

# emyria (ASX:EMD)

Creating tomorrow's therapies from today's patient stories

Strategic Update & Rights Issue Launch September 2023 | mwinlo@emyria.com

# emyria

# **OUR MISSION**

Set a new standard for global mental health care by blending compassionate care, data insights and pioneering therapies.







# 7 INVESTMENT HIGHLIGHTS for EMYRIA (ASX: EMD)

Australia is leading the charge globally in new treatments for mental health	At the forefront of psychedelic assisted treatment	Novel MDMA products	Unparalleled access to patient data	Clinics delivering revenue	CBD "Side bets"	Experienced management team
The TGA's decision to legalise psychedelics, which came into force in July 2023, puts Emyria and Australia potentially years ahead of other jurisdictions like the US.	Emyria has the infrastructure (clinics and team) and approved care models needed to provide psychedelic treatments under TGA rules.	Emyria has partnered with UWA to develop a number of novel MDMA-like treatments.  The goal is to modify MDMA and unlock new therapeutics for neuropsychiatric disorders like Parkinson's disease.	Through our clinics, Emyria has access to opt-in patient data and uses a state-of-the-art data platform - Palantir Foundry - to reveal unique insights.	Emyria provides wraparound, multidisciplinary mental health care services to patients.  We made \$1.6M last FY, targeting \$5.7M this FY.	Emyria is developing Ultra-Pure CBD for the treatment for anxiety symptoms and pain.  We have secured a commercial partner and are working with others, such as, the National Institutes of Health in the US to advance the program	Emyria's Board and Management are highly qualified in technology-backed clinical services, data and drug development.
A regulatory environment that advantages Emyria	Ready to be one of the first ASX companies providing these treatments	Strong IP covering potentially unique medicines	Data that informs better care practices and drug development opportunities	Revenues subsidise R&D	CBD products in clinical trials	Global advisors to support our global ambitions



# THE GLOBAL MENTAL HEALTH CHALLENGE | SEEKING NEW SOLUTIONS

# Rising Demand, **Inadequate Solutions**

# \$225 Billion

US Spending (2019) 1

Despite large costs, a gaping need for affordable, effective and durable treatments persists.

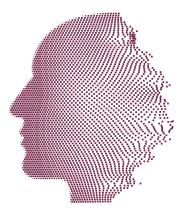
# The **Promise** of **Psychedelic-Assisted Therapy**



Psychedelic-assisted therapy is showing promising results in large clinical trials.<sup>2</sup>

This is encouraging significant clinical interest and investment, globally.

# The **Challenge** of **Psychedelic-Assisted Therapy**



Safe delivery of psychedelic-assisted therapy demands cooperation between therapists and psychiatrists, thoughtful preparation of the clinic environment and careful diagnosis, screening, expectation setting and monitoring with patients.

Very few clinical services are prepared for these treatments, limiting patient access.



# AUSTRALIA'S FRONTIER | EMBRACING DRUG-ASSISTED THERAPIES

# Leading the Global Charge

TGA's recent rescheduling <sup>1</sup> of **MDMA**-assisted therapy (MDMA-AT) for PTSD & **psilocybin**-assisted therapy (P-AT) for treatment resistant depression creates immense potential for innovators in mental health.



Australia's proactive stance on psychedelic therapies places it at least a year ahead of the rest of the world.

# Not Just Drugs, But Holistic Care

"For approval to prescribe, psychiatrists will need to demonstrate appropriate training, patient selection, evidence-based treatment protocols and patient monitoring.

Further, ongoing psychotherapeutic support remains an essential component of the psychedelic treatment model."

-RANZCP (College of Psychiatrists) <sup>2</sup>



# Emyria's Model is Well Positioned

The future of mental healthcare will intertwine new drugs with new care models.

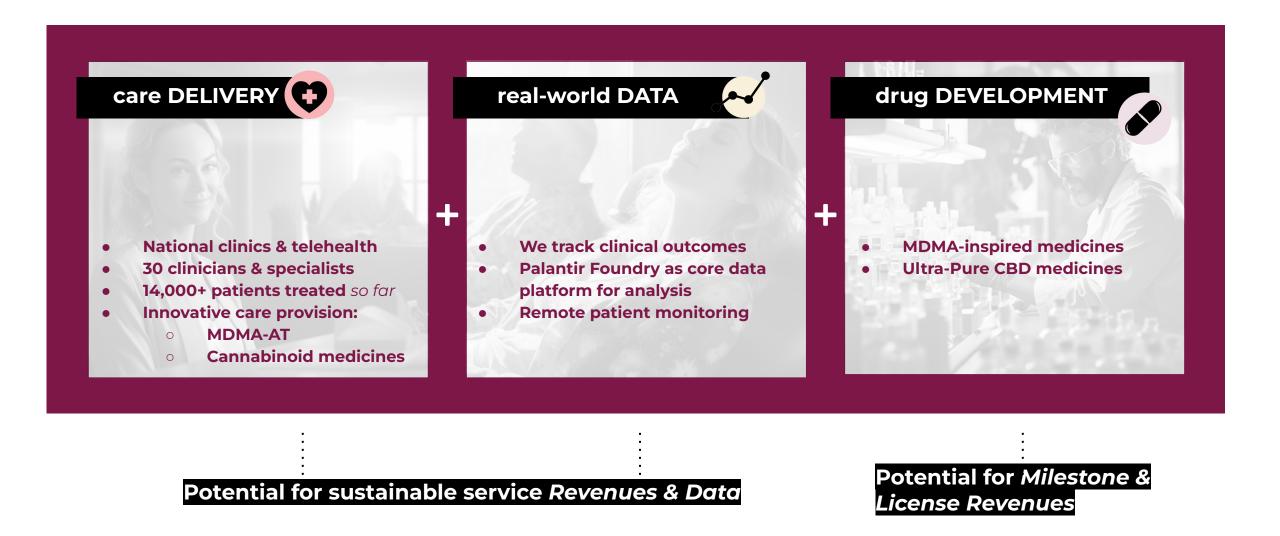
With unique expertise in drug development & care delivery, underpinned by data, Emyria is uniquely prepared to lead this new frontier.

# emyria REAL - WORLD DATA

THERAPY DEVELOPMENT

#### SOURCES:

# EMYRIA'S UNIQUE BUSINESS MODEL | MERGING CARE DELIVERY & DRUG DEVELOPMENT





# CREATING & CAPTURING VALUE | OUR STRATEGY FOR GROWTH & IMPACT

# (1) Solidify Multiple Potential Revenue Streams Via:

#### **DIRECT PATIENT TREATMENTS:**

Provides potential to generate steady revenues from patients and health payers. We specialise in emerging treatments.

#### STRATEGIC CLINICAL PARTNERS:

By licensing our methodologies we can potentially unlock additional revenues and foster innovation. 1

#### **DRUG PROGRAM LICENSES:**

As our drug development initiatives mature and succeed, they may present revenue opportunities through licensing and partnerships.

# (2) Sustainable National and Global Growth Via:

#### **TECH-DRIVEN OPTIMISATION**

Leveraging technology ensures efficient operations, better patient outcomes, & scalability.

#### **EXTENDING OUR FOOTPRINT:**

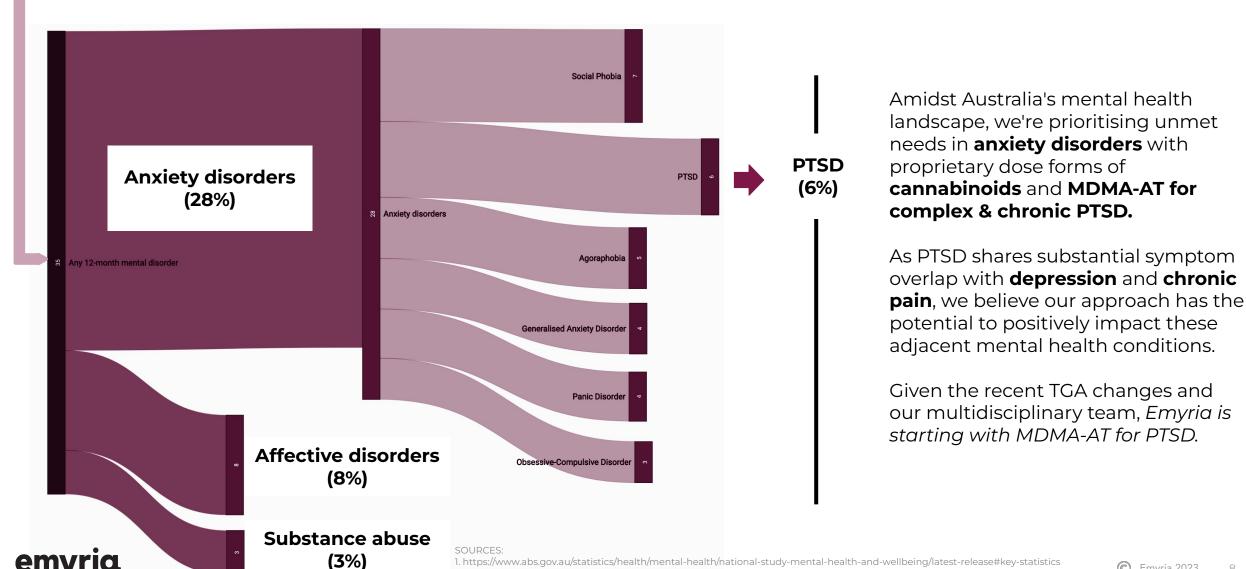
With a robust model in place, we can expand organically or via strategic partnerships or acquisitions.





# **OUR CURRENT FOCUS** | COMPLEX MENTAL HEALTH

35% of Australian adults experienced at least 1 mental health challenge in the last 12 months 1



# WHAT IS POST-TRAUMATIC STRESS DISORDER (PTSD)? 1

A chronic, debilitating mental health disorder that can occur following a traumatic event

# **Symptoms**

#### Re-experiencing:

Intrusive memories, flashbacks, and nightmares

#### **Avoidance:**

Evading reminders of the trauma and feeling detached

#### Increased arousal:

Irritability, sleep issues, and being easily startled

#### **Mood & cognition:**

Persistent negative emotions and distorted blame

#### **Physical symptoms:**

Palpitations, sweating, and gastrointestinal issues

# Current **Treatments**

TREATMENT OPTIONS FOR PTSD



**PSYCHOTHERAPY** 







**THERAPY** Re-imagining events in a environment

Up to 50% treatment resistance  $^2$ 

# Market for MDMA-AT<sup>3</sup>

#### **Total Addressable Market (TAM)**

In any 12 month period, PTSD affects 6% of Australian adults ~1,000,000 (much greater globally)



#### Serviceable Addressable Market (SAM)

50% of sufferers have treatment chronic/severe PTSD; ~22% not suitable Eligible for MDMA-AT ~400,000



#### **Early Target Market**

1-10% of patients suitable for MDMA-AT in Western Australia: ~300 to 3,000 patients

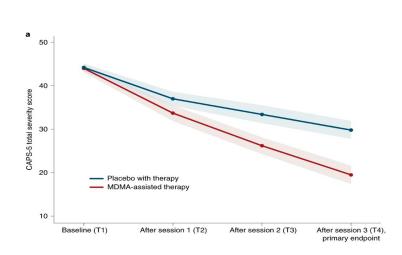
At ~\$30k/pt for three MDMA-AT sessions, there exists an opportunity for transformative healing for patients and a promising revenue stream to support our growth



1. Davis LL, Schein J, Cloutier M, et al. The economic burden of posttraumatic stress disorder in the United States from a societal perspective. J Clin Psychiatry. 2022;83(3):21m14116 2. Committee on the Assessment of Ongoing Efforts in the Treatment of Posttraumatic Stress Disorder; Board on the Health of Select Populations; Institute of Medicine. Washington (DC): National

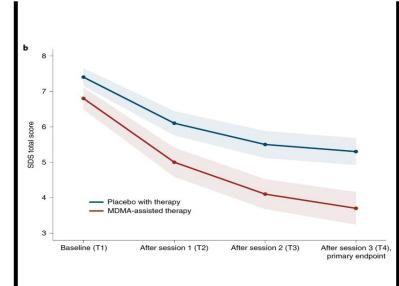
# MDMA-ASSISTED THERAPY (MDMA-AT) SHOWING REMARKABLE PROMISE FOR PTSD 1

## Improves symptoms



**MDMA-AT significantly attenuated PTSD** symptomology, as shown by the change in CAPS-5 total severity score from baseline to 18 weeks after baseline<sup>1</sup>

# Improves function



MDMA-AT significantly reduced clinician-rated functional impairment, implying an improved quality of life, as shown by the change in Sheehan Disability Scale score from baseline to 18 weeks after baseline<sup>1</sup>

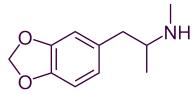
# **Durable** benefits

The majority of participants reported lasting benefits at Long Term Follow-Up, and over half reported benefits continued to grow, suggesting participants were able to successfully integrate therapeutic experiences into their daily lives to cultivate continued healing and growth" 1



#### **HOW DOES MDMA-AT WORK?**

# **MDMA**



MDMA (3,4-methylenedioxymethamphetamine or "ecstasy")

Causes release of 3 neurotransmitters:

#### Serotonin

contributes to mood, prosocial effects

#### **Dopamine**

associated with reward, euphoria

#### Noradrenaline

stimulant activity, attention

## **Clinical Effects of MDMA**

MDMA is an "entactogen" - drugs that produce feelings of emotional communion, oneness, relatedness, emotional openness & fear extinction.

## **INCREASES**

feelings of wellbeing sociability & extroversion interpersonal trust

# AN ALERT STATE OF CONSCIOUSNESS

**DECREASES** 

feelings of fear & defensiveness

# **Role in Therapy**

MDMA is thought to assist patients access traumatic memories without overwhelming distress.

The improved feelings of trust and wellbeing while under the influence of the medication can support open communication and strengthen the therapeutic alliance between patient and therapist.

Reduced defensiveness is thought to facilitate more honest introspection and acceptance of therapeutic guidance.

Ultimately, these features are believed to improve the efficacy of skilled psychotherapy.

#### **Risks & Exclusions**

Patients with cardiovascular disease or psychotic disease are generally excluded from therapy. The main side effects of therapy can include anxiety, restlessness, fatigue, jaw-clenching, headache and transient increases in blood pressure - all of which are closely monitored during therapy.

#### **EMYRIA'S MDMA-AT MODEL**

# Ethics-Approved Care Model 1

Fit-for-purpose clinical space
Trained multidisciplinary team
Stringent clinical governance & oversight
Two therapists for all sessions
GMP-grade medicine & tight supply chain

**PRE-TREATMENT** PERIOD 2-12 weeks

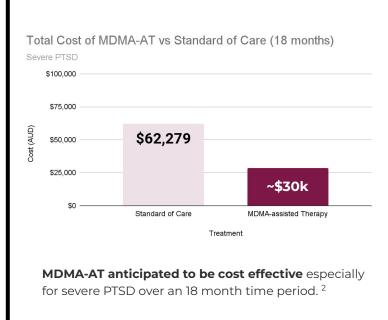


**3 CONSECUTIVE TREATMENT & INTEGRATION** PERIODS (12 weeks)



**FOLLOW-UP** PERIOD (12 months from last Treatment Session)

# Anticipated Cost-Effective Compared to Standard Care<sup>2</sup>



Avenceña et al noted that increased access to MDMA-AT could save lives and improve the health of patients with chronic and severe PTSD, while reducing healthcare costs. <sup>3</sup>

# Who Might Pay For MDMA-AT?

#### Health insurers and government

We will approach payers to offer our support in the evaluation cost-effectiveness for these new treatment approaches.

Individual patients - patients will not be expected to pay while participants in clinical trials, however, once Authorised Prescriber status has been obtained there is the possibility to offer access to patients able to pay out-of-pocket



SOURCES

<sup>1.</sup> See ASX release 08 June 2023

<sup>2.</sup> Cost estimates from internal evaluation. Majority of costs related to Standard of Care related to in-patient treatment costs. Majority of costs related to MDMA-AT related to length of therapist engagement 3. See Avanceña, A.L.V., et al. The Costs and Health Benefits of Expanded Access to MDMA-assisted Therapy for Chronic and Severe PTSD in the USA: A Modeling Study. Clin Drug Investig 42, 243–252 (2022) AND

# **OUR TEAM'S ADVANTAGES |** LEADERS IN *CARE*, *DATA* and *DRUG DEVELOPMENT*

# Innovative Care Delivery

Our team has experience across clinical care, consulting, and academia. With backgrounds ranging from specialist medical practitioners with esteemed roles in primary health care and medical councils, our team understands the challenges and intricacies of sustainable healthcare delivery.









# Data, Research & Technology

With experience at from Silicon Valley tech giants to innovative healthcare tech startups, our team understands the world of complex data integration and analysis. With experience advising the FDA on tech initiatives and leadership roles in healthcare data firms, we understand the potential for modern tech and data to revolutionise mental health care.











# Global Drug Development Success

Our team has experience across the vast spectrum of the drug development lifecycle. With involvement in numerous clinical trials, major regulatory approvals across continents, and leadership in global biotech firms, we have the breadth and depth of knowledge to navigate the intricate pathways of drug innovation.









#### **OUR BOARD**



CHAIRMAN **Dr Stewart Washer** PhD (Microbiology) Serial entrepreneur Multiple ASX listings



**NE-DIRECTOR Prof Sir John Tooke** FRCP. FMedSci Clinician-researcher Expert in learning health systems



E-DIRECTOR **Dr Karen Smith** MD, PhD, MBA, LLM US-based biopharma executive. Multiple FDA approvals



MANAGING DIRECTOR **Dr Michael Winlo** MBBS(Hons), MBA Entrepreneur, big data, clinical trials and drug development



**NE-DIRECTOR Dr Mohit Kaushal** Technology enabled clinical services, strategy and investment



MEDICAL DIRECTOR C/Prof Alistair Vickery MBBS, FRACGP, FCHSM Medical Director Epidemiological researcher

#### **CLINICAL & SCIENTIFIC LEADERSHIP**



**Claire Kullak** BSc (Nursing) Trauma-specialist and nationally recognised trainer



**Dr Jon Laugharne** MBBS, FRCP (UK), **FRANZCP** Consultant psychiatrist & therapist



**Dr Jenny Morgan** MBBS, FRANZCA Consultant pain specialist



**Prof Matt Piggott** BSc, PhD (Chemistry) Specialist in amphetamine chemistry and novel drug design



Dr David Gunn MBBS, FRACGP Cannabinoid expert Substance abuse & mental health treatment



**Dr Jeremy Tannenbaum** BSc, MBBS (Hons), FRANZCP Consultant Pain Specialist Consultant Psychiatrist













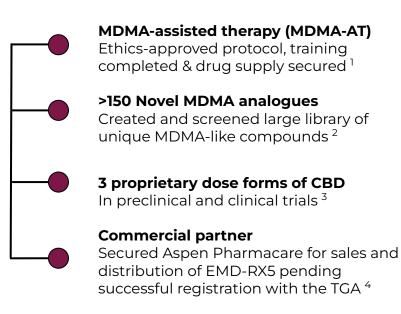






# PROVEN MOMENTUM | TRACTION TO DATE

# **Key Milestones Achieved**





# **Robust Patient Outcomes**

#### 14.000

Patients treated through our clinical services network

#### 30% reduction in opioids

After 6 months care at Fmerald Clinics 5



## **4 years** of symptom improvement

Across anxiety, depression, stress & sleep 6

# **Strategic Growth Initiatives**



Acquisition of Australia's leading, multidisciplinary psychological trauma treatment centre 7

# **Q** Palantir

Member the Foundry For Builders Program providing access to the world's most advanced data platforms 8

#### **Future:**

Launch new care programs Advance drug development programs Clinical partnerships



1. See ASX release 08 June 2023

2. See ASX release 20 March 2023

3. See ASX release 04 April 2023

4. See ASX release 04 April 2023

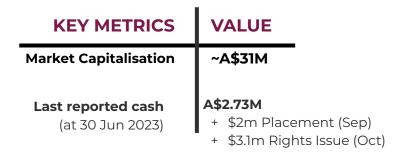
SOURCES: 5. See ASX release 07 June 2021 6. Vickery AW, et al (2022) A large Australian longitudinal cohort registry demonstrates sustained safety and efficacy of oral medicinal cannabis for at least two years. PLOS ONE 17(11): e0272241

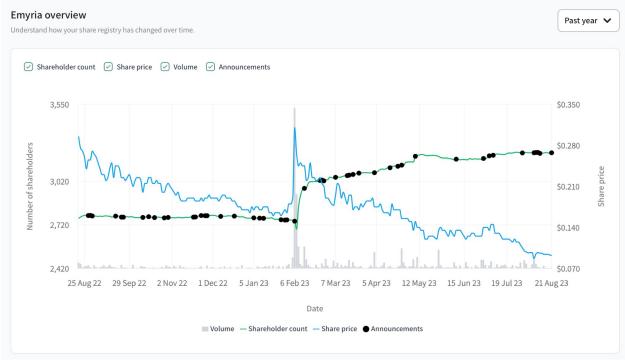


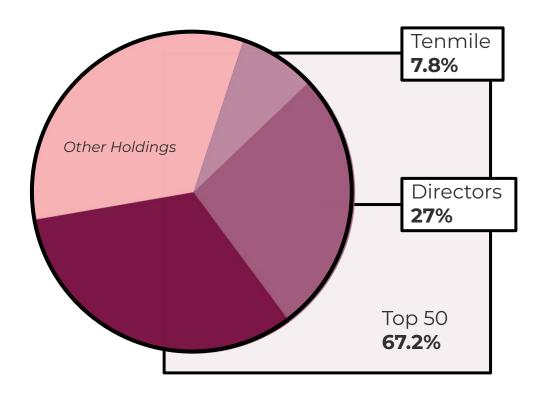
# **OUR ROADMAP**

#	PROGRAM	MILESTONE 1	MILESTONE 2	MILESTONE 3	OTHERS
1	Deliver MDMA-AT	Begin treatment on first patient (MDMA)	Emyria psychiatrists obtain Authorised Prescriber status	Complete patient recruitment for Phase 2b trial (MDMA)	Complete Phase 2b trial for MDMA
2	Develop Novel MDMA Treatments	Animal study results for fast-acting MDMA analogue	Animal study results for Parkinson's MDMA analogue	Identify lead drug candidates for Phase 1 trial	
3	Expand to Psilocybin & Ketamine Therapies	Approval for ketamine assisted therapy protocol	Begin treatment on first patient (ketamine)	Secure key approvals for psilocybin use	Begin treatment on first patient (psilocybin)
4	CBD "Side Bet" Clinical Trials	Recommence Phase 3 trial of low-dose CBD for stress & anxiety	Begin Phase 1 trial of high-potency CBD treatments	Results of Phase 1 trial of high-potency CBD treatments	
5	Scale Clinical Health Services & Engage Payers	Secure a major payer partnership	Licence a care model to a clinical partner	Open a new clinic or form new clinical partnership	
6	Expand Intellectual Property & Build Partnerships	Receive Clear Search Report from international patent examiner	Secure granted patents in national phase	File new patent family provisionals	Updated commercial license with UWA

## **OUR CORPORATE STRUCTURE**







**ENTITLEMENT OFFER TO RAISE \$3.1m** 

# ENTITLEMENT OFFER | OVERVIEW

Emyria (EMD) is launching a Entitlement Offer ("Offer") to provide existing shareholders the opportunity to invest in advancing the next phases of our highly promising clinical programs.

Offer is expected to raise
 \$3.1m (before costs) to fund Emyria's leading programs.

Under the Offer, all shareholders holding
 Emyria shares by the Record Date (Wed, Sep 13th) will be eligible to participate.

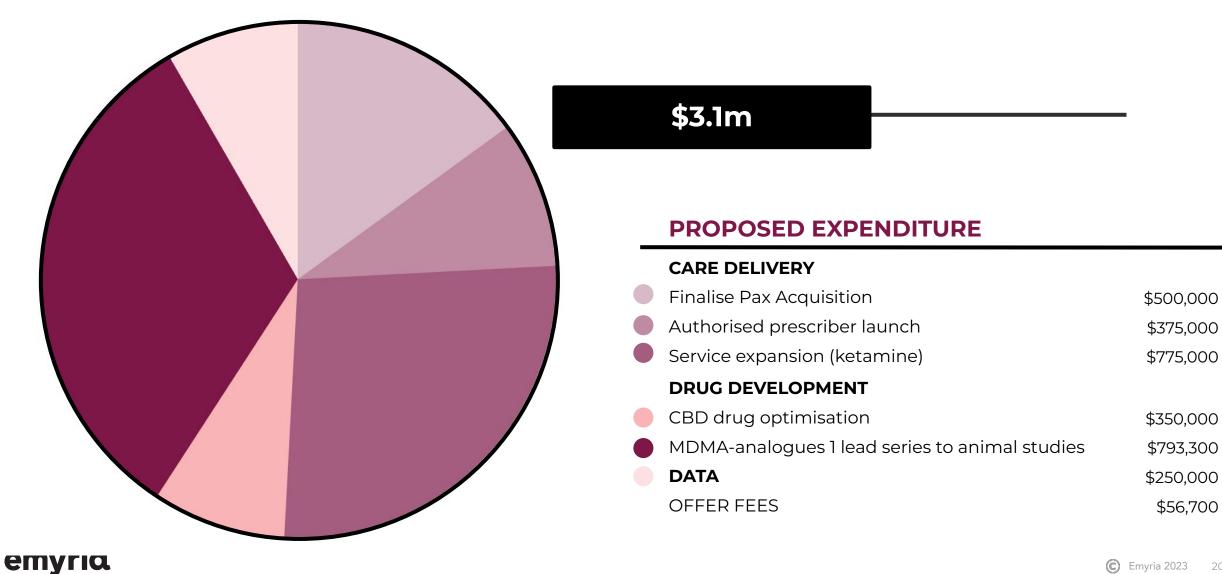
Full Details and Prospectus available 6 September 2023.

For every 7.5 shares held by the Record Date, shareholders will be eligible to apply for 1 shared priced at \$0.075.

New shares issues will rank *pari passu* with existing shares from their date of issue.

In addition, each successful applicant will be entitled to 1 free attaching, unlisted option for every 2 shares purchased under the Offer.

# **ENTITLEMENT OFFER |** USE OF FUNDS



# ENTITLEMENT OFFER | INDICATIVE TIMETABLE

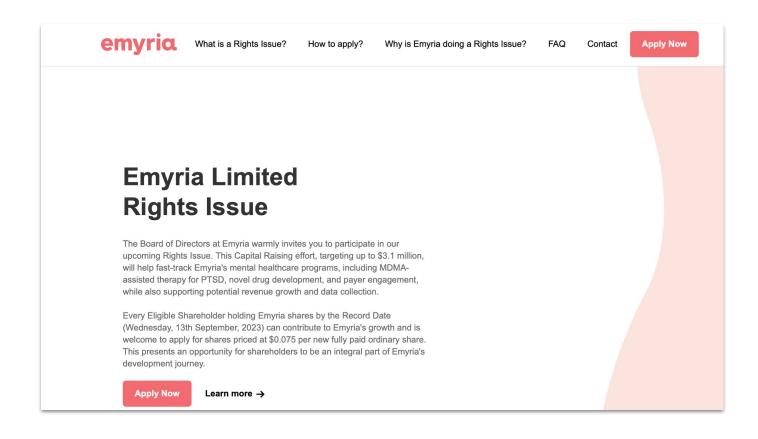
Event	Date (2023)
Lodgement of Entitlement Offer Prospectus with ASIC	5 September
Announcement of Entitlement Offer Prospectus and investor presentation on ASX	6 September
Entitlement Offer "Ex" date Expected date for quotation of new shares issued under the Placement	12 September
Record Date to identify security holders entitled to participate in the Entitlement Offer	13 September
Entitlement Offer Prospectus and personalised entitlement and acceptance forms made available to persons entitled and announcement that this has occurred Entitlement Offer opening date	18 September
Entitlement Offer closes at 5:00pm (AWST)	28 September
Announcement of the results of the Entitlement Offer Appendix 2A and 3G for Entitlement Offer	5 October

<sup>\*</sup> Emyria retains the discretion to alter any or all of these dates



# ENTITLEMENT OFFER (RIGHTS ISSUE) | WEBSITE EXPLAINING THE OFFER

## **OFFER.EMYRIA.COM**





# **ENTITLEMENT OFFER |** DISCLAIMER

In accordance with section 734(6) of the Corporations Act, the Company notes that:

- the Entitlement Offer will be undertaken pursuant to a disclosure document issued by the Company in accordance with section 713 of the Corporations Act (the Prospectus);
- the Prospectus is available on the Company's website (www.emyria.com) and the ASX Market Announcements Platform under the Company's ASX code "EMD";
- participants in the Entitlement Offer should consider the Prospectus in full before deciding to participate and acquire securities under the Entitlement Offer; and
- any participants in the Entitlement Offer will be required to complete the application form that will be in or will accompany the Prospectus.



**Investors** 

Media

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General info@emyria.com

**INVESTOR HUB:** 

https://investorhub.emyria.com/



**APPENDIX:** 

# **DISCLAIMER** to presentation

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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



# EMYRIA CLINICS | OUR EXPANDING MENTAL HEALTH FOOTPRINT

# We offer a suite of solutions & ongoing support, not just a single service

A data-centric clinic working with newly rescheduled treatments like THC & CBD. We monitor & care for patients when "nothing else has worked"









- **GP-led** clinical service
- ~10,000+ patients
- 40+ clinical conditions
- Cannabinoid-based medicine specialists
- World's largest data registry on cannabinoid-based therapies and outcomes <sup>1</sup>
- Leveraging **Q Palantir Foundry** <sup>2</sup>

Australia's leading, multidisciplinary treatment centre for psychological trauma









- **Psychiatrist**-led service for **complex trauma care** <sup>1</sup>
- Diverse service offering
- 19 clinicians: psychiatrists, mental health nurses, psychologists, counsellors, OTs & social workers, physical therapists
- Ethics-approved **psychedelic** assisted therapy model <sup>2</sup>



# EMYRIA CLINICS | A PERSONALISED PATH TO MENTAL WELLNESS

We offer wraparound care before, during and after treatment

# ACTIVE ASSESSMENT, DATA COLLECTION & REVIEW

Neuropsychiatric disorders share an overlapping imprint of poor body health which is why Emyria's care models prioritise both physical and mental well-being. By providing comprehensive care we can achieve and measure exceptional health outcomes as well as develop new therapies and approaches, **including our own.** 

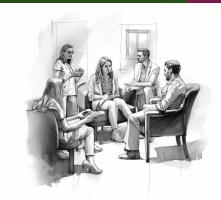
#### **EVIDENCE-BASED CARE**

#### **EMERGING TREATMENTS**

#### **CLINICAL TRIALS**



Rapid **intake** and **assessment** 



**Evidence-based** care led by **psychiatrists** & managed by **GPs** and specially-trained **therapists** 



TMS and / or Cannabinoid Therapy



Psychedelic-assisted Therapy



**Experimental Treatments** 

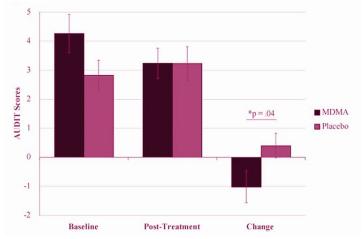
# EMYRIA CLINICS | MULTIDISCIPLINARY MODEL

SERVICE MODEL KEY STRENGTHS		KEY LIMITATIONS	EMYRIA ADVANTAGES		
GP Clinics	Accessible, generalised care	Limited support; not specialised	✓ Provides specialised care with robust support		
Specialists	High-level, specialised care	Often do not address physical health	✓ Offers multidisciplinary care covering mental & physical health		
<b>"Single service"</b> clinics (eg. "Ketamine Clinics")	Specialised service	Referral risk for clinicians. "Where do my patients go if treatment fails?"	✓ Offers <u>a suite of services</u> before, during & after care		
Academic & Research Centers	Cutting-edge research and treatments	Not focused on scalable, cost effective delivery	✓ Combines innovative approaches that translate to the community <u>cost effectively</u>		
EMYRIA MODEL	Multidisciplinary, data-driven, revenue-generating		✓ The infrastructure and team to deliver new and emerging treatments while collecting data to support ongoing innovation and development		



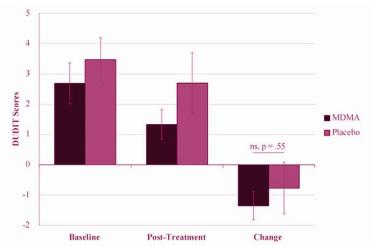
# MDMA-AT EFFECTS On Alcohol and Substance Disorder ("ASUD") & Suicidality

# MDMA-AT may lead to subclinical improvements in alcohol use



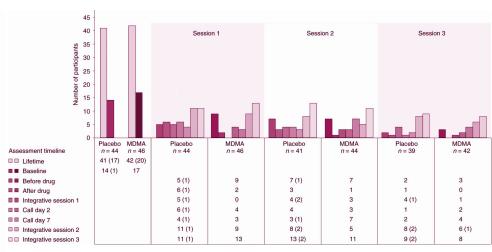
Compared to Placebo+therapy, MDMA-AT was associated with a significantly greater reduction in mean AUDIT change scores as compared to placebo.<sup>1</sup>,<sup>2</sup>

# MDMA-AT does not increase risk of illicit drug use



Changes in DUDIT scores were not significantly different between treatment groups.<sup>1</sup>

#### MDMA-AT may reduce the risk of suicidality



Serious suicidal ideation (a score of 4 or 5 on the C-SSRS) was minimal during the MAPPI study and occurred almost entirely in the placebo arm.<sup>1</sup>

#### Sources:

- 1. Nicholas CR, Wang JB, Coker A, Mitchell JM, Klaire SS, Yazar-Klosinski B, Emerson A, Brown RT, Doblin R. The effects of MDMA-assisted therapy on alcohol and substance use in a phase 3 trial for treatment of severe PTSD. Drug Alcohol Depend. 2022 Apr 1;233:109356. doi: 10.1016/j.drugalcdep.2022.109356. Epub 2022 Feb 11. PMID: 35286849; PMCID: PMC9750500.
- 2. 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



# **EPIDEMIOLOGY OF POST-TRAUMATIC STRESS DISORDER** <sup>1</sup>

	Adults aged > 18 (millions)	% with current PTSD	Adults with PTSD	% with chronic and severe	Adult PTSD cases that are chronic or severe	% with disqualifying condition	Adult PTSD cases eligible for MDMA-AT	Cost to Treat	ТАМ
USA	250.5	3.60%	9,018,000	50%	4,509,000	22%	3,517,020	\$30,000	\$105,510,600,000
AUSTRALIA	20.7	3.60%	745,200	50%	372,600	22%	290,628	\$30,000	\$8,718,840,000
WESTERN AUSTRALIA	2.07	3.60%	74,520	50%	37,260	22%	29,063	\$30,000	\$871,884,000

Sources:



Phoenix Australia



# emyria



**First Patient** 

Consented

**First Patient** 

**Treated** 

# MEDICINE-ASSISTED THERAPIES



**Drug Supply** 

Secured

**Ethics-Approved** 

Care Model

Trained Team ( )

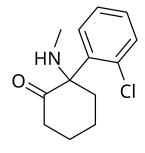
Sources:

See ASX release 18 April 2023

<sup>1.</sup> See ASX release 08 August 2023

#### **WHAT'S NEXT?** Ketamine-AT

# KETAMINE ON HIN



#### A dissociative anesthetic

Has a complex influence...

#### NMDA Receptor Antagonism:

Blocks NMDA receptors in the brain, involved in pain signaling and synaptic plasticity

#### **Enhances Neuroplasticity:**

Stimulates the growth and formation of synapses

Release of Neurotransmitters: Including glutamate, which then activates AMPA receptors and contributes to antidepressant effects

### **Clinical Effects**

Clinical effects of ketamine can vary depending on the dose, route of administration, and individual patient factors. In general, main effects are:

**Anesthesia and Analgesia:** Used for pain relief and producing a trance-like unresponsiveness

# Neuronal Growth & Anti-inflammatory:

Stimulates neuroplasticity and promotes brain cell regrowth

#### **Antidepressant**

Yields rapid mood uplift, especially in treatment-resistant depression.

# **Role in Therapy**

Ketamine induces a brief dissociative state, allowing patients to view memories or thoughts differently.

Its fast-acting antidepressant effects create an immediate therapeutic window, enhancing patient engagement in therapy.

Ketamine's stimulation of neuronal growth may reinforce and consolidate therapeutic insights.

Together, these unique features of ketamine treatment are believed to enhance the therapeutic process, leading to more lasting benefits.

## **Risks & Exclusions**

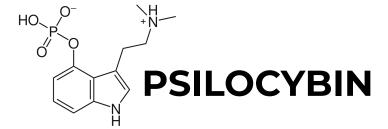
Some individuals might experience challenging emotional responses or unsettling hallucinations. Additionally, patients with a history of psychosis, certain heart conditions, or on specific medications might be excluded from its use



#### **Key Recent Research:**

- Loo, C., et al (2023). Efficacy and safety of a 4-week course of repeated subcutaneous ketamine injections for treatment-resistant depression (KADS study): Randomised double-blind active-controlled trial. The British Journal of Psychiatry, 1-9. doi:10.1192/bjp.2023.79
- 2. Anand, A., et al (2023). Ketamine versus ECT for Nonpsychotic Treatment-Resistant Major Depression. New England Journal of Medicine, 2023; 388:2315-2325 DOI: 10.1056/NEJMoa2302399

# WHAT'S NEXT? Psilocybin-AT



#### Hallucinogenic

Main biological effects

#### 5-HT2A Receptor Agonism:

Psilocybin and metabolite, psilocin, act as agonists at the 5-HT2A receptors. Believed to be central to hallucinations

#### 5-HT1A Receptor Agonism:

Psilocin also shows affinity for 5-HTIA, which might contribute to the overall experience induced by psilocybin.

#### **Dopamine Release:**

Psilocybin might have an effect on dopamine D2 receptors, although this is less pronounced than its effect on serotonin (5HT) receptors.

#### **Clinical Effects**

The clinical effects of psilocybin can vary depending on the dose, route of administration, and individual patient factors. In general, main effects are:

#### **Altered Perception:**

Psilocybin leads to hallucinations and a distorted sense of time.

#### **Emotional Release:**

Users often experience intense emotions, facilitating therapeutic breakthroughs

#### **Sense of Connection:**

Psilocybin can induce feelings of unity, diminished ego, and enhanced empathy, valuable in therapeutic contexts.

# **Role in Therapy**

Psilocybin is understood to amplify emotional understanding and connection, making it easier for people to revisit and heal from tough memories.

It also gives many a feeling of unity and interconnectedness, offering a fresh perspective that can break negative thought cycles. Additionally, psilocybin seems to enhance the brain's adaptability, making it more receptive to positive change.

Some people even describe profound, meaningful experiences during sessions, which can leave a lasting sense of purpose and interconnectedness. All these effects combined can be transformative, especially when guided by trained therapists in a safe environment

## **Risks & Exclusions**

Some individuals might experience challenging emotional responses or unsettling hallucinations. Additionally, patients with a history of psychosis, certain heart conditions, or on specific medications might be excluded from its use

#### **Key Recent Research:**





# EMYRIA DRUG DEVELOPMENT | MDMA-ANALOGUES

# One of the world's largest libraries of MDMA analogues developed





#### **Dopamine**

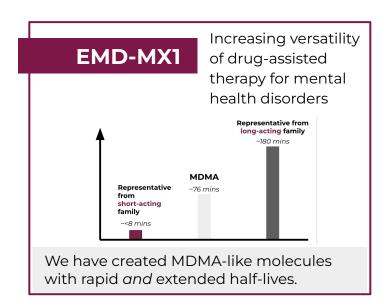
associated with feelings of pleasure and satisfaction

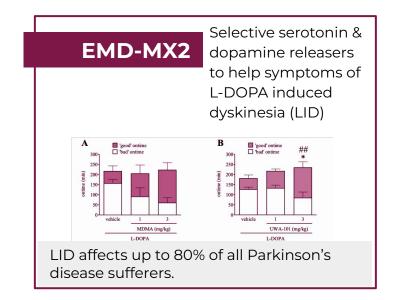
#### Serotonin

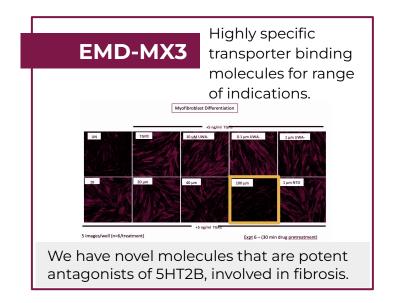
thought to contribute to feelings of well-being

#### **Noradrenaline**

affects attention and related to "fight or flight" response







# **Target Indication &** Market

MDMA looks very promising as an adjunct with psychotherapy for PTSD.

However...

Half-life (~6 h): requires long clinical sessions which increase costs Stimulant features: can cause anxiety when coming on and at low doses increases blood pressure and heart rate Euphorigenic: an abuse liability (is euphoria necessary for psychotherapy?)

#### MX1 Program Goals

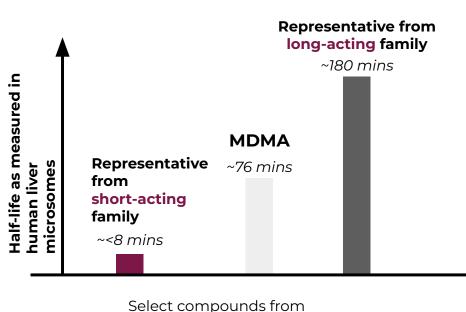
SERT reversal ⇒ serotonin release ⇒ prosocial, fear extinguishing effects V

NET reversal ⇒ noradrenaline release ⇒ stimulant activity X

euphoria X

# **Key Preclinical Results**

Metabolic studies performed to-date demonstrate Emyria's compound library contains novel MDMA analogues with both short-, and long-, acting metabolism profiles.



**Emyria's MDMA Analogue Library** 

# **Next Steps**

Emyria and partner the University of Western Australia (UWA) are developing a broad set of candidates inspired by these insights and we are actively developing new compounds inspired by the unique Structure Activity Relationships (SARs) observed in the compounds tested to take.

The creation of these new compounds is underway at UWA.

These next generation compounds will be screened for unwanted or "off-target" effects and sent for further metabolic studies.



# **Target Indication &** Market

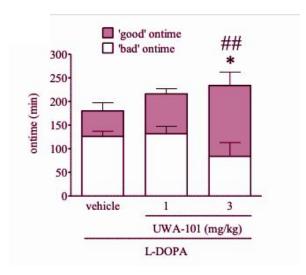
Parkinson's Disease (PD) is the world's fastest growing neurological disorder. The most common treatment for PD is to replace the depletion of dopamine with a precursor called levodopa (L-DOPA). However, prolonged treatment with L-DOPA can lead to a movement disorder called L-DOPA induced dyskinesia (LID). 80% of PD patients will develop LID, 30% within just 3 years. Globally, this is 5-6m individuals. 1

There is a significant unmet need for a medication that can improve the symptoms of LID.

The most recently approved treatment -OngentysTM (opicapone) - only increases **good** "ON-time" by ~6% over 24 hours. <sup>2</sup>

# **Key Preclinical Result**

In a gold-standard primate model of Parkinson's Disease, MDMA-analogue UWA-101, had a significant effect on increasing the duration of **total** and **good** ON-time.



UWA-101 increased the **total** duration of L-DOPA-induced antiparkinsonian benefit (total ON-time) by up to 30%. In addition, UWA-101 (3 mg/kg) significantly increased the duration of **good** quality ON-time by 178%.

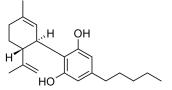
# **Next Steps**

Emyria and partner the University of Western Australia (UWA) are developing a broad set of candidates inspired by the insights of UWA-101. Some of these compounds are currently being evaluated in global laboratories.

The best performing compounds identified will then progress to animal models with partners at the University of Sydney. Set-up of those experiments is underway.



# EMYRIA DRUG DEVELOPMENT | ULTRA-PURE CBD



# We've developed multiple dose forms targeting registration as capsule medicines

## **EMD-RX5**



An Ultra-Pure CBD capsule for over-the-counter treatment of anxiety and stress symptoms.

15% of all adults.

In **Phase 3** clinical trials.

**Commercialised** to Aspen Pharmacare Australia.<sup>2</sup>

# **EMD-RX7**



High bioavailability Ultra-Pure CBD for **prescription** indications, like opioid-sparing.

Opioid use disorder is a \$471.0 billion expense in the US. 3

In preclinical screening in USA.

Currently being assessed by the NIH (USA) in their Preclinical Screening Program for Pain (PSPP) program. 4

# **EMD-RX9**



High potency, high bioavailability Ultra-Pure CBD for **prescription** indications. 5

Market leader: **Epidiolex (\$1B/yr)** <sup>6</sup>

Preparing for Phase 1 clinical trials.

Seeking commercialisation partners.



<sup>1.</sup> Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221.

<sup>2.</sup> See ASX release 04 April 2023

<sup>3.</sup> https://www.cdc.gov/injury/features/health-econ-cost-of-injury/index.html

# **Update**

During routine quality assessments a difference in dissolution rates between two batches of EMD-RX5 was identified. For clarity, "dissolution rates" refer to how quickly a substance dissolves in a simulated solvent

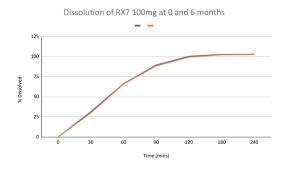
For all products seeking registration, consistency in the dissolution rates is expected between batches of the same product as well as over time. In this case, Batch 1, used for the first half of the trial, and the newly introduced Batch 2 showed a discrepancy in their dissolution rates (see Fig 1). It's important to note that both Batches still met all stringent guidelines for safety and CBD purity and that there are no safety concerns; the issue is solely with the dissolution rates.

Having used all of Batch 1 in the trial, the Company has paused recruitment to investigate the matter with Batch 2 further, in line with the rigorous standards set by the Therapeutic Goods Administration ("TGA"). Our preliminary investigations indicate that the issue is likely a manufacturing variation affecting one of the excipients (inactive substances used as carriers for the active ingredients). The Company has ruled out other potential causes (for example chemical changes or the outer capsules).

#### **Data**



<u>Figure 1:</u> Difference in dissolution rates between Batch 1 and Batch 2 of EMD-RX5 at 6 months



<u>Figure 2:</u> No difference in dissolution rates between a single batch of EMD-RX7 showing tight consistency over time

## **Next steps**

A new manufacturing method is being developed, using an updated manufacturing process and a new batch will be produced and monitored for stability. An update on this program is expected towards end of H2, 2023. In the meantime, Emyria's Contract Research Organisation ("CRO") is conducting a full quality review of all study data gathered to date (~50% recruitment), to ensure readiness for analysis when appropriate.

Emyria's portfolio also includes two other Ultra-Pure CBD capsules, RX7 and RX9. These products remain unaffected by stability or dissolution issues. RX7 has shown remarkable stability and bioavailability (the rate at which a drug is absorbed into the bloodstream), outperforming other registered CBD products in preclinical assessment. RX9 is also progressing well, with method development underway. Both candidates hold promise as high potency, highly bioavailable, solid oral dose forms of Ultra-Pure CBD nearing readiness for Phase 1 clinical trials.

# EMYRIA DATA | Palantir Foundry - ADVANCED DATA INTEGRATION & ANALYSIS

# AIP Features



#### **AI-Optimized Data Foundation**

Run LLMs and other AI on a secure, real-time, multi-modal foundation.



#### **AIP Assist**

Build everything from pipelines to applications faster, with human-Al collaboration.



#### **AIP Logic**

Author no-code functions that use LLMs. Manage, chain and wield those functions in custom applications.



#### Agents

Define LLM agents to pursue specific, scoped goals.



#### **Action Graph**

Implement decisions across your underlying operational systems.



#### **AIP Automate**

Monitor the activity of Al agents in realtime, with fine-grain control over both user-approved and autonomous tasks.



#### **Control Panel**

Monitor, govern, and control the activity and reach of LLMs and other Al in realtime.



#### Safe Al Handoff

Connect LLMs to trusted models across your enterprise with safe handoff functions.



#### **Digital Footprint**

Audit the full trail of all Al prompts, outputs, explanations, recommendations, and actions.



#### Human-in-the-Loop

Dictate when decisions require human input, including multi-stakeholder checks.



#### **Decision Capture & Learning**

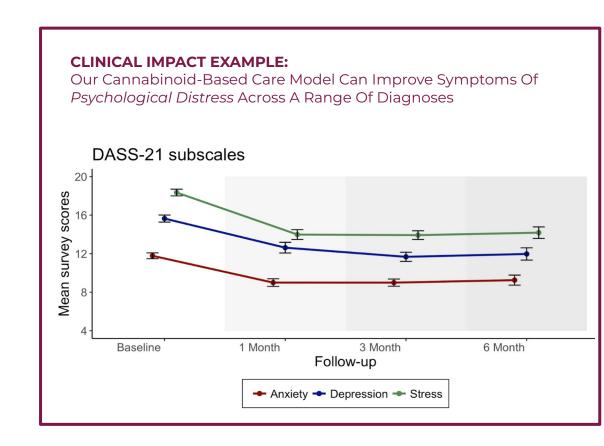
Capture decisions and outcomes for continuous AI validation and improvement.



# EMYRIA DATA | EMERALD CARE MODEL IMPROVES QUALITY OF LIFE SYMPTOMS

# We are experienced in tracking clinical outcomes & personalising care

emerald clinics	% of patients with "moderate" to "severe"  ANXIETY, DEPRESSION, STRESS						
TOP 10 indications:	ANXIETY 1	DEPRESSION 1	STRESS 1	INSOMNIA <sup>2</sup>			
Chronic non-cancer pain	73	52	39	60			
Insomnia	76	49	42	95			
Cancer pain	75	37	24	75			
Anxiety	57	70	73	85			
PTSD	42	82	76	95			
Autism	68	54	80	77			
Depression	76	71	67	83			
Migraine/headache	74	44	40	84			
Irritable bowel syndrome	62	45	42	85			
Parkinson's disease	59	52	43	89			

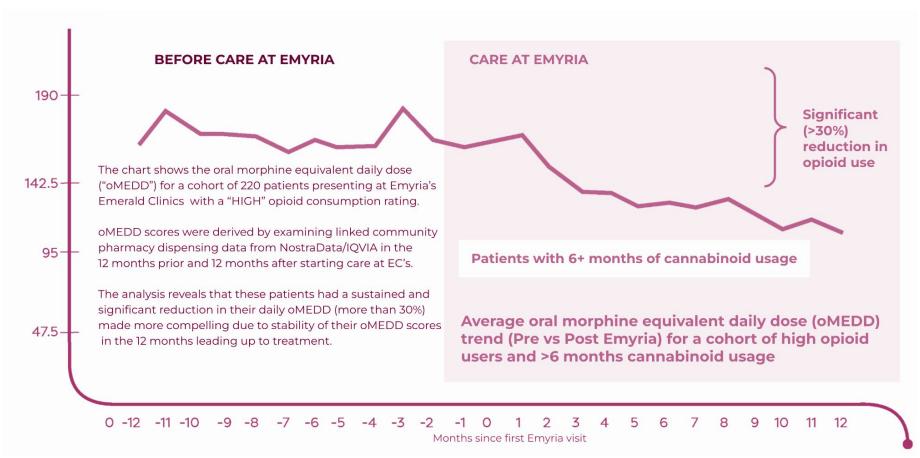




# EMYRIA DATA | EMERALD CARE MODEL REDUCES OPIOID USE

# We are experienced in tracking clinical outcomes & personalising care

#### CLINICAL IMPACT EXAMPLE: OUR CANNABINOID-BASED CARE MODEL CAN REDUCE OPIOID USE





# **EMYRIA INTELLECTUAL PROPERTY**

TITLE	OFFICIAL NO.	STATUS
MDMA Analogues	2021903836	PCT filed (search report due '23)
Cannabidiol Dosing Regime	2021902001	PCT filed
Cannabinoid Dosage Form	2022900479	PCT filed
Use of Cannabidiol for the Treatment of Psychological Distress	2020904152	PCT filed
Use Of Cannabidiol for the Treatment of Psychological Distress	2021901086	Provisional filed
Use Of Cannabidiol for the Treatment of Irritable Bowel Syndrome Symptoms	2021901672	Provisional filed
Use Of Cannabinoid Combination for the Treatment of Irritable Bowel Syndrome Symptoms	2021901674	Provisional filed
rs in development covering unique delivery platforms, dose responses and clinical indications	Additional provisi	ionals expected

Others

