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MIND MEDICINE AUSTRALIA

EMD forms **partnership** with MMA [1]

MMA runs inaugural **Certificate in Psychedelic-Assisted Therapies** (CPAT) course

1st CPAT-trained **therapists graduate**

EMD appoints Dr Eli Kotler, PI for EMDMA-001 [2]

EMD to submit Phase 2a trial to **ethics** committee

Psychedelic treatments to commence in Australia

2020 | **2021**

Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec

Australian Government
Department of Health
Therapeutic Goods Administration

TGA announces **interim decision** *not* to down-Schedule MDMA

TGA assembles **Independent Expert Panel Review** to review interim decision

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

MAPS publish results of pivotal **Phase 3 MDMA study**

TGA to publish **Independent Panel's Report**

TGA to announce **final rescheduling decision**

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1. ASX Announcement 19 November 2021
2. ASX Announcement 29 June 2021



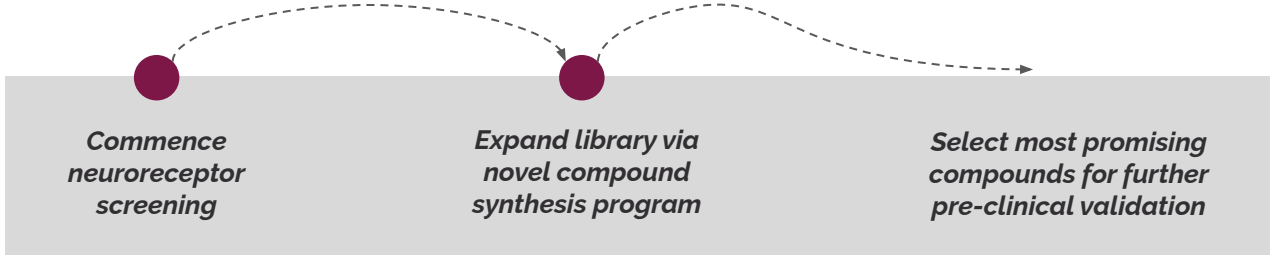
Novel MDMA analogue development

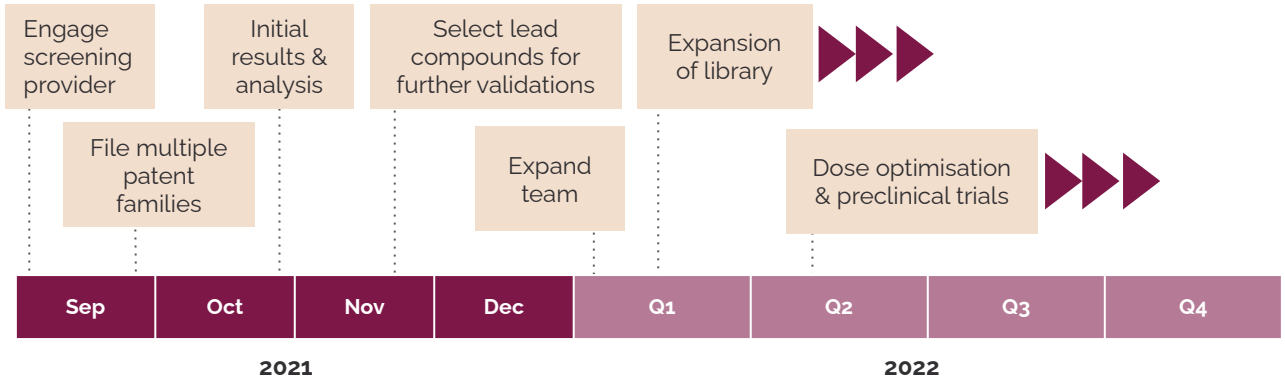
Emyria's MDMA-analogues - a novel drug discovery pipeline

	Emyria's MDMA-analogues
Scope	>10 years in development, portfolio of >100 MDM-analogues
Accelerated exemplification and patent strategy	(1) In-house expertise and partners to conduct target-to-hit and hit-to-lead screening via neuro-receptor analysis and validation studies (2) Lead compound selection informed by clinical, pharmacological and medicinal chemistry experts (3) Multiple patent families filed to protect all distinct, drug classes identified



Compound screening and expansion program







Dr Matthew Piggott *(above) has spent the past 10 years developing MDMA analogues for Parkinson's and other neurological diseases*



Dr Mathew Martin-Iverson *(above), is the Head of Psychopharmacology at UWA, and has over 35 years of experience studying amphetamines and other psychostimulants*

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1. ASX Announcement 05 August 2021
2. ASX Announcement 20 August 2021



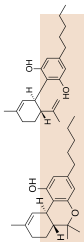
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Emyria's upcoming milestones

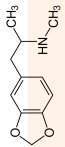


Upcoming milestones

Q3 2021



- Optimise synthetic cannabinoid dose form
- Additional formulation development for new indications



- Commence MDMA analogue screening program with UWA
- File multiple MDMA-analogue patent families
- **Independent report on MDMA de-registration provided to TGA (Sep 30)**

Q4 2021

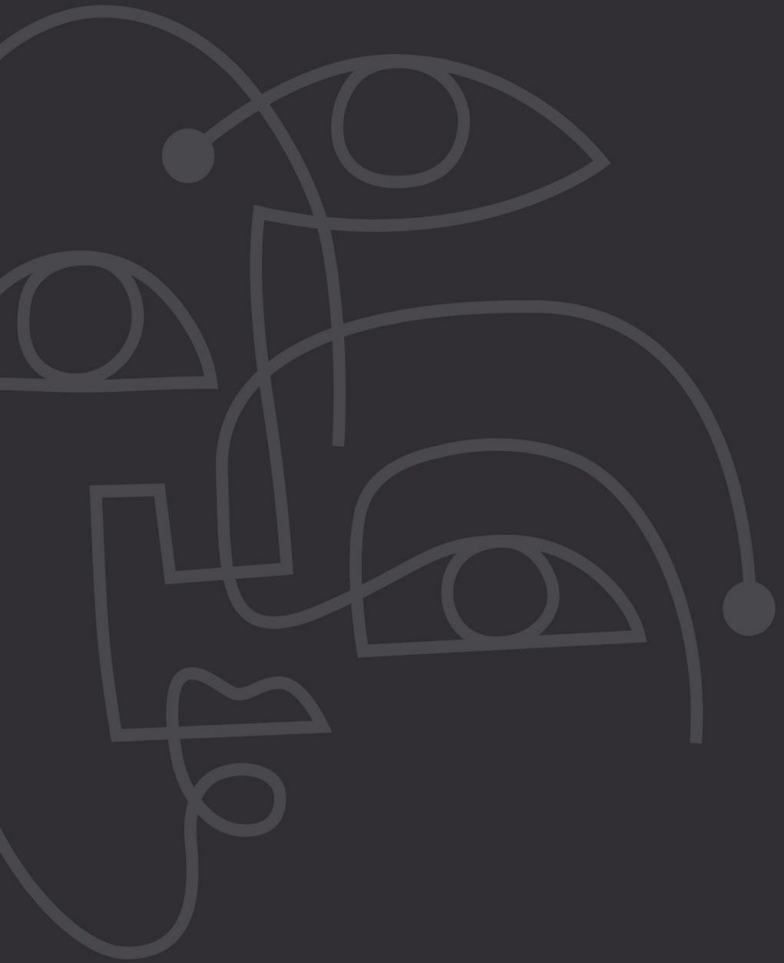
- Review of bioavailability and toxicology data
- New indications generated for FDA registration programs
- Ethics approval for Phase I and EMD-003 pivotal clinical trials

- Validation studies on highest priority novel MDMA-analogues
- Phase IIb MDMA-assisted psychotherapy trials for PTSD
- **Final TGA decision expected on MDMA de-registration**

Q1 2022

- Commence pivotal clinical trials for EMD-003
- Complete Phase 1 trials for synthetic platform
- Prepare for FDA registration

- Commence expansion of MDMA-analogue library
- Conduct preclinical validation studies and dose optimisation on highest priority MDMA compounds



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