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## ASX Announcement 27 October 2021

### **2021 Annual General Meeting Presentation**

Cogstate (ASX.CGS) attaches its 2021 Annual General Meeting Presentation, being provided to shareholders at today's meeting.

This announcement was authorised for release by a sub-committee of the Board of Directors of Cogstate Ltd.

#### **About Cogstate**

Cogstate Ltd (ASX:CGS) is the neuroscience technology company optimising brain health assessments to advance the development of new medicines and to enable earlier clinical insights in healthcare. Cogstate technologies provide rapid, reliable and highly sensitive computerised cognitive tests across a growing list of domains and support electronic clinical outcome assessment (eCOA) solutions to replace costly and error-prone paper assessments with real-time data capture. The company's clinical trials solutions include quality assurance services for study endpoints that combine innovative operational approaches, advanced analytics and scientific consulting. For over 20 years, Cogstate has proudly supported the leading-edge research needs of biopharmaceutical companies and academic institutions and the clinical care needs of physicians and patients around the world. In the Healthcare market, in August 2019 Cogstate entered into an exclusive licensing agreement with the pharmaceutical company Eisai, under which Eisai will market Cogstate technologies as digital cognitive assessment tools in Japanese markets. In October 2020, Cogstate extended its agreement with Eisai to the Rest of the World. The product, branded as NouKNOW, launched in Japan on 31 March 2020 (nouknow.jp). For more information, please visit <u>www.cogstate.com</u>.

#### For further information contact:

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# **Annual General Meeting**

Wednesday 27 October 2021 Start time: 11am Australian eastern summer-time



## Disclaimer

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# **Board of Directors**



Martyn Myer Non-Executive Chairman

Member: Audit, Risk & Compliance Committee Chair: Remuneration & Nomination Committee



Brad O'Connor Managing Director / CEO



David Dolby Non-Executive Director Member: Remuneration & Nomination Committee



Richard Mohs

Member: Audit, Risk & Compliance Committee Member: Remuneration & Nomination Committee



Ingrid Player Non-Executive Director

Chair: Audit, Risk & Compliance Committee Member: Remuneration & Nomination Committee



Richard van den Broek Non-Executive Director

Member: Remuneration & Nomination Committee



Kim Wenn Non-Executive Director

Member: Audit, Risk & Compliance Committee Member: Remuneration & Nomination Committee

# **Founding Vision**

To make assessment of brain health as simple, common and informative as assessment of blood pressure

# Global License Agreement



### Who is Eisai?

Tokyo listed, global pharma, A\$31bn market cap

## **Exclusive license**

Eisai marketing Cogstate technology globally as a digital assessment of cognition

## **Commercial terms**

Up-front royalty US\$15m

Ongoing double-digit royalty on all revenue, not less than US\$30m over 10 years

## **Development funding**

Eisai funding ongoing development and improvement of Cogstate technology for launch into new markets

## **Commercial team**

Eisai are responsible for, and fund, all regulatory and commercial activities

# **FDA Approval of Aduhelm**

First ever disease modifying treatment of Alzheimer's to be jointly marketed by Biogen and Eisai

- Approved by FDA on 7 June 2021
- Also submitted applications to regulators in:
  - Europe (Announced Oct 2020)
  - Japan (Announced Dec 2020)

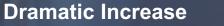
Other late stage potential candidates granted "breakthrough therapy designation" by FDA:

Lecanemab (aka BAN2401) : Eisai / Biogen

- Have submitted rolling application to FDA
  Donanemab : Eli Lilly & Co
- Have announced intention to lodge this year



## Adapting to a global pandemic: Decentralised Clinical Trials





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### **Ripe for disruption**

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**Patient centered** 

Since the beginning of the pandemic, the whole industry has seen an increase in demand for remote assessment in clinical trials There will always be a place for trial sites, but the adoption of remote assessment is expected to have long term implications for trial design Conventional clinical trials (catering to investigators at physical sites) can be slow and expensive Not only are decentralised trials more efficient for the pharma/biotech companies, but they are less burdensome for patients

Digital cognitive assessments (such as Cogstate's) are well suited to decentralised trials

# FY21 Financial Highlights (All figures in US\$)

A return to profitability, a solid cash balance and improving outlook

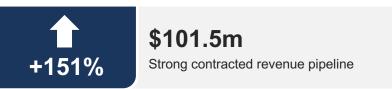
### **Record clinical sales contracts executed**

# **1**+15%

### **\$47.3m** Alzheimer's disease represented 65% of the value of contracts executed in FY21

### **Record Group Revenue**

### **Record contracted future revenue**



### **Transitioned to positive PBT**



## \$32.7m

Clinical Trials up 36% to \$28.7m Healthcare up 162% to \$3.8m

### Strong operating cash flow



## \$16.8m

Incl. \$13.8m net proceeds from Eisai upfront license fee payment Excl. customer pass-through costs

# PCP -\$3.0m

## \$5.8m

Guidance was \$5.2-\$5.7m. Underlying PBT \$3.9m (excludes one-offs). Strong 2H21.

### Net Cash balance



## US\$22.4m

An increase of \$16.5m during the year

## **Clinical Trials Sales Contracts**



## **Record 1st Quarter**

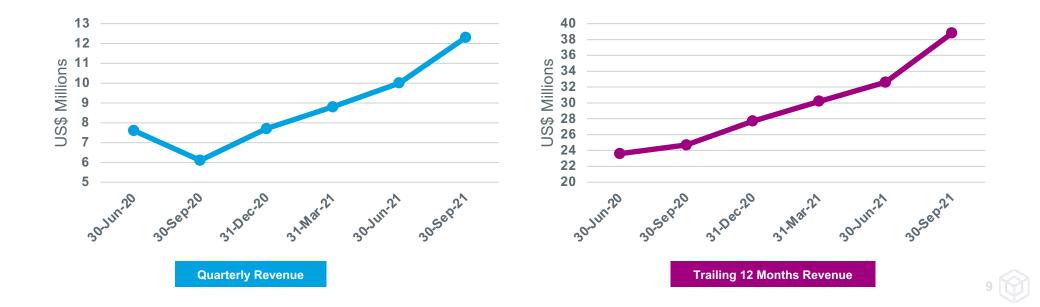
Landmark Sep quarter underpinned by a large phase 3 Alzheimer's disease trial.

392% increase from the same period last year

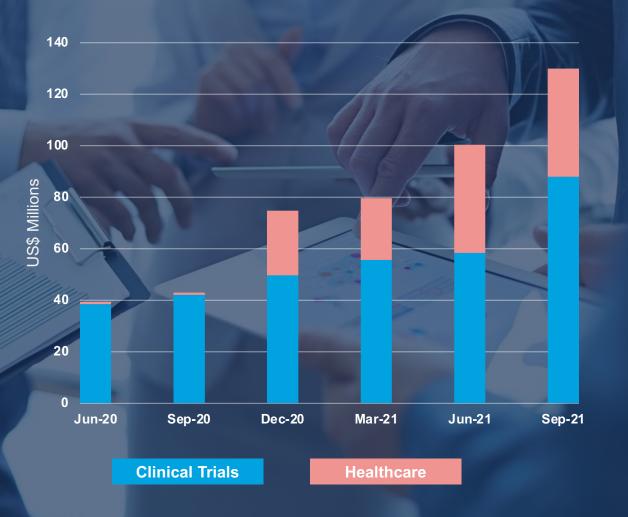
86% of last year's full-year result in just the first quarter

## **Group Revenue**

- 1Q22 revenue of \$12.3m, up 99% from 1Q21 and 23% from 4Q21
  - 1Q22 Clinical Trials revenue \$11.1m, up 93% from 1Q21 and 26% from 4Q21
  - 1Q22 Healthcare revenue \$1.1m, up 255% from 1Q21 and flat compared to 4Q21
- Trailing 12-month revenue of \$38.8m, up 57% from 1Q21 and 19% from 4Q21



## **Contracted Revenue Backlog**



## \$130m at 30-Sep-21

Contracted revenue backlog provides insight into future revenue performance.

Up 209% since last year (Sep-20)

Up 28% since last quarter (Jun-21)

### Clinical Trials Backlog \$88.0m

- Up 109% since last year
- Up 51% since last quarter

### Healthcare Backlog \$42.0m

- Up 4,616% since last year
- Down 0.14% since last quarter

## FY22 & FY23 Contracted Revenue



### FY22: Revenue under contract at 30-Sep-21 is \$38.1m

- Clinical Trials \$33.9m (01-Jul-21: \$24.5m)
  - 1Q22 actual \$11.1m
  - 2Q22 4Q22 contracted \$22.8m
- Healthcare \$4.2m
  - 1Q22 actual \$1.2m
  - 2Q22 4Q22 contracted \$3.0m
- New sales contracts executed during 2Q22 4Q22 will generate additional Clinical Trials revenue in FY22

### FY23: Revenue under contract at 30-Sep-21 is \$30.8m

- Clinical Trials \$26.7m
- Healthcare \$ 4.1m

# Macro Trends Positively Impacting Future Revenue

- 1. Breakthrough Alzheimer's treatments expected to create demand for cognitive assessment in the community
- 2. Impending launch of Cogstate technology, by Eisai, in multiple countries to feed into that demand
- 3. Alzheimer's R&D expected to increase over coming years as approved treatment(s) provide regulatory path to market
- 4. Increased adoption of decentralised trial design provides additional sales opportunities for digital assessments

# FY 2022 Outlook



### **Clinical Trials**

- Revenue under contract at 30-Sep-21 of \$33.9m
- Additional revenue will be generated from contracts executed 2Q22 4Q22
- Expect FY22 contribution margin to remain consistent with FY'21 performance, allowing for investment in technology to support the shift to decentralised trials

### Healthcare

- Expect to recognize \$4.2m of deferred revenue associated with Eisai Royalties in FY22.
- Earnings contribution expected to be in the range of \$2.5m to \$3.0m

### **Group Earnings**

- Research segment contribution consistent with FY21 result.
- Operating Expense expected to be in the range of 31% to 33% of revenue, an improvement of 5% to 7% percentage points on FY'21
- EBIT margins expected to be in the range of 15-18%.
- Underlying operating cash flow expected to be 30-35% of EBITDA, allowing for amortisation of Eisai revenue as well as amortisation of software development at an amount consistent with FY21.

## **Cogstate Investment Case**

# Record revenue backlog with earnings leverage

- Momentum in Clinical Trials continues to build.
- Eisai partnership to deliver Royalties of not less than \$43m over next 10yrs (including future cash payments of not less than \$30m).
- Expecting to record revenue and profit growth in FY22
- FY23 contracted revenue > \$30m



# Significant leverage to an Alzheimer's treatment

- · Aduhelm approval crystallises the opportunity
- Other potential treatments from Eisai and Lilly granted "breakthrough therapy designation" by FDA
- Likely to see increased investment in R&D/Clinical Trials in related therapies
- CGS is uniquely positioned to provide highly scalable digital tools for the early identification of patients



# Unique technology and large addressable markets

- Technology developed over 20 years, scientifically validated, approved by regulators and provides strong barriers to entry.
- Global healthcare represents a large addressable market.
- Launching new mHealth\* & telehealth products; opportunity to become the world's leading provider of digital brain health assessments



### Strong balance sheet

 Underpinned by a strong balance sheet – net cash position of \$23.4m\*\* as at 30 Sep 21

\*\*Based on gross cash less borrowings and cash held for future passthrough payments.



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