

# Emyria's drug registration model

EMD-003 Snapshot

ASX:EMD

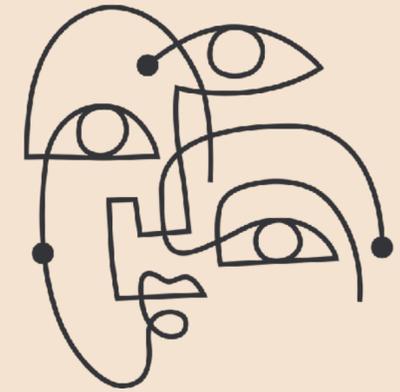
myriad data.  
individual care.

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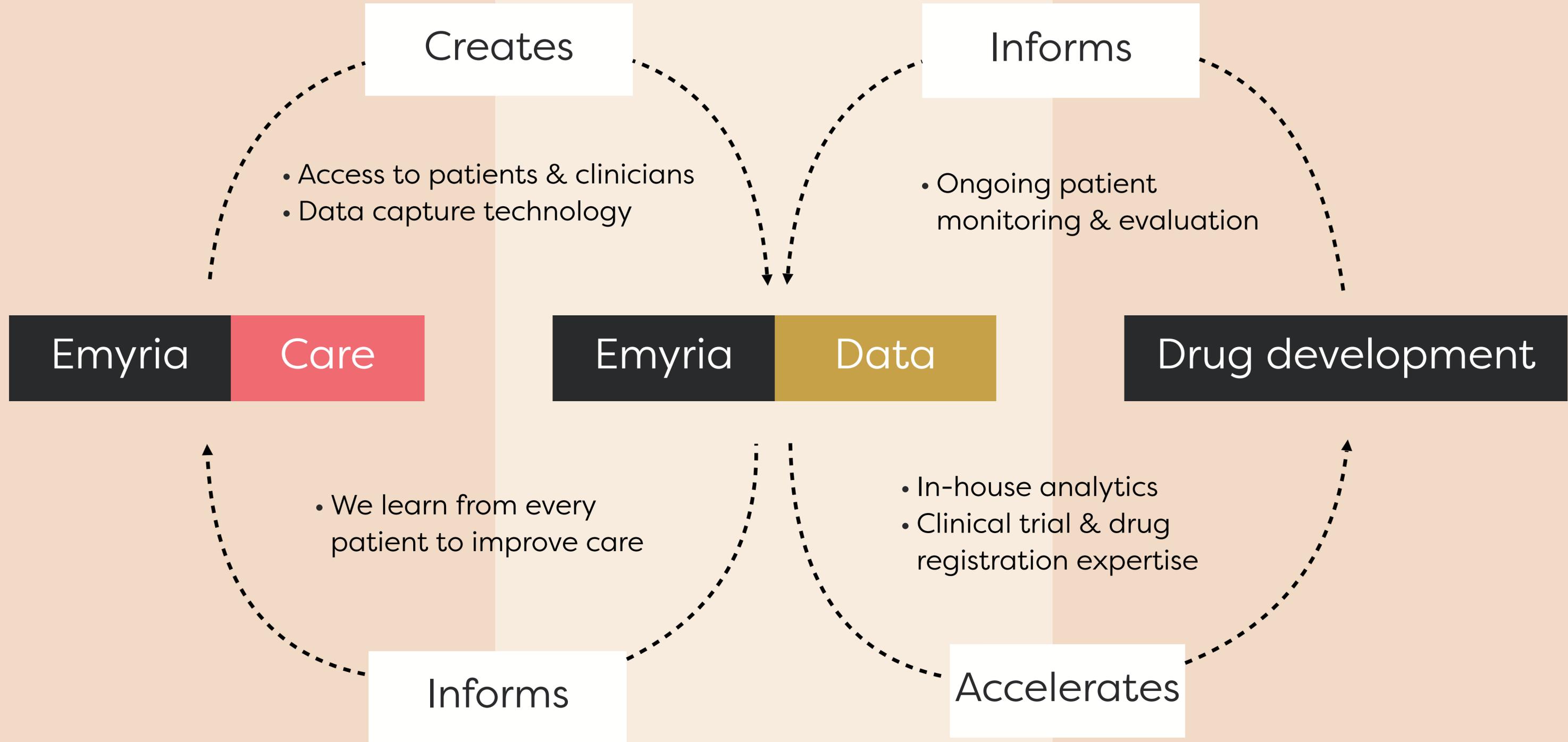
**Emyria creates registered treatments  
for large, under-served populations using our  
proprietary clinical evidence**



*“Emyria owns clinics, cares for patients, invests in technology, generates data, creates evidence and develops programs to accelerate the registration of new treatments, including our own.”*

**Dr Michael Winlo, MD and CEO**

# Emyria's platform



# Emyria's platform

Emyria

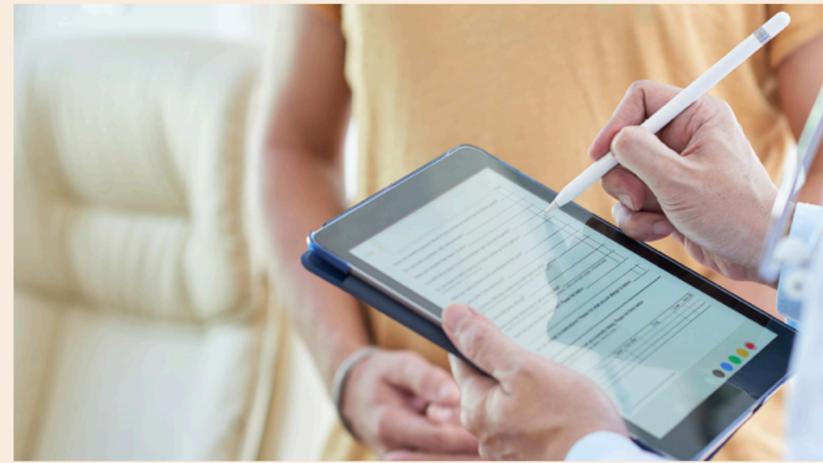
Care



- **7 sites** around Australia
- **GCP-trained** clinical team
- **3,500 patients** and growing
- Patients aged **2 - 96 years**
- Over **40 clinical indications**

Emyria

Data



- **2.6M** data points
- **Validated** assessments
- Source of **IP**
- Unique **dose response** insights
- More than **100 products**

Emyria's current drug development programs



EMD-003

Targeting **mental health**

- *CBD medicine*
- *Entering clinical outcomes studies*
- *Seeking Schedule 3 registration*



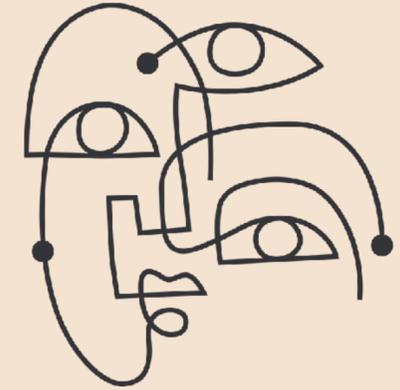
EMD-004

Targeting **irritable bowel syndrome**

- *Real-world studies underway*

**EMD-003**

A strategic partnership with **CANN** GROUP LIMITED to accelerate the registration of a Schedule 3, (over-the-counter), CBD medicine



*“Our first drug registration program brings together Emyria’s unique insights on what is working in which patients with a highly differentiated CBD dose form that we already have substantive real-world data on.”*

**Dr Michael Winlo, MD and CEO**

# EMD-003: Target indication

## Unmet needs in mental health



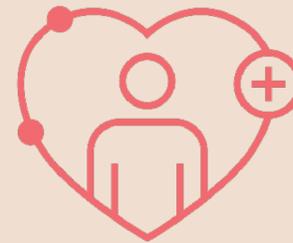
### Major growing health concern

Psychological distress is growing in incidence

Affects 20.1% of all Australians

There has been a 13% rise in mental health conditions in the last decade

Global unmet need



### Need for new treatments

There is a growing interest for readily available, registered treatments with fewer:

- Adverse events
- Treatment costs
- Withdrawal symptoms
- Overdose risks

Emyria Data has unique insights



### Affects Emyria patients

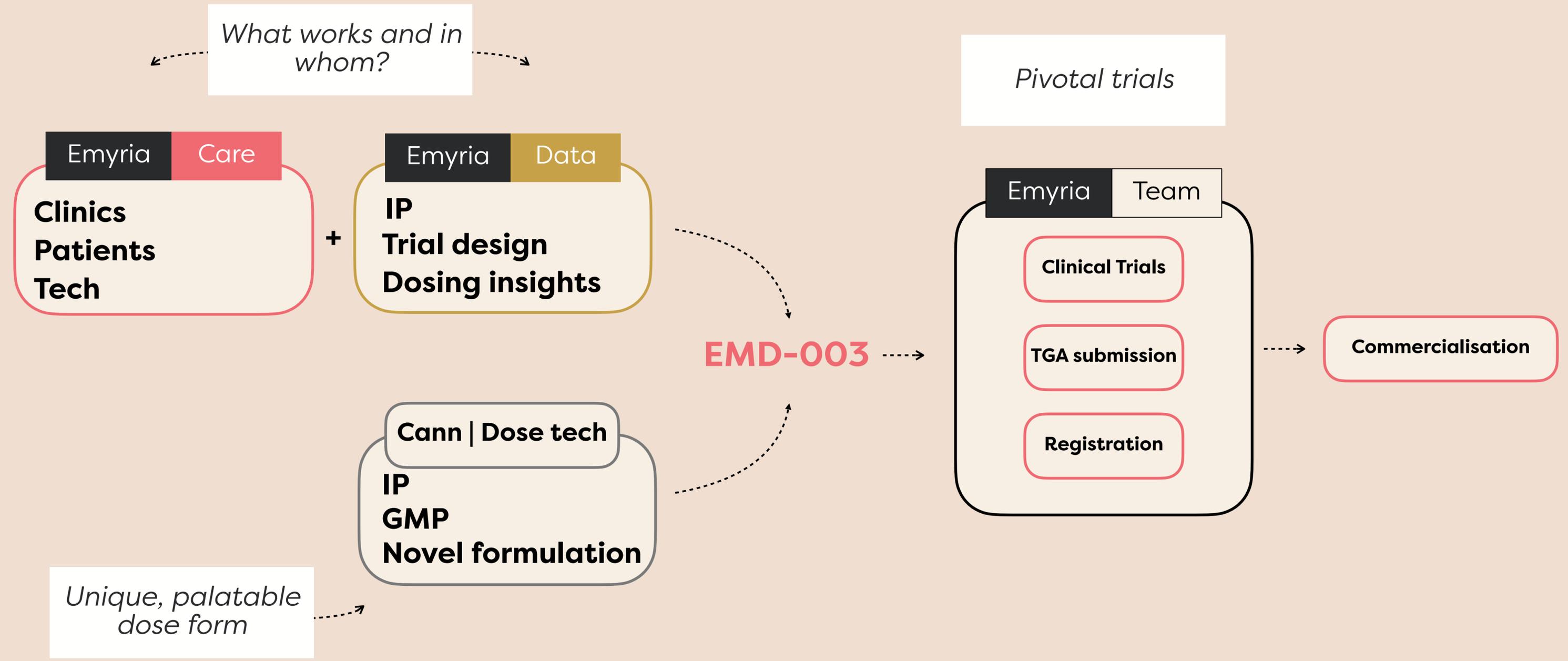
>60% of Emyria patients have Mild to Severe anxiety, depression and / or stress

>10% of Emyria patients have primary mental health concern

**Real-world data already gathered on efficacy and safety of target dose form**

# EMD-003: Program summary

*Partnership accelerates registration pathway*



# EMD-003: Unique success factors in place

## Strategic partnership accelerates path to S3 registration

**emyria**



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

- Longitudinal clinical data on over 3,500 patients and growing
- Over 400 prescriptions already written for target dose form



### **IP on “method of use”**

- Unique insights support growing patent portfolio
- Emyria patents cover indication and dose range



### **Streamlined access to patients + clinical trial infrastructure**

- 7 locations in Australia
- All GPs, GCP-trained
- Already running a clinical-trial-grade data capture platform



### **Protocols developed**

- Clinical outcomes trials developed using Emyria Data insights and expertise of team



### **Regulatory strategy**

- Engaged experienced regulatory consultant with prior S3 successes



### **Experienced drug development team**

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

**Cann Group**



### **Phase 1 & Stability data**

- Phase 1 complete for target dose
- > 30+ months stability data



### **Unique, dose form protected by IP**

- Covers use of novel delivery technology (Gelpell)



### **Large scale, GMP manufacturing**

- Factory in Europe, transferring technology to Australia

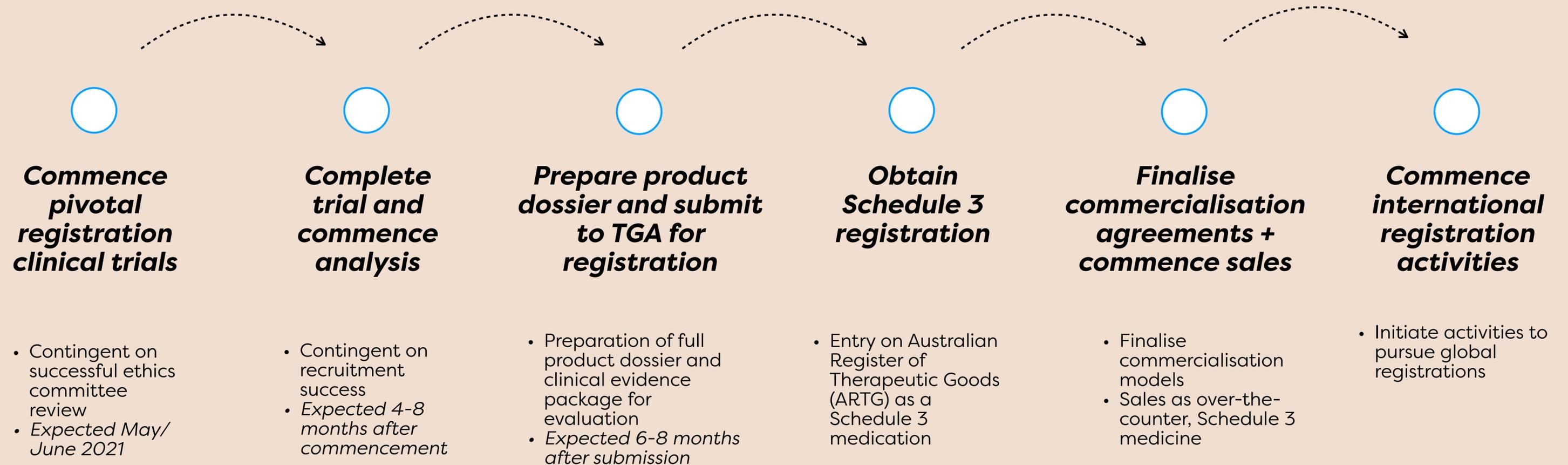
*This partnership greatly accelerates Emyria’s EMD-003 drug development program by combining Emyria’s unique clinical data and drug development expertise with Cann Group’s best-in-class CBD delivery technology.*

*Cann Group’s CBD has already completed robust stability testing as well as Phase 1 clinical trials as required by the TGA. This allows us to move straight to pivotal clinical outcomes trials saving significant time and money.*

**Dr Michael Winlo, MD and CEO**

# EMD-003: Milestones in year ahead

## Value drivers next 12 months



# EMD-003: Proposed patient channel

## A registered, over-the-counter, Schedule 3 medicine

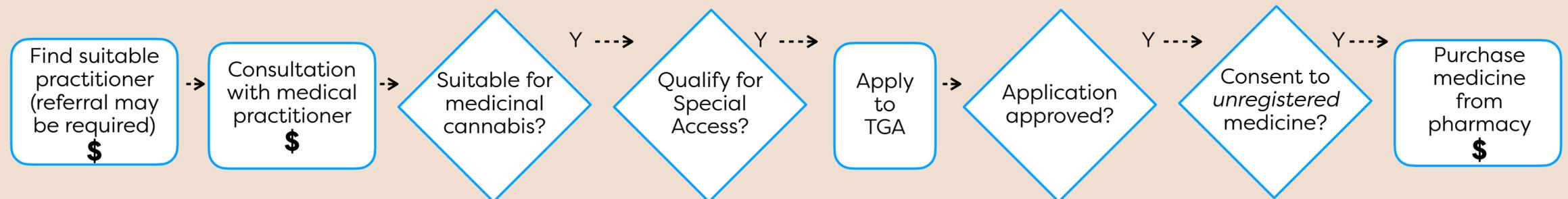


FreshLeaf estimates that the pharmacist only CBD market in Australia will grow to \$250m in product sales at market maturity, capturing around 2 million consumers<sup>12</sup>.

Today, almost 1 in 4 medicinal cannabis patients take a CBD product at a daily dose below 150mg, spending an average of \$8.02 per day<sup>13</sup>.

FreshLeaf expects that this patient cohort will migrate to the pharmacy channel once low-dose CBD products become available over the counter meaning that the first product/s to hit the S3 market will take the lion's share of this group – around 10,000 patients spending almost ~\$29M a year.

### Current 'Special Access Scheme' Path

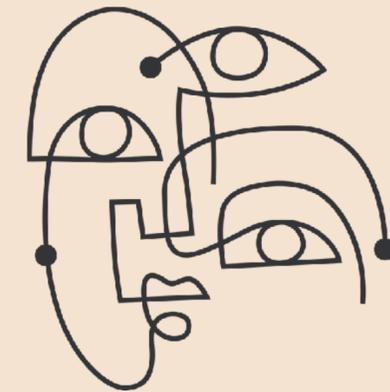


### Potential Schedule 3 Path

*If a low-dose CBD product can be successfully registered*



# Drug registration changes patient access



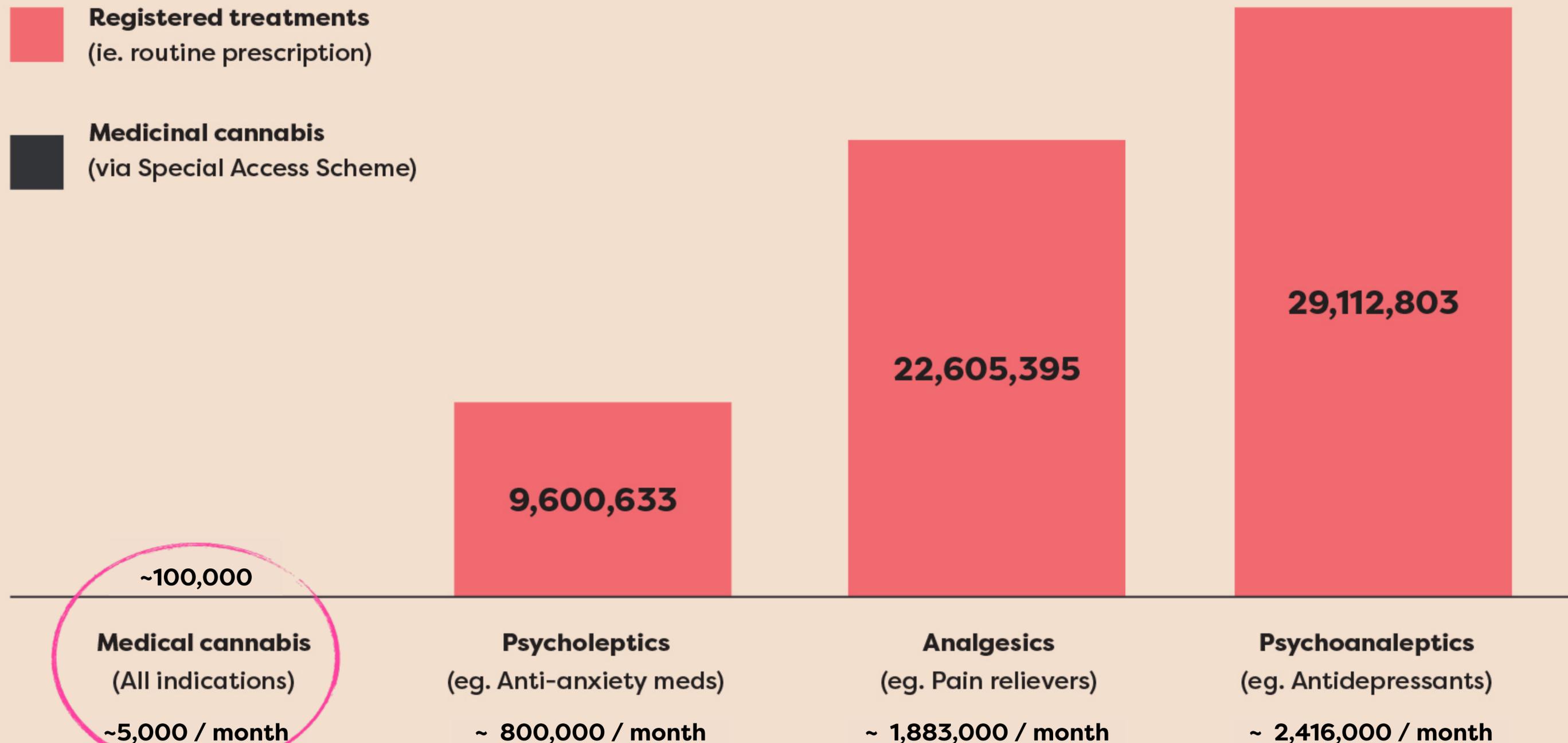
*“Achieving formal drug registration demonstrates a product’s quality, safety and efficacy, makes a medicine mainstream and can improve patients’ access.”*

**Dr Michael Winlo, MD and CEO**

# Medicinal cannabis vs registered prescriptions (via select drug groupings in Australia over 12 months)

 **Registered treatments**  
(ie. routine prescription)

 **Medicinal cannabis**  
(via Special Access Scheme)



# Medicinal cannabis access in Australia

**190 medicinal cannabis products available in Australia - most “unregistered”**

1

**Most medicinal cannabis** products in Australia are “unregistered” and only available only via:

- Special Access Schemes
- Authorised Prescriber programs or;
- Clinical trials



**Only 1 registered product** is **available via prescription** [Epidyolex - GW Pharma] for **rare forms of epilepsy** with an estimated prevalence of 1 in 20k-40k

GW Pharma spent an estimated \$560M on R&D between 2017 & 2020

# Recent deals | Jazz acquires GW Pharma (\$7.2B USD)



\*\*\*

Jazz Pharmaceuticals®

## **Jazz Pharmaceuticals to Acquire GW Pharmaceuticals plc, Creating an Innovative, High-Growth, Global Biopharma Leader**

February 3, 2021

**Adds high-growth commercial franchise to Neuroscience portfolio with Epidiolex®, the first and only FDA-approved prescription cannabidiol medicine and a potential near-term blockbuster**

**Enhanced product diversification of combined company expected to provide accelerated double-digit revenue growth**

**Anticipated to be accretive in first full year of combined operations and substantially accretive thereafter**

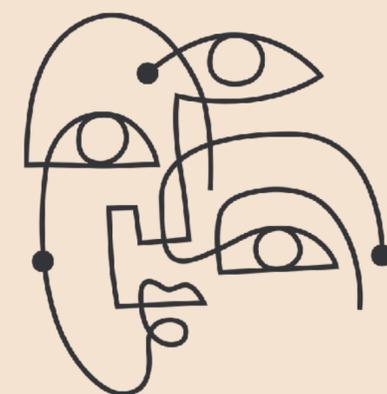
**Conference call today at 8:30 AM ET**

DUBLIN and LONDON, Feb. 3, 2021 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and GW Pharmaceuticals plc (Nasdaq: GWPH) today announced the companies have entered into a definitive agreement for Jazz to acquire GW for \$220.00 per American Depositary Share (ADS), in the form of \$200.00 in cash and \$20.00 in Jazz ordinary shares, for a total consideration of \$7.2 billion, or \$6.7 billion net of GW cash. The transaction, which has been unanimously approved by the Boards of Directors of both companies, is expected to close in the second quarter of 2021.

Upon close of the transaction, the combined company will be a leader in neuroscience with a global commercial and operational footprint well positioned to maximize the value of its diversified portfolio.

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*Emyria recently appointed Dr Karen Smith, Ex-Chief Medical Officer and Global Head of Research & Development at Jazz Pharmaceuticals to Chair Emyria's Strategic Advisory (See ASX Announcement 22 February 2021)*

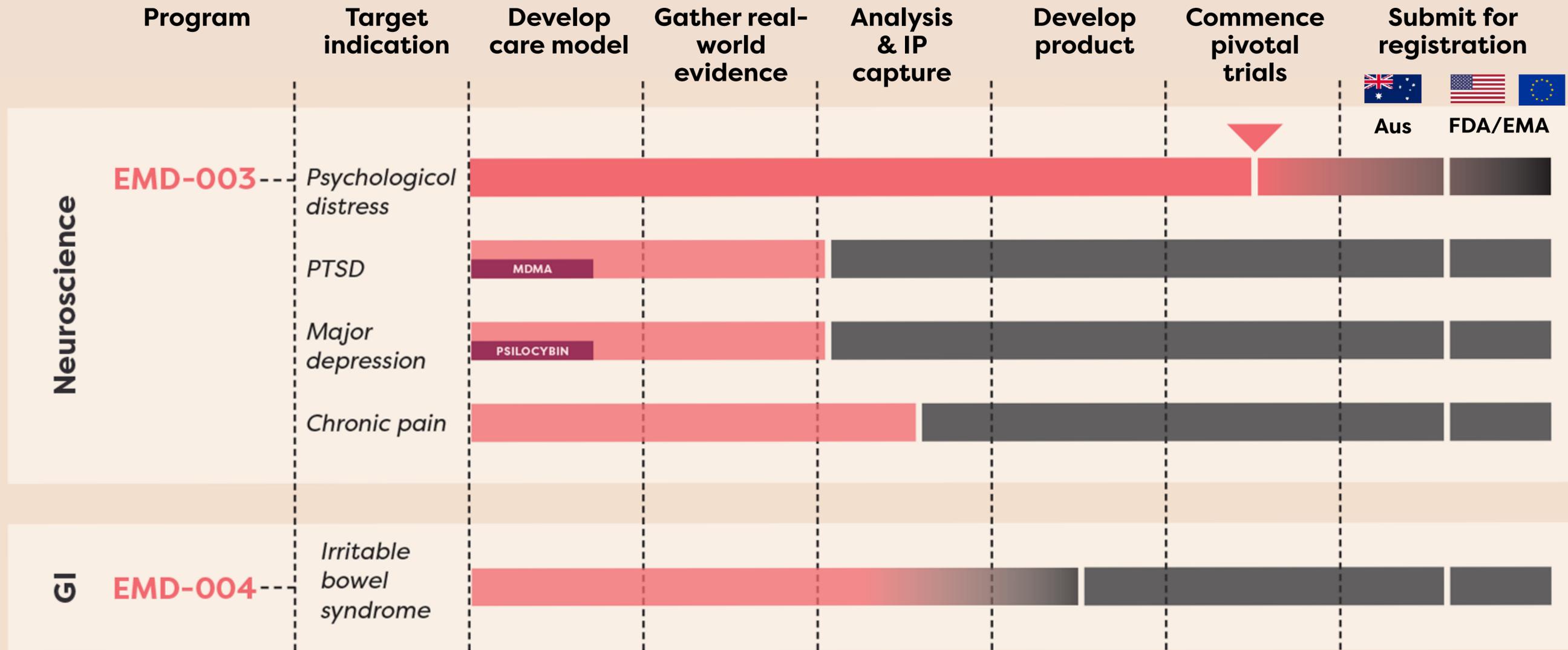


## Emyria's growing drug registration pipeline

*Given our unique assets and the high-quality data we generate during care, the Emyria platform can generate multiple, independent drug development programs for new and emerging treatments.”*

**Dr Michael Winlo, MD and CEO**

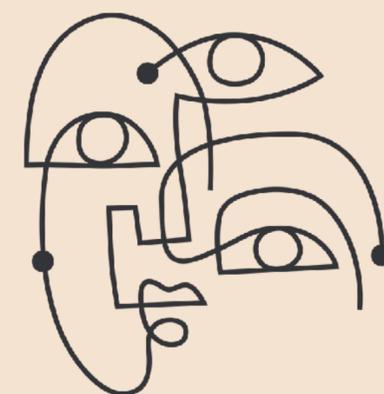
# Emyria's pipeline targets large, under-served markets



**+ 40** other indications

Cannabinoid
  Psychedelic therapy
  In planning
  Where we are now

\* Under Australia's Therapeutic Goods Administration (TGA), psychedelic medications such as psilocybin and MDMA are currently Schedule 9 of the Uniform Scheduling of Medicines and Poisons (which deals with Prohibited Substances). They are only available via approved research trials that include oversight by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes. This work is with partner Mind Medicine Australia.



## Emyria's experienced drug development team

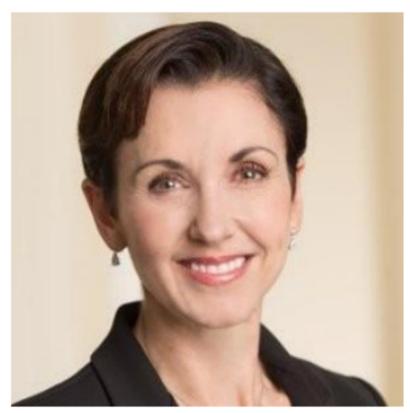
*“Our team has overseen more than 100 clinical trials and multiple drug registrations including with the FDA.”*

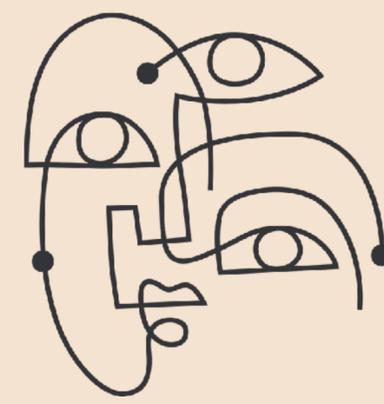
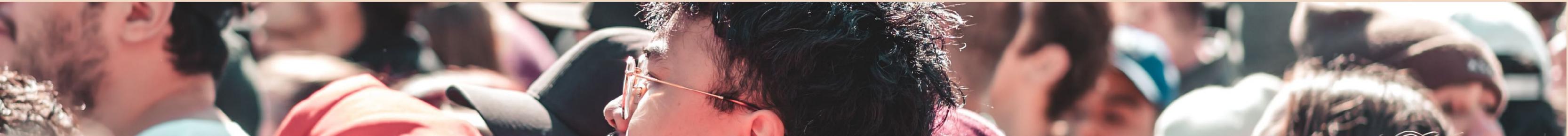
**Dr Michael Winlo, MD and CEO**

# Board with deep clinical and commercial expertise

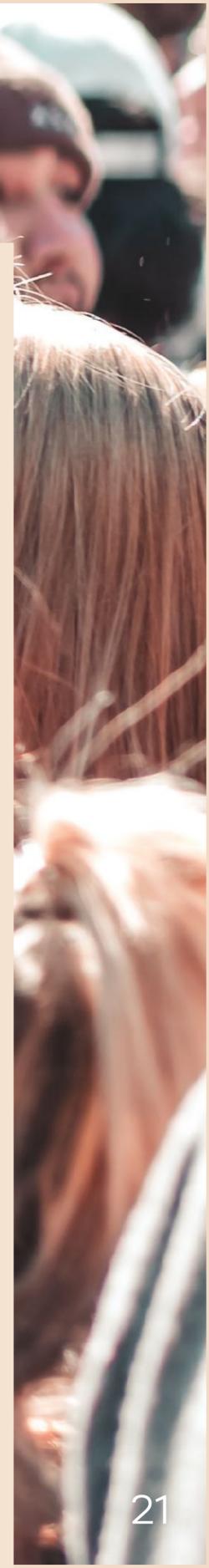
Key Person	Role
	<p><b>Dr Stewart Washer</b> <b>Chairman &amp; Founder</b></p> <p><b>Cynata</b> (ASX:CYP) – stem cells <b>Orthocell</b> (ASX:OCC) – regenerative medicine <b>Botanix</b> (ASX:BOT) – CBD (synthetic)</p> 
	<p><b>Dr Michael Winlo</b> <b>Managing Director</b></p> <p><b>Medical doctor</b> Director at <b>Linear Clinical</b> Health Lead at <b>Palantir</b> MBA from <b>Stanford University</b></p> 
	<p><b>Dr Alistair Vickery</b> <b>Medical Director</b></p> <p>Specialist <b>general practitioner</b> Chair of <b>Black Swan Health</b>, - mental health Associate <b>Professor of Primary Health Care</b></p> 
	<p><b>Matt Callahan</b> <b>NED &amp; Founder</b></p> <p>Founder <b>Botanix</b> (ASX:BOT), Founder <b>Orthocell</b> (ASX:OCC) 4 products through <b>FDA approval</b>. More than 20 years' <b>legal and IP experience</b></p> 
	<p><b>Professor Sir John Tooke</b> <b>Independent NED</b></p> <p><b>Knighted</b> in the UK for Services to Medicine Senior Independent Director, <b>BUPA Chile</b> Head of Medical Sciences at <b>UCL</b> Review board of <b>Google DeepMind</b> Immediate past <b>President Academy of Medical Sciences</b></p> 

# Recently appointed Key Advisors

Key Person	Role
	<p data-bbox="669 714 1402 757"><b>Dr Karen Smith</b> M.D., Ph.D., M.B.A., L.L.M</p> <p data-bbox="669 799 1279 846"><b>Chair of Strategic Advisory</b></p> <ul data-bbox="1419 555 2402 1052" style="list-style-type: none"> <li>• Experienced <b>pharmaceutical expert</b></li> <li>• <b>Multiple Directorships</b> with innovative pharmaceutical companies</li> <li>• Ex-<b>Chief Medical Officer and Global Head of R&amp;D at Jazz Pharmaceuticals</b></li> <li>• Overseen more than <b>100 clinical trials and 20 regulatory approvals</b></li> <li>• Appointment boosts Emyria’s global clinical trial and regulatory approval expertise to accelerate drug registration</li> <li>• Appointment to support innovation across Emyria’s drug development programs, clinical studies and evidence-generating care model</li> </ul> 
	<p data-bbox="669 1339 1236 1386"><b>Dr Richard Magtengaard</b></p> <p data-bbox="669 1427 1202 1474"><b>Consultant Psychiatrist</b></p> <ul data-bbox="1419 1127 2402 1699" style="list-style-type: none"> <li>• <b>Consultant Psychiatrist</b> and retired <b>Naval Officer</b></li> <li>• Current <b>Director of Military Trauma Recovery</b> Programme for sustained physical and psychological traumas</li> <li>• active member of the <b>Australasian Military Medical Association (AMMA)</b> and has developed lasting affiliations with <b>ADF Joint Health Command (JHC)</b>, <b>Returned Services League WA (RSLWA)</b>, <b>St John Ambulance (SJA)</b>, <b>West Australian Police (WAPOL)</b>, <b>Department of Fire and Emergency Services (DFES)</b>, <b>Australian Federal Police (AFP)</b> and numerous other Ex-Service Organisations (ESOs)</li> <li>• Appointment boosts Emyria’s clinical expertise in mental health care</li> </ul> 



**Emyria is poised for growth**



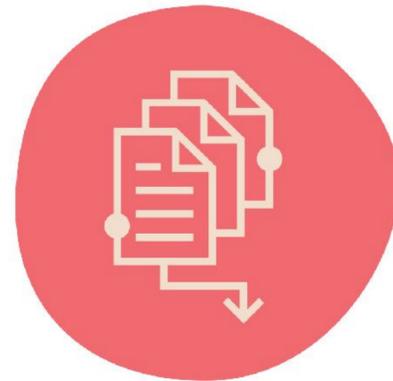
# Within 12 months we have...



- Over **3,500 patients** with unmet needs
- **7 clinic locations** Emerald Clinics
- **Specialist advisors & GCP-trained GPs**
- **Over 400 referring clinicians**



- Launched **2 drug development programs**:
- **EMD-003** (schedule 3 medicine for psychological distress)
- **EMD-004** (cannabinoid for IBS)



- Over **2.6M validated data points**
- \$1M of data deals inc. with **Canopy Growth Corp**



- Multiple **PhD-trained data analysts**
- Informing **strategic trial design**
- **Patents** already filed

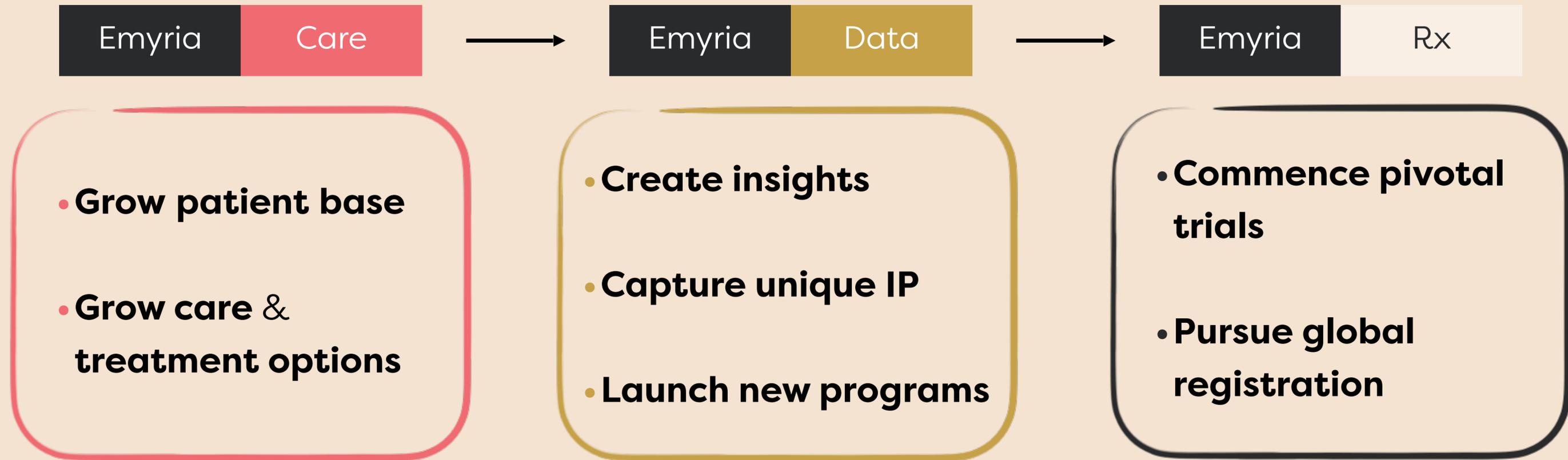


- **TGA registered** remote monitoring systems
- **Major WA Health grant award** (\$880k) for remote monitoring of vital signs and mental health



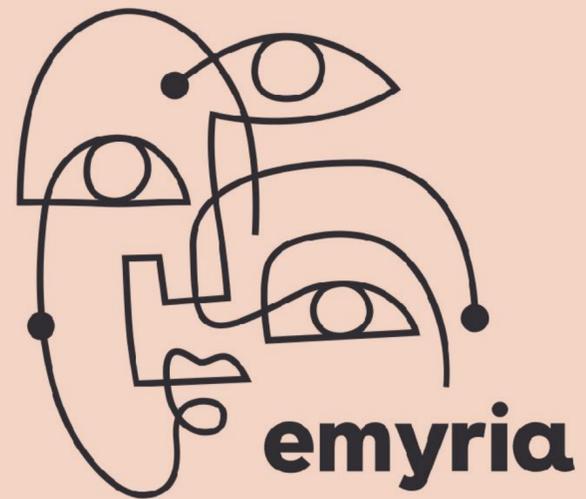
- **UK** clinical partner - Sapphire Medical (London)
- **USA** strategic partner - Mt Sinai (New York)
- Partnership with Mind Medicine **Australia** to develop psychedelic-assisted therapy model

# Emyria positioned to rapidly & repeatedly develop new treatments



Emyria's Digital Health Platform

- Obtain further **TGA registrations**
- Incorporate best-in-class vital sign technology to develop **digital biomarkers**
- Work with **partners (eg Mt Sinai)** to extend platform capability



**myriad data.  
individual care.**

## Contact Information

Michael Winlo: [mwinlo@emyria.com](mailto:mwinlo@emyria.com)

Investors: [investors@emyria.com](mailto:investors@emyria.com)

Media: [media@emyria.com](mailto:media@emyria.com)

General: [info@emyria.com](mailto:info@emyria.com)

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