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# FY21 Financial Results & Business Outlook

**ASX Announcement** 

25 August 2021

### All figures in US\$ Reporting Period: 30 June 2021. Prior Corresponding Period (PCP): 30 June 2020

Cogstate Ltd (ASX:CGS) has today released its Appendix 4E and Annual Report to Shareholders for the year ended 30 June 2021 (FY21). A summary of the FY21 result is provided below.

- Record Group Revenue of \$32.69m for FY21, up 44% on PCP.\*
- **Transition to positive Earnings:** Profit Before Tax (PBT) of \$5.82m (*vs. guidance of \$5.2-5.7m and PCP -\$2.99m*) and Net Profit After Tax (NPAT) of \$5.23m (*PCP -\$1.96m*)\*. Excluding the impact of non-recurring items, underlying PBT was \$3.88m (*\$6.87m improvement on PCP*).
- Momentum in 2H21: Revenue in 2H21 increased \$4.97m (or 36%) from 1H21, resulting in an improvement in underlying PBT from ordinary operations of \$4.16m. The improvement, which means 84% of the revenue increase from 1H21 to 2H21 was translated into an increase in PBT, resulted from excess capacity that has now been absorbed.
- Clinical Trials A record breaking year and strong momentum into FY22
  - The Clinical Trials segment produced several records for the FY21 year, with the value of executed new sales contracts in FY21 up 15% on PCP to a record of \$47.34m. Benefitting from the substantial increase in Clinical Sales contracts executed in FY21 and FY20, Clinical Trials revenue was up 36% on PCP to a record \$28.67m.
  - At the end of FY21, the Clinical Trials segment has a record high revenue backlog of US\$58.4m, with \$24.5m of contracted revenue expected to be recognised in FY22.
- Healthcare Landmark 10yr license agreement with Eisai & FDA approval of Alzheimer's drug
  - In October 2020, Cogstate entered into a global licensing agreement with Japanese pharmaceutical company Eisai Co., Ltd (Eisai). Then in June 2021, a disease modifying therapy for Alzheimer's disease, developed by Eisai and their development partner Biogen Inc, received accelerated approval for release in the USA.
  - Cogstate received an upfront licence fee from Eisai of \$15m cash in 2Q21 (\$13.8m net of costs) and will receive future Royalty payments of not less than \$30m cash over 10yrs. The combined \$45m will be recognised as revenue on a straight-line basis over 11 years (10-year term + 12 months to commence).
  - Healthcare revenue was up 162% on PCP to \$3.76m, benefitting from commencement of the global license agreement with Eisai.
- Strong Cash Flow/Balance Sheet: Net cash in-flow from operations of \$16.1m (PCP \$0.7m) and a net cash balance at 30 Jun 21 of \$22.4m (gross cash less borrowings and cash held for customer pass-through costs).
- Record high contracted future revenue: Following execution of the global license agreement with Eisai, contracted future revenue increased to \$101.5 million, up 151% on PCP (\$28.7m to be recognised in FY22).

- Covid impact: increased adoption of decentralised clinical trials: Cogstate has been able to successfully migrate staff to a virtual work environment with no disruption to its customers. More broadly within the industry, since the beginning of the pandemic, the whole industry has seen an increase in demand for remote assessment in clinical trials (known as decentralised clinical trials). Cogstate digital assessments are well suited to such remote assessment.
- FY22 outlook Continued Revenue and Earnings Growth
  - Clinical Trials: revenue under contract at 1 July 2021 was \$24.5m. Sales contracts of \$35.4m have been executed since 01 July 2021, which is expected to add approximately \$6.0m of revenue to FY22 – therefore taking the contracted FY22 Clinical Trials revenue to approximately \$30.5m.
  - Historical guide: 2Q'21-4Q21 saw \$38m of new contracts executed, adding approximately \$12m to FY21 revenue
  - Expect FY22 Clinical Trials contribution margins to be consistent with FY21, allowing for investment in technology to support the shift to decentralised clinical trials.
  - Healthcare: Contracted revenue of \$4.2m, producing a segment contribution in the range of \$2.5m
    \$3.0m
  - Research: segment contribution consistent with FY21 result
  - Operating expenses: as a percentage of operating revenue are expected to be in a range of 31-33%, an improvement of 5-7% points compared to FY21.
  - 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 upfront royalty received as cash from Eisai in FY21 but revenue amortised over the 11-year life of the licence as well as capitalisation of software development at an amount consistent with FY21.

#### Summary of Results (All figures are stated in US\$)

	30 June 2021	30 June 2020*	MOVEMEN	NT
	US\$	US\$	US\$	%
Total revenue from ordinary activities	32,686,396	22,771,196	9,915,200	43.5
- Clinical Trials revenue	28,667,707	21,075,922	7,591,785	36.0
- Healthcare revenue	3,758,790	1,435,498	2,323,292	161.8
- Research revenue	259,899	259,776	123	0.0
EBITDA**	5,711,737	(890,440)	6,602,177	n/a
Profit Before Tax**	5,820,270	(2,994,590)	8,814,860	n/a
Underlying Profit Before Tax***	3,880,270	(2,994,590)	6,874,860	n/a
Net Profit After Tax**	5,233,283	(1,956,584)	7,189,867	n/a
EPS**	0.031	(0.012)	0.043	n/a
Net operating cash flow	16,114,410	730,211	15,384,199	2,107

\* FY20 numbers have been restated following a review of the Group's accounting policy in respect of revenue 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. These changes were implemented with the 1H21 result (see explanatory notes and reconciliation table on page 5 of this release).

\*\* Reported PBT, NPAT and EPS include a \$2.4m contribution from PPP Loan forgiveness in FY21. This \$2.4m is not included in reported FY21 EBITDA or EBIT.

\*\*\* Underlying PBT is a non-statutory measure that excludes non-recurring items. In FY21 there was a net \$1.9m positive contribution to reported PBT from the following non-recurring items: a +\$2.4m gain from PPP Loan forgiveness and a -\$0.5m expense relating to Adviser fess associated with the Eisai global agreement.

#### **CEO Commentary**

Commenting on the result, Cogstate's CEO, Brad O'Connor, said: "FY21 was a milestone year for Cogstate. The company delivered record sales, transitioned to positive earnings and operating cash flow, executed a record level of clinical trials sales contracts and as at 30 June 2021 had a balance sheet with net cash of \$22.4m and a record forward order book of \$101.5m."

"Encouragingly momentum in the business continued to build over the course of the year, underpinned by a strong performance from the Clinical Trials business that saw revenue grow across every quarter. This, together with cost management and a full six-month contribution from Eisai drove a strong PBT performance in 2H21 and saw us finish the year with a PBT result slightly ahead of the guidance range we provided in our July 2021 update."

Mr O'Connor continued, "The year included a number of landmark developments:

- In October 2020, Cogstate signed a 10-year global license agreement with international pharmaceutical company, Eisai Co., Ltd. to exclusively distribute Cogstate's scientifically validated digital brain assessments in all markets except clinical trials. This landmark agreement provides Cogstate with an opportunity to launch digital brain health assessments to physicians and consumers in major markets around the world.
- In June 2021, Eisai and their development partner, Biogen, received accelerated approval from the USA based Food & Drug Administration (FDA) for the first Alzheimer's disease modifying therapy (with applications pending regulatory review in other jurisdictions). Also in June 2021, the FDA granted breakthrough therapy designation for two other new potential treatments that are being developed by Eisai and Eli Lilly & Co., thereby accelerating the potential path of both prospective treatments to market. Cogstate through its partnership with Eisai is uniquely positioned to provide highly scalable tools to identify patients suffering from cognitive decline, who may be appropriate for new therapies. At Cogstate, we believe that, collectively, these developments are likely to drive further investment in Clinical Trials for other potential treatments for Alzheimer's disease.
- The global health pandemic has led to adoption of technology solutions at a rate previously unseen, including remote clinical trials, also known as decentralised clinical trials. This emerging trial design threatens to disrupt the traditional site centric model of clinical trials and represents an exciting opportunity for Cogstate in an environment where digital native assessments have obvious benefits.

Together, these developments have significantly enhanced the commercial opportunities for Cogstate and take us a step closer to realising our founding vision of using scalable digital technology to make assessment of brain health as simple, common and informative as assessment of blood pressure."

# FY21 Segment Reporting

	FY21 Segment
$\gg$	
	Revenue from ope
	Clinical Trials
	Revenue
	Direct Cost (excludi
	Gross margin
	SG&A
	Clinical Trials Seg
	Contribution Margin
	Healthcare Solutio
	Revenue
	Direct costs
	Healthcare Solutio
	Contribution
	Contribution Margin
	Research Solution
	Revenue
	Direct costs
	Research Solution
	Other and the
	Other operating co
	EBITDA*
	Depreciation and an
	Profit/(loss) before income
	Interest income
	Interest expense
	Other income (non- Net profit/(loss) be
))	
	* EBITDA does not inclu
	of this table.

	Half Year 31 Dec 20 US\$	Half Year 30 June 21 US\$	Full Year 2021 US\$	(Restated) Full Year 2020 US\$
Revenue from operations	13,856,762	18,829,634	32,686,396	22,771,196
Clinical Trials				
Revenue	12,577,589	16,090,118	28,667,707	21,075,922
Direct Cost (excluding direct depreciation)	(4,912,772)	(4,964,021)	(9,876,793)	(8,785,813)
Gross margin	7,664,817	11,126,097	18,790,914	12,290,109
SG&A	(1,504,218)	(1,832,682)	(3,336,900)	(3,449,861)
Clinical Trials Segment Contribution	6,160,599	9,293,415	15,454,014	8,840,248
Contribution Margin	49.0%	57.8%	53.9%	41.9%
Healthcare Solutions				
Revenue	1,149,883	2,608,907	3,758,790	1,435,498
Direct costs	(396,859)	(403,012)	(799,871)	(114,718)
Healthcare Solutions Segment Contribution	753,024	2,205,895	2,958,919	1,320,780
Contribution Margin	65.5%	84.6%	78.7%	92.0%
Research Solutions				
Revenue	129,290	130,609	259,899	259,776
Direct costs	(334,965)	(396,823)	(731,788)	(936,718)
Research Solutions Segment Contribution	(205,675)	(266,214)	(471,889)	(676,942)
Other operating costs	(5,995,936)	(6,233,371)	(12,229,307)	(10,374,526**)
EBITDA*	712,012	4,999,725	5,711,737	(890,440)
Depreciation and amortisation	(1,068,588)	(1,230,422)	(2,299,010)	(2,008,204)
Profit/(loss) before tax, interest and other income	(356,576)	3,769,303	3,412,727	(2,898,644)
Interest income	94	10,100	10,194	11,989
Interest expense Other income (non-operating)	(36,040)	(10,811) 2,444,200	(46,851) 2,444,200	(107,935)
Net profit/(loss) before tax	(392,522)	6,212,792	5,820,270	(2,994,590)

\* EBITDA does not include the \$2.4m contribution from PPP Loan forgiveness in FY21 and therefore is operating EBITDA for the purposes of this table.

# **Explanatory Notes**

- 1. **Sales contracts:** In the Clinical Trials division, Cogstate enters into contracts ("sales contracts") with both pharmaceutical and biotechnology companies for the provision of Cogstate technology and services, for use in clinical research trials, to determine the extent to which their investigational compound is impacting the cognition of the patient population. The contract value will differ for each clinical trial, depending upon the scope of the technology and services provided by Cogstate, as well as the complexity and length of the trial. An increase in the total value of sales contracts executed will increase the revenue backlog and will, over time, result in an increase to revenue recognised by Cogstate.
- 2. Calculation of revenue from Clinical Trials division: Revenue from sales contracts is recognised over the life of the contract. The length of a clinical trial can vary from several months for a phase 1 study and up to 4-5 years for a phase 3 study. Revenue is recognised based upon achievement of pre-determined milestones. During each period, revenue may be recognised from (i) contracts in the backlog at the beginning of the period, as well as (ii) sales contracts executed during the period. Usually there is a time lag between an increase or decrease in the level of sales contracts executed and a corresponding change to recognised revenue.
- Contracted future revenue backlog: Executed sales contract values that have not yet been recognised as revenue at period end are referred to as "contracted future revenue". The revenue from these contracts will be recognised upon achievement of predetermined milestones, in both Clinical Trials and Healthcare segments. The contracted future revenue figure provides insight into future revenue performance.
- 4. Paycheck Protection Program (PPP) Loan forgiveness: In May 2020, Cogstate Inc., a US domiciled, wholly owned subsidiary of Cogstate Ltd, 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. For further information, refer to the Cogstate ASX announcement on 15 June 2021.
- 5. **Healthcare revenue:** Cogstate has developed tools specifically designed to aid healthcare professionals, in general and specialist practice medicine, with objective assessments of cognition in patients. Cogstate's Healthcare offering includes the system branded as Cognigram<sup>™</sup>, a medical device which allows for regular and standardised testing to assist in the early detection of cognitive decline that could be related to a range of factors, including neurodegenerative diseases such as Alzheimer's disease. On 26 October 2020, Cogstate announced an exclusive global licensing agreement with pharmaceutical company Eisai (was previously just Japan), under which Eisai will market Cogstate technology as digital cognitive assessment tools targeting physicians, corporations, municipalities and also directly to consumers.

Due to the significance of the global licensing agreement, the group announced in its 1H21 results that it had reviewed the application of its accounting policy in respect of revenue 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 2019 in respect of a license for Japan and \$15m in Dec 2020 in respect of a global license - 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 **\$0.9m** reduction in Healthcare revenue in FY20 from a reported **\$2.3m** to a restated **\$1.4m**. This restatement has no impact on cash. See reconciliation table below.

	(Restated) FY20	Adjustment	(As Reported) FY20	
	US\$		US\$	
Healthcare Revenue	1.4	(0.9)	2.3	

Under the 10-year global (ex-Japan) agreement between Eisai and Cogstate executed on 26 October 2020:

- In addition to the upfront payments from Eisai of US\$15 million, Cogstate is also due to receive an ongoing royalty on revenue derived by Eisai from the sale of Cogstate technology. Over the course of the 10-year global agreement, the contractual terms prescribe that the royalty payments shall not be less than an additional \$30 million (\$10 million over years 1-5 and \$20 million over years 6-10).
- The full \$45m (upfront payment of \$15m plus the minimum royalties of \$30m due over the course of the global license agreement) is being amortised on a straight-line basis over 11 years (10-year term + 12 months to commence). Actual cash royalties paid in each period will be the higher of (i) royalty amount calculated based on sales of product or (ii) minimum annual royalty.

# FY21 Analysis:

Clinical Trials - a strong result with momentum building.

- Clinical Trials revenue in FY21 increased 36% on PCP to \$28.7m (FY20 \$21.1m), benefitting from the substantial increase in Clinical Trials sales contracts executed in recent periods, and the increased level of trial activity through the period.
- Contribution margin in FY21 increased to 54% (PCP 42%), benefitting from existing capacity within the business segment which allowed management to maintain tight cost control. Of the \$7.6m increase in Clinical Trials FY21 revenue, 87% flowed through to an increase in the segment earnings contribution.
- The value of sales contracts executed in FY21 totalled \$47.3m, up 15% on the \$41.3m achieved in FY20. For the first time, contracts executed in the second half of the financial year exceeded the result in the first half, with 2H21 up 9% on 1H21. New contracts executed included the first contract awarded via our partnership with ERT (the global leader in clinical endpoint data collection) and an increasing mix towards Alzheimer's disease, which accounted for 65% of new clinical trial sales contracts executed in FY21, compared to 60% in FY20. Sales contracts executed in FY21 were with both existing and new customers.
- Cogstate continues to win work across a number of different indications, with 33% of Clinical Trials revenue backlog as at 30 Jun 20 related to indications other than Alzheimer's disease.
- In 2020, Cogstate restated the contracted future revenue backlog to exclude third-party services (such as the cost of the eCOA technology solution provided by Clinical Ink) to better reflect future net revenue that Cogstate is expected to derive under existing contracts. During 2021, reported new contract signings have excluded third-party services, however, in the prior years, Cogstate reported contracts inclusive of third-party services. A reconciliation is provided below to allow comparison to the prior year results:

	1Q US\$	2Q US\$m	1H US\$m	3Q US\$m	4Q US\$m	2H US\$m	Full US\$m
2021							
Cogstate technology & services Third-party services	<b>8.3</b> 0.9	<b>14.3</b> 0.8	<b>22.6</b> 1.7	<b>13.3</b> 1.5	<b>11.4</b> 1.2	<b>24.7</b> 2.6	<b>47.3</b> 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

• As at 30 June 2021, Cogstate had record high Clinical Trials contracted revenue backlog of \$58.4m, with \$24.5m expected to be realised as revenue in FY22.

Future Backlog Revenue:

	-	FY21	FY20	VARIANCE FAV/(UNFAV)	
		US\$	US\$	US\$	%
	Contracted Clinical Trials Revenue	58,424,721	39,437,244	18,987,477	48.1
	Eisai Licence – Global (commercial years 1-10)	42,211,299	-	42,211,299	N/A
	Eisai Licence – Japan (10 year licence)	815,494	915,412	(99,918)	(10.9)
	Total Contracted Future Revenue	101,451,514	40,352,656	61,098,858	151.4

## Healthcare segment boosted by Eisai global partnership

- On 26 October 2020 Cogstate announced an exclusive global licensing agreement with pharmaceutical company Eisai Co., Ltd. (the previous agreement related to Japan only), under which Eisai will market Cogstate technology as digital cognitive assessment tools targeting physicians, corporations, municipalities and direct to consumers. Under the license, Eisai paid Cogstate a \$15m upfront license fee in 2Q21 (\$13.8m net of costs) and will pay royalties of at least \$10 million in years 1-5, and at least US\$20 million in years 6-10.
- Healthcare revenue in FY21 increased 162% on PCP to US\$3.8m (as previously noted, revenue in the prior period was restated down from \$2.3m to \$1.4m to reflect the change in revenue recognition policy), with approximately \$2.9m of revenue recognised in relation to Eisai royalty payments. This leaves \$42.2m to be realised over the remaining global licence period (global royalty revenue will be recognised on a straight-line basis over 11 years = 10 year term + 12 months to commence). The associated cash royalties received in each period will be the higher of (i) royalty amount calculated based on sales of product or (ii) the minimum annual royalty. Cogstate received an upfront cash payment of \$15m in 2Q21 (\$13.8m net of costs), leaving not less than \$30m to be paid by Eisai over the remaining term of the license.
- The earnings contribution from the segment increased 124% on PCP to \$3.0m, representing a contribution margin of 79%. The margin was lower than the 92% achieved in the PCP due to costs incurred in respect of the management of the Eisai relationship but remains significantly above levels seen in the prior years, following the decision made in 2018 to cease direct marketing of Cogstate technology in the Healthcare segment and the associated restructuring of the cost base in FY19.

## Profit before tax

- Higher group revenue combined with cost management saw the business transition to a positive PBT of \$5.8m in FY21. This was slightly above the guidance range provided in the company's July trading update of \$5.2-\$5.7m and compared to a loss -\$3.0m recorded in the PCP.
- Momentum in the business built over the course of the year, with a strong +\$6.2m PBT in 2H21 more than offsetting the -\$0.4m recorded in 1H21. As previously noted, these results included one-off adviser expenses of -\$0.5m in 1H21 and a one-off gain of +\$2.4m in 2H21 related to PPP loan forgiveness.<sup>1</sup> Removing the impact of these non-recurring items, PBT on an adjusted basis was +\$3.9m (+\$0.1m in 1H21 and +\$3.8m in 2H21).
- Staff costs increased 13% to \$20.8m reflecting (i) an increase in full-time equivalent (FTE) headcount from 158.6 in FY20 to 161.4 in FY21 and (ii) increases in staff bonus payments accrued at 30 June 2021, reflecting the improved financial results. During FY21 \$2.1m of software development costs were capitalised, compared to \$2.2m in FY20.
- Depreciation and amortisation expense increased from -\$2.0m in FY20 to -\$2.3m in FY21.
- Direct costs in Research reduced from -\$0.9m in FY20 to -\$0.7m in FY21.

<sup>&</sup>lt;sup>1</sup> See explanatory note 4 on page 5 of this release.

#### Net Profit after tax

- The Company reported a net profit after tax in FY21 of \$5.2m vs a loss of -\$2.0m in FY20.
- A tax expense of -\$0.6m was incurred in FY21 compared to a \$1.0m tax benefit in FY20.

#### Cash Flow/Balance Sheet

- The Company reported a positive Net Operating Cash Flow of \$16.1m in FY21 compared to an outflow of \$0.7m in PCP. Operating cash flow included:
  - The receipt of a net \$13.8m upfront royalty payment from Eisai for the Global licence in 2Q21, with \$15m gross proceeds partly offset by withholding tax levied in Japan (-\$0.75m) and direct advisory costs (-\$0.45m).
  - Payments of -\$0.7m associated with passthrough charges to Clinical Trial Clients. This represents a timing difference for Cogstate. In many contracts, Cogstate charges up front for passthrough costs that will be incurred in future periods. These cash inflows are fully offset by cash outflows as the expense in incurred.
- The FY21 result included recognition of approximately \$2.9m of revenue associated with the Eisai licencing agreement. There were no cash payments from the Eisai Global (ex Japan) partnership in the period, these will commence with the earlier of first commercial sale or 12mths (and will equate to a minimum of \$30m over the 10 commercial years of the agreement).
- Non-Government grant funds received in FY21 totalled \$0.6m (\$0.7m in PCP). The funds received relate to the Alzheimer's Drug Discovery Foundation for the development of a cognitive app.
- As at 30 June 2021, Cogstate had no debt and gross cash of \$23.6m, which included \$1.2m of cash held on behalf of customers for future passthrough payments. Excluding cash held for passthrough payments, Cogstate had a net cash balance of \$22.4m.

## FY22 Outlook:

The 10 year global license agreement secured with Eisai in FY21, followed by the FDA's accelerated approval of the first ever disease modifying Alzheimer's therapy has significantly enhanced the future commercial opportunities for Cogstate.

### **Clinical Trials Sales Contracts and Revenue Expectations**

The FDA approval of an Alzheimer's therapy in June 2021, as well as the breakthrough therapy designation the FDA granted for two other new potential treatments in development, is expected to result in an increase in momentum in the space. History has shown that approvals of the first drug in a new category reduce perceived R&D risk, resulting in increased investment while also encouraging innovation.

We are also excited about the opportunity that an increasing trend towards adoption of technology to facilitate remote (decentralised) clinical trials could represent for Cogstate technology in coming years. Cogstate digital cognitive assessments offer the ability for remote or unsupervised assessment, appropriate for use in decentralised clinical trials.

Clinical Trials revenue is a function of revenue from contracts secured in prior periods that have revenue milestones in the current financial year, as well as revenue recognised from new sales contracts executed throughout the current financial year. As 30 June 2021, Cogstate had \$58.4m of Clinical Trials revenue secured by customer contracts, which will be recognised in future periods as technology and services are provided by Cogstate in accordance with the contracts. Of that amount, \$24.5m is expected to be recognised in FY22, a record start to a full-year period. Over the last 5 years, excluding FY19 which included a number of trial cancellations, revenue backlog at the beginning of each year has ranged between 49% and 54% of final revenue for that year.

#### Healthcare Revenue

Digital brain assessments are expected to be a key plank of consumer and physician engagement as part of the launch of the first Alzheimer's disease therapies. Cogstate through its partnership with Eisai is uniquely positioned to provide highly scalable, scientifically proven digital tools required for early patient diagnosis and then the monitoring that will be part of ongoing patient management.

During FY22, Cogstate expect to see ongoing commercialisation activity with Eisai in Japan and pre-launch activity in the USA and Asia. Eisai have committed to launch within the USA inside 1 year, EU within 3 years and China within 4 years. The FY22 result will also see a full 12-month contribution from Eisai Global (ex Japan) Royalties (\$4.1m) compared to just 8 month's in FY21 (\$2.8m).

### **Earnings Expectations**

- Clinical Trials: revenue under contract at 1 July 2021 was \$24.5m. Sales contracts of \$35.4m have been executed since 01 July 2021, which is expected to add approximately \$6.0m of revenue to FY22 therefore taking the contracted FY22 Clinical Trials revenue to approximately \$30.5m.
- Historical guide: 2Q'21-4Q'21 saw \$38m of new contracts executed, adding approximately \$12m to FY21 revenue
- Expect FY21 Clinical Trials contribution margins to be consistent with FY21, allowing for investment in technology to support the shift to decentralised clinical trials.
- Healthcare: Contracted revenue of \$4.1m, producing a segment contribution in the range of \$2.5m \$3.0m
- Research: segment contribution consistent with FY21 result
- Operating expenses: as a percentage of operating revenue are expected to be in a range of 31-33%, an improvement of 5-7% points compared to FY21.
- 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 upfront royalty received as cash from Eisai in FY21 but revenue amortised over the 11-year life of the licence as well as capitalisation of software development at an amount consistent with FY21.

A further update will be provided at the company's AGM on Wednesday 27 October 2021.

### **Cogstate Investor Webcast**

Investors are invited to join Cogstate CEO, Brad O'Connor for a live webcast and Q&A presenting the annual financial results today, Wednesday 25 August 2021, at 11:00am Australian eastern standard time.

Investors can register via the following weblink to join the live event or receive the recording if unable to attend: https://bit.ly/3dji0CN

Additionally, a video recording of the presentation will be available later today at the Cogstate Investor Centre homepage: <u>https://www.cogstate.com/investors/</u>.

This announcement was authorised for release by 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 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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