ASX Announcement

12/05/2021

emyria
myriad data.
individual care.

Emyria obtains TGA Approval for medical grade, smartphone enabled, cardiovascular monitoring software

Highlights:

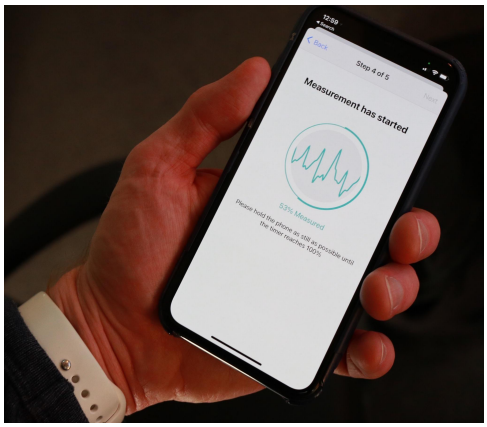
- Emyria has received an Australian-first, **Class IIa "software-as-a-medical-device"** (SaMD) registration with the Therapeutic Goods Administration (TGA) for a unique smartphone-based, **medical-grade, heart rate (HR), heart rate variability (HRV) and atrial fibrillation (AF)** monitoring application using only a smartphone camera

- Running on both Apple and Android phones, the medical-grade monitoring tool opens up further opportunities for Emyria to remotely capture objective health data for its **drug development**, **telemedicine** and **consumer healthcare** projects

- Emyria plans to initially use its software platform to capture objective, clinical measures remotely during these upcoming clinical trials and projects:
  - **EMD-003** - pursuing a Schedule 3 registration of a cannabinoid-based medicine targeting psychological distress [1]
  - **EMDMA-001** - An MDMA-assisted psychotherapy trial for post-traumatic stress disorder (PTSD) [2] and;
  - **EDICT** - *"An advanced digital monitoring and engagement platform for at-risk and confirmed COVID-19 individuals"* - part of the WA Health Grant awarded in Feb 2021 [3]

- The successful TGA registration highlights Emyria's leading position in the development of Real-World Evidence (RWE) technologies and a commitment to meeting the highest regulatory standards for new treatments for unmet needs.

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed treatment development and clinical services company, is pleased to announce it has achieved a Class IIa "Software as a Medical Device" registration on the Australian Register of Therapeutic Goods (ARTG) from Australia's Therapeutic Goods Administration (TGA).



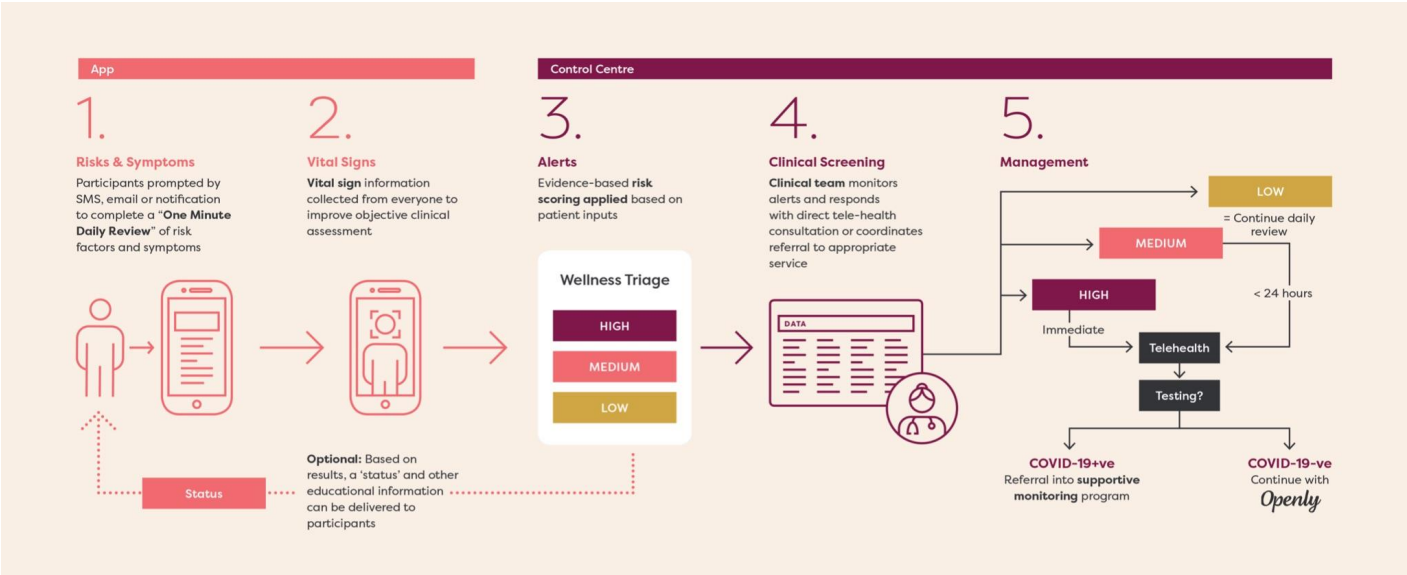
The product is titled *"Smartphone camera home cardiovascular monitoring application software"* (ARTG code: 365211)

Emyria's Managing Director, Dr Michael Winlo, said: *"Obtaining this classification highlights Emyria's commitment to formal regulatory approval of novel drug treatments and technologies for unmet clinical needs.*

Class IIa registration means Emyria's Real-World Evidence platforms are now capable of capturing medical grade vital signs using just an Apple or Android smartphone.

Emyria plans on using this capability in our upcoming drug development programs which allows our clinical teams to remotely monitor additional safety and efficacy outcomes data in our trial participants.

We also believe this capability has applications in a variety of medical and consumer health monitoring settings where medical-grade remote monitoring can improve the care of patients with complex needs."



Emyria's 'Openly' RWE technology platform

Openly is Emyria's remote Real-World Evidence (RWE) technology platform and was initially developed as a contactless, remote COVID-19 screening and management tool using just a smartphone. By leveraging the capabilities of an individual's smartphone, one can overcome the significant challenges of obtaining, distributing and maintaining stand-alone medical hardware. *(ASX announcement 15 Sep 2020)*

With this Class IIa registration, Openly is now recognised as being able to capture **medical-grade** measurements of an individual's heart rate, heart rate variability and atrial fibrillation status, remotely. When heart rate and heart rate variability change from baseline it can be a sign of early infection or a physical manifestation of stress or mental distress. [1]

Remotely captured vital sign measurements complement patient-reported outcomes data by providing **objective measures** of physiological status. These data can be provided to a clinician to support clinical management decisions and referral thresholds as well as support ongoing analysis of the safety and efficacy of novel treatments.

Emyria's leading position in developing Real World Evidence data technology

The TGA assesses medical devices before they can be approved for use in Australia. Devices must be included on the ARTG before they can be lawfully sold in Australia.

A Class IIa classification applies to software that is intended to provide information used to make decisions with diagnostic or therapeutic purposes. Successful classification as a Class IIa device requires passing detailed verification and clinical evaluation procedures and attracts a higher level of scrutiny.

Manufacturers of Class IIa medical devices must also obtain conformity assessment certification from an independent body (eg, the TGA) prior to inclusion in the ARTG.

Emyria's Class IIa classification applies to a unique software development kit (SDK), developed with technology partner Happitech. The SDK can be incorporated into Emyria's smartphone applications and Real-World Evidence platforms. Emyria is the exclusive Sponsor of this registration and will continue to work with Happitech to develop additional medical-grade cardiovascular and respiratory monitoring functionality for the platform.

Initial applications and ongoing development

The TGA approval of the expanded functionality of the Openly platform provides a unique opportunity to remotely monitor patients in **clinical studies**, provide **telehealth services** to patients and enable other **consumer healthcare products**. Software based medical devices are rapidly gaining importance as platforms, such as Apple's HealthKit, extend the accuracy and utility of expensive, hospital-based medical equipment.

Emyria plans to use Openly to remotely capture objective clinical measures from patient's during pivotal and landmark clinical trials and projects in planning. Initially:

- **EMD-003** (targeting **psychological distress**)
- **EMDMA-001** (targeting **PTSD**) and;
- **EDICT** - "*An advanced digital monitoring and engagement platform for at-risk and confirmed COVID-19 individuals*"

Remotely captured vital signs data complements routinely gathered clinical assessment and patient-reported outcomes measures. Such data can also assist in the development of companion smartphone apps which, if properly validated and registered, could facilitate self-care and support for patients, and remote patient monitoring for clinicians, for newly registered treatments.

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

For further information on **Emyria**:

Dr Michael Winlo
Managing Director
(08) 6559 2800
mwinlo@emyria.com

Lexi O'Halloran
Investor Relations
+ 61 (0) 404 577 076
lexi@janemorganmanagement.com.au

Andrew Williams
Media Relations
+61 (0) 412 614 125
andreww@profilemedia.com.au

References

[1] See ASX announcement 07 APR 21
[2] See ASX announcement 05 MAR 21
[3] See ASX announcement 05 FEB 21
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5900369/

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.