## **Investor Briefing**

July 2021

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#### **Positive Developments Impacting Cogstate Opportunity**

## The Opportunity in Alzheimer's Has Changed

#### First drug approved

Digital brain assessments are expected to be a key plank of consumer & physician engagement as part of the launch of the first Alzheimer's disease therapies Which Has Changed The Commercial Opportunity For Cogstate

#### Eisai license + drug approval

1. Clinical Trials business will benefit from expected increase in clinical trials; and

2. Healthcare business will benefit from diagnosis and monitoring that will be part of patient management

#### Market Dynamics are Also Changing

#### Remote (virtual) assessment

Health pandemic has changed behaviour and led to adoption of technology at increased rate.

Cogstate digital assessments are well suited for remote (decentralised) trials

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#### **Cogstate Digital Brain Health Strategy**

#### Offering

#### Software

- Scientific & commercial validation
- Proprietary digital assessments

#### **Services**

• Scientific & operational expertise



#### Market Dynamics & Cogstate Positioning



Approval of first ever Alzheimer's therapy & positive data from other Alzheimer's trials

Large and growing market for digital healthcare solutions



Existing relationships with large pharma customers / partners

Strong balance sheet FY21 : Profitable, cash flow positive

#### Markets

#### **Clinical Trials**

- Pharma customers
- Our established business

#### Healthcare

- Global license agreement
- Our next frontier



All figures in US\$

#### New Contracts Executed \$47.3M Up 15% on PCP\*

Contracted Backlog \$101.5M

Up 151% on FY20 \*\*\*

**Revenue \$32.7M** Up 44%\*\* on PCP

Positive Profit before Tax (estimated range \$5.2 - \$5.7M)

#### **Positive Cash Flow**

PCP = previous corresponding period

\*\* FY20 numbers have been restated following a review of the application of the Group's accounting policy. These changes were implemented with the 1H21 result (see explanatory notes in appendix).

\*\*\* In 2020, Cogstate restated the contracted future revenue backlog to exclude third-party services to better reflect future net revenue that Cogstate is expected to derive under existing contracts. During 2021, the reported new contract signings has excluded third-party services, however, in the prior years, Cogstate reported contracts inclusive of third-party services

#### **New Clinical Trial Sales Contracts Executed \$47.3M**

- Up 15% compared to FY20
- \$11.4M contracts in 4Q21, up 51% compared to 4Q20
- 2H21 contracts exceeded 1H21 contracts
  - the first time that 2<sup>nd</sup> half contracts have exceeded 1<sup>st</sup> half
- Increase in Alzheimer's disease ("AD") mix reflecting growing number of AD clinical trials
  - AD trials represent 65% of the value of total contracts executed in FY21 (up from 60% in FY20)



Refer to appendix for reconciliation of new contract signings and third party signings

All figures in US\$

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#### Contracted Revenue Backlog \$101.5M

Record high level of contracted future revenue backlog:

- Up 151% on PCP
- Clinical Trials revenue backlog of \$58.4M
- Healthcare revenue backlog of \$43.0M, increased to reflect the \$20m of minimum Royalties Eisai is now obliged to pay over year 6-10

The chart below shows how the \$101.5M is expected to roll-off as revenue in financial years FY22 – FY26, with pcp comparison to show the growth in backlog achieved during the FY21 year



All figures in US\$

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#### **Clinical Trials revenue backlog coverage**

- On average over the last 5 years, revenue backlog at the beginning of each year has has represented 52% of final revenue for that year.
  - FY21 Clinical Trials contracted revenue at beginning of year was \$15.4M, representing 54% of actual Clinical Trials revenue for FY21 of \$28.7M
  - Where sales contracts executed during any year under perform vs the prior year (such as FY19) the historical trend does not hold.
  - As revenue and backlog both grow, contracts executed during the year are expected have less impact on the revenue result in that same year.
- Contracted clinical trials revenue at 01 July 2021 that is expected to be recognised in FY22 is \$24.5M (up 59% compared to PCP)



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#### Group revenue \$32.7M for FY21

- FY21: Revenue \$32.7M, up 44% compared to PCP
- 2H21: Revenue \$18.8M, up 36% from 1H21 (\$13.9M)
  - Clinical Trials 2H21 \$16.1M, up 28% from 1H21 (\$12.6M)
  - Healthcare 2H21 \$2.6M, up 127% from 1H21 (\$1.1M)
- 4Q21: Revenue \$10.0M, up 30% compared to PCP
  - Clinical Trials 4Q21 \$8.8m, up 25% on PCP and 21% higher than 3Q21
  - Healthcare 4Q21 \$1.1m, up 75% on PCP, but 28% lower than 3Q21

Revenue	FY21	FY20	Variance
	US\$ m	US\$ m	%
Clinical Trials	28.67	21.08	36%
Healthcare	3.76	1.44	162%
Research	0.26	0.26	0%
Total Revenue	32.69	22.78	44%

All figures in US\$

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#### **Positive Profit Before Tax (PBT)**

- PBT estimated to be in the range of \$5.2 \$5.7M for FY21
  - PBT includes a one-off \$2.4M gain as a result of forgiveness of PPP loan<sup>1</sup>. Therefore, normalised PBT in the range of \$2.8 - \$3.3M
  - 1H21 Loss before Tax of \$0.4M, therefore 2H21 PBT in the range of \$3.2 -\$3.7M (normalised)
- Strong Clinical Trials activity and cost management driving improved margins in that segment
- Recognition of Healthcare (Eisai) revenue
- Maintaining Operating Expense within Expense/Revenue margins

<sup>1</sup> In May 2020, Cogstate Inc secured a US\$2.44 million loan from Citibank under the Paycheck Protection Program (PPP) as part of the CARES Act in response to the COVID-19 pandemic. The PPP allowed businesses and non-profits with fewer than 500 employees to obtain loans of up to \$10 million to incentivise companies to maintain their workforce as they managed the business disruptions caused by the COVID-19 pandemic. On 15 June 2021, Cogstate announced that it had been advised by the Small Business Administration that all interest and principal payable under the terms of the loan had been forgiven.

All figures in US\$

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## FY21 Operating cash inflow \$16.8M, including net \$13.8M received from Eisai

	Cogstate Operations	Customer Related Pass-Through Expenses	Total
	US\$m	US\$m	US\$m
Cash at 01 July 2020	8.4	1.9	10.3
Cash flow from operations Eisai upfront payment (net of costs)* Cash flow from ordinary operations <b>Total cash flow from operations</b> Cash flow from investing Capitalised software development Property, Plant & Equipment Grant funds received <b>Total cash flow from investing</b>	13.8 3.0 <b>16.8</b> (2.6) (0.6) 0.6 <b>(2.6)</b>	(0.7) (0.7)	13.8 2.3 <b>16.1</b> (2.6) (0.6) 0.6 <b>(2.6)</b>
Cash flow from financing	(0.2)	-	(0.2)
Cash at 30 June 2021	22.4	1.2	23.6

\* Net upfront cash payment of \$13.8m received from Eisai

- Gross \$15.0M
- Withholding tax \$0.75M
- Associated costs \$0.45M

#### **Alzheimer's Opportunity in Clinical Trials**

Dementia is one of the major causes of disability and dependency among older people worldwide, representing a significant health crisis.

The recent FDA approval of an Alzheimer's therapy is likely to see Clinical Trials momentum in the space increase further. History has shown that approvals of the first drug in a new category reduce perceived R&D risk, resulting in increased investment and encourages innovation.

<b>50m</b>		Estimated dementia cases globally; expected to triple by 2030				
	\$818 Bn	Annual global cost of dementia; expected to rise to \$2 trillion by 2030				
	60-70%	Alzheimer's as a % of total dementia				

Pharma investment in dementia (specifically AD), as measured by the number of new trials initiated, is increasing:

# of AD Trials (USA Only)	Year to 3Q'20	Year to 3Q'21	ΥΤΥ%
Phases 1 to 3 only	50	85	70%

Sources: World Health Organization

www.clinicaltrials.gov

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#### **Alzheimer's Opportunity in Healthcare**

A disease modifying therapy will require early detection of cognitive decline in order to intervene and slow progression – creating a significant global market for scalable and sensitive dementia screening.

#### 320 million people over age 65, key markets only

USA:	53.2 million people
EU:	71.5 million people
China:	160.3 million people
Japan	35.4 million people

World Bank staff estimates using the World Bank's total population and age/sex distributions of the United Nations Population Division's World Population Prospects: 2019 Revision.

# Expanded Eisai partnership takes Cogstate a step closer to realizing its vision

Global leaders in development and commercialization of total

dementia care ecosystem, from identification to intervention

#### Current Opportunity

Increasing awareness of need to monitor Brain Health

Eisai

#### Early detection of memory impairment important for:

- Maintaining the safety of patients
- Promoting healthy lifestyle
- Reducing risk relating to Alzheimer's disease
- Care planning

## Enablers using Cogstate Technology:

Scalable, sensitive and reliable digital tools for early detection, screening, monitoring and awareness

- Home-based self assessment
- GP-based annual assessment screening tools
- Specialist-based diagnostic support tools
- Tools for monitoring response to therapy

#### Potential Future Opportunity



Identifying patients who would benefit from Alzheimer's therapy

#### Early detection of memory impairment critical for:

• Therapeutic intervention to slow progression of Alzheimer's

FDA approved first ever treatment, which is expected to be a major driver of demand for digital health solutions for cognitive assessment

#### Market Size = at risk age bracket = >65yrs old = Significant addressable market





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 Donanemab : Eli Lilly & Co

Lilly have announced that they intend to lodge a Biologics License Application (BLA) in respect of donanemab late in 2021



### **Cogstate Investment Case**

## Record revenue pipeline > \$100m with earnings leverage

- Momentum in Clinical Trials continues to build (record \$58.4m revenue backlog).
- Eisai partnership to deliver Royalties of not less than \$43m over next 10yrs (including future cash payments of not less than \$30m).
- Relatively stable cost base should see margins expand as revenues rise
- Transitioned to profit in FY21



#### Significant leverage to an Alzheimer's treatment

- · Aduhelm approval crystallises the opportunity
- 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 \$22.4m\*\* as at 30 June 21
- \*\*Based on gross cash less borrowings and cash held for future passthrough payments. Note that \$2.4m PPP loan has now been forgiven



\*mHealth refers to the concept of mobile self-care — consumer technologies like smartphone and tablet apps that enable consumers to capture their own health data, without a clinician's assistance or interpretation



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#### **Restatement of prior period revenue**

Due to the significance of the Eisai global licensing agreement, the group announced in its 1H21 results that it had reviewed the application of its accounting policy in respect of revenue recognition relating to the grant of licences, provision of supporting services and the provision of server access, in accordance with the requirements of AASB 15 Revenue from Contracts with Customers.

The group considers that recognising the upfront cash payments received From Eisai (\$1m in Dec 19 for Japan and \$15m in Dec 20 for Global (ex Japan)) as revenue on a straight-line basis over the licence periods better reflects its performance in providing access to the licences, continuing support services and servers. As required by the accounting standards, this change is applied retrospectively, and as a result, the group has restated comparative figures. This resulted in a \$0.03m increase in Healthcare revenue in 4Q20 from a reported \$0.60m to a restated \$0.63m. This restatement has no impact on cash. See reconciliation table below.

	(Restated) 4Q20 US\$	Adjustment US\$	
Healthcare Revenue	0.63	0.03	0.60

#### **Reconciliation of new contract signings**

In 2020, Cogstate restated the contracted future revenue backlog to exclude third-party services to better reflect future net revenue that Cogstate is expected to derive under existing contracts. During 2021, the reported new contract signings has excluded third-party services, however, in the prior years, Cogstate reported contracts inclusive of third-party services

	1Q US\$m	2Q US\$m	1H US\$m	3Q US\$m	4Q US\$m	2H US\$m	Full US\$m
2021							
Cogstate technology & services	8.3	14.3	22.6	13.3	11.4	24.7	47.3
Third-party services	0.9	0.8	1.7	1.5	1.2	2.6	4.4
Total value of contracts executed	9.2	15.1	24.3	14.8	12.6	27.4	51.7
2020							
Cogstate technology & services	6.7	17.5	24.2	9.5	7.6	17.1	41.3
Third-party services	1.0	1.7	2.7	1.2	0.8	2.0	4.7
Total value of contracts executed	7.7	19.2	26.9	10.7	8.4	19.1	46.0

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#### Contracted Future Revenue All results provided in US\$

		31-Jun-21	31-Mar-21	VARIANCE FAV/(UNFAV)		
		US\$	US\$	US\$	%	
J	Contracted Clinical Trials Revenue	58,424,721	55,673,915	2,750,806	4.9	
	Eisai License – Global (commercial years 1-10)*	42,211,299	23,191,465	19,019,834	82.0	
/	Eisai License – Japan (10 year license)	815,494	840,268	(24,774)	(2.9)	
)	Total Contracted Future Revenue	101,451,514	79,705,648	21,745,866	27.3	

\*Following the FDA approval of Aduhelm, in addition to the minimum contractual royalty payments over commercial years 1-5 of US\$10 million, Eisai are now also contractually obliged to make the minimum royalty payments to Cogstate over commercial years 6-10, being an additional aggregate payment of US\$20 million over that period.

#### Contracted Future Revenue > \$100M

FY22 contracted revenue \$28.7M at 01 July 2021

- Clinical Trials contracted revenue \$24.5M
- Healthcare contracted revenue
   \$4.2M

FY23 contracted revenue > \$25M at 01 July 2021

 Cogstate expects to start FY23 with a new record level of contracted revenue for that year (given current high level and 12 months before the start of FY23)

#### 44% Revenue Growth in FY21

FY21 revenue of \$32.7 million is a record result for Cogstate and is up 44% compared to pcp (FY20 \$22.8m).Clinical Trials revenue benefitting from the substantial increase in new sales contracts executed in recent periods.Healthcare revenue benefitting from recognition of revenue associated with the Eisai licencing agreement.

Devenue	4Q21	4Q20	Variance	FY21	FY20	Variance
Revenue	US\$ m	US\$ m	%	US\$ m	US\$ m	%
Clinical Trials	8.83	7.08	25%	28.67	21.08	36%
Healthcare	1.10	0.63*	75%	3.76	1.44*	162%
Research	0.07	0.02	250%	0.26	0.26	0%
Total Revenue	10.0	7.73	30%	32.69	22.78	44%

\*4Q20 and FY20 numbers have been restated following a review of the application of the Group's accounting policy. These changes were implemented with the 1H21 result (see explanatory notes in appendix).

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