

ASX Announcement

25 February 2021

1H21 Financial Results & Business Outlook (All figures in US\$)

Cogstate Ltd (ASX:CGS) has today released its Appendix 4D – half year report for the six months ended 31 December 2020 (1H21). A summary of the 1H21 result is provided below.

- **Group Revenue** increased 59% on pcp to \$13.9m in 1H21*.
- **Earnings:** PBT of -\$0.4m (pcp -\$3.9m) and NPAT of -\$0.4m (pcp -\$2.7m)*. The result included one-off adviser expenses of -\$0.5m (pre-tax) relating to the Global agreement with Eisai.
- **Clinical Trials - Strong result despite ongoing COVID disruptions.**
 - Clinical trials revenue was up 52% on pcp to \$12.6m, benefitting from the substantial increase in Clinical Sales contracts over the last 18 months.
 - Executed new sales contracts in 1H21 totalled \$22.6m, lower than a record \$26.9m in pcp, but a solid result in light of ongoing COVID disruptions in our key offshore markets.
 - Record high revenue backlog in Clinical trials of US\$49.7m as at 31 December 2021.
- **Healthcare - landmark partnership with Eisai**
 - Eisai will now exclusively distribute Cogstate technology globally (previously just Japan) as a digital tool to assess brain-health in Healthcare and other markets (excludes Clinical Trials).
 - Cogstate received an upfront licence fee from Eisai of \$15m in 2Q21 and will receive minimum Royalty payments of \$10m over the first 5yrs. A further \$20m minimum Royalty is payable over yrs 6-10yrs, subject to a termination right Eisai currently has after completion of yr5.
- **Cash Flow/Balance Sheet:** Net cash flow from operations of \$13.2m (pcp -\$1.2m). The Company had \$18.5m net cash as at 31 Dec 20 (calculated as gross cash less borrowings).
- **Contracted future revenue:** Following the execution of the global license agreement with Eisai, contracted future revenue has increased to \$74.8 million, up 96% on PCP (approx. \$12.2m to be recognised in 2H21)
- **FY21 outlook:** Targeting positive FY21 profit before tax. This assumes new and ongoing Clinical Trials revenue in 2H21 is not materially impacted by COVID.

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

	1H21 US\$	1H20* US\$	MOVEMENT US\$	%
Total revenue from ordinary activities	13,856,762	8,722,068	5,134,694	59
- Clinical Trials revenue	12,577,589	8,252,878	4,324,711	52
- Healthcare revenue	1,149,883	333,081	816,802	245
- Research revenue	129,290	136,109	(6,819)	(5)
EBITDA	712,012	(2,930,490)	3,642,502	124
Net Profit Before Tax	(392,522)	(3,867,688)	3,475,166	90
Net Profit After Tax	(448,085)	(2,739,942)	2,291,857	84
EPS	(0.003)	(0.018)	0.015	83
Net operating cash flow	13,216,098	(1,188,202)	14,404,300	1,212

* 1H20 numbers have been restated following a review of the application 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 (see explanatory notes and reconciliation table on p.4 of this release).

CEO commentary

Commenting on the result, Cogstate's CEO, Brad O'Connor, said: "Cogstate delivered a strong improvement on 1H20 with revenue benefitting from the significant increase in Clinical Trials sales contracts over the last 18 months and cashflow benefitting from an upfront licence fee payment associated with our now global partnership with Eisai Co. Ltd in the Healthcare segment."

"Clinical Sales contracts executed during 1H21 of \$22.6m, while down on the record \$26.9m in pcp, was nonetheless a solid outcome given the ongoing COVID related disruptions in our key offshore markets. Contracted sales in the Clinical Trials segment finished the period at a record \$49.7m."

"It was particularly pleasing to see the addition of new Clinical Trials customers during the period given the restrictions on client interactions. Cogstate was also named as preferred partner for ERT, the global leader in clinical endpoint data collection, which will see Cogstate's computerised cognitive assessments deployed in Clinical trials on ERT's technology platform, opening up additional sales opportunities"

"In our Healthcare segment, the expanded partnership with Eisai is a landmark step for Cogstate. We now have the opportunity to become the leading provider of digital cognition testing solutions around the world. This takes us a step closer towards realising our founding vision of developing an assessment of brain health as simple, common and informative as assessment of blood pressure."

"In collaboration with Eisai, we expect Cogstate cognition testing solutions to be marketed as a digital tool to facilitate early detection of memory impairment. This includes:

- the development of mobile phone and computer-based applications for home based self-assessments;
- tools to help facilitate annual health checks for memory impairment at GP's offices;
- tools to help specialists identify likely candidates for therapeutic treatments should one become available;
- tools for monitoring the response to therapy.

"As an industry, we have never been closer to a disease modifying therapy than we are now with a number of potentially disease modifying treatments for Alzheimer's disease in phase II and phase III studies, and one treatment in front of the FDA. Cogstate through its partnership with Eisai is uniquely positioned to provide highly scalable, scientifically proven digital tools required to identify the earliest signs of memory impairment, should a therapy be approved by regulators. Even without a pharmaceutical treatment, there is growing evidence and awareness of the benefits of early diagnosis including lifestyle changes, such as exercise and diet, which can have a meaningful impact on brain health. Early detection is also critical for meaningful intervention around care planning and symptomatic treatments."

1H21 Segment Reporting

	(Restated) Half Year 31 Dec 2019 US\$	Half Year 31 Dec 2020 US\$	(Restated) Full Year 2020 US\$	Full Year 2019 US\$
Revenue from operations	8,722,068	13,856,762	22,771,196	21,834,374
Clinical Trials				
Revenue	8,252,878	12,577,589	21,075,922	21,353,341
Direct Cost (excluding direct depreciation)	(4,225,837)	(4,912,772)	(8,785,813)	(8,566,199)
Gross margin	4,027,041	7,664,817	12,290,109	12,787,142
SG&A	(1,701,032)	(1,504,218)	(3,449,862)	(3,097,228)
Clinical Trials Segment Contribution	2,326,009	6,160,599	8,840,248	9,689,914
Contribution Margin	28.2%	49.0%	41.9%	45.4%
Healthcare Solutions				
Revenue	333,081	1,149,883	1,435,498	296,384
Direct costs	(69,482)	(396,859)	(114,718)	(1,106,276)
Healthcare Solutions Segment Contribution	263,599	753,024	1,320,780	(809,892)
Contribution Margin	79.1%	65.5%	92.0%	(373.3%)
Research Solutions				
Revenue	136,109	129,290	259,776	184,649
Direct costs	(466,193)	(334,965)	(936,718)	(822,860)
Research Solutions Segment Contribution	(330,084)	(205,675)	(676,942)	(638,211)
Other operating costs	(5,190,014)	(5,995,936)	(10,374,525)	(11,586,775)
EBITDA	(2,930,490)	712,012	(890,440)	(3,344,964)
Depreciation and amortisation	(899,562)	(1,068,588)	(2,008,204)	(495,439)
Profit/(loss) before tax, interest and other income	(3,830,052)	(356,576)	(2,898,644)	(3,840,403)
Interest income	11,862	94	11,989	19,574
Interest expense	(49,498)	(36,040)	(107,935)	(29,890)
Net profit/(loss) before tax	(3,867,688)	(392,522)	(2,994,590)	(3,850,719)

Commentary in respect of FY20 results:

Revised revenue recognition policy and associated adjustment to prior corresponding period

Due to the significance of the global licensing agreement, the group has 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. This has resulted in a change to the application of the previous policy.

In the prior period, the group recognised all of the \$1 million upfront payment, received from Eisai, as revenue upon granting of the licences for the Japan region. The group considers that recognising the upfront payment as revenue on a straight-line basis over the licence period better reflects its performance in providing access to the licence, 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 revenue figures. This resulted in a \$0.97m reduction in Healthcare revenue in 1H20 from a reported \$1.30m to a restated \$0.33m. As a result of this restatement, the Healthcare pre-tax earnings contribution also reduced by \$0.97m from a reported \$1.23m to a restated \$0.26m. This restatement has no impact on cash. See reconciliation table below.

	Restated 1H20	Adjustment	As Reported 1H20
	US\$		US\$
Healthcare Revenue	333,081	(965,234)	1,298,315
Healthcare Direct Costs	(69,482)	-	(69,482)
Healthcare Contribution	263,599	(965,234)	1,228,833

1H21 Analysis:

Solid clinical trials result despite COVID disruptions.

- Clinical Trials revenue in 1H21 increased 52% on pcp to \$12.6m (1Q21 \$5.8m, 2Q21 \$6.8m), benefitting from the substantial increase in Clinical Trials sales contracts booked in the last 18mths.
- Contribution margin in 1H21 increased to 49% (pcp 28%) benefitting from cost management and a strong period on period improvement in contract delivery performance
- New contract signings in 1H21 totalled \$22.6m (1Q21 \$8.3m, 2Q21 \$14.3m). While this was lower than the record \$26.9m in pcp (1Q20 \$7.7m, 2Q20 \$19.2m), it was nonetheless a solid outcome given the COVID disruptions in Cogstate's key offshore markets. The prior period included the execution of a large phase III trial with a total value in excess of US\$13m, whereas the largest contract executed in 1H21 was \$4.8m. New sales contracts executed in 1H21 were with both existing customers and new customers.
- In July 2020, ERT, the global leader in clinical endpoint data collection, announced a preferred partnership with Cogstate. This will see Cogstate's computerised cognitive assessments deployed in Clinical trials on ERT's electronic Clinical Outcome Assessment (eCOA) technology platform. Whilst Cogstate has not yet signed any contracts via this joint offering, the Company remains well placed to leverage this preferred partnership.
- As at 31 Dec 20, Cogstate had record high Clinical Trials contracted revenue backlog of \$49.7m, with \$10.1m expected to be realised as revenue in 2H21.

Future Backlog Revenue:

	1H21	1H20	VARIANCE FAV/(UNFAV)	
	US\$	US\$	US\$	%
Contracted Clinical Trials Revenue	49,668,291	37,170,604	12,497,687	34
Eisai Licence – Global (commercial years 1-5)*	24,224,099	-	24,224,099	N/A
Eisai Licence – Japan (10-year licence)	865,042	965,234	(100,192)	(10)
Total Contracted Future Revenue	74,757,432	38,135,838	36,621,594	96

- Cogstate continues to win work across a number of different indications, with 37% of Clinical Trials revenue backlog as at 31 Dec 20 related to indications other than Alzheimer's disease.

Healthcare segment boosted by Eisai partnership

- On 26 October Cogstate announced an exclusive global licensing agreement with pharmaceutical company Eisai (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 US\$15m upfront license fee in 2Q21 and will pay royalties of at least US\$10 million in years 1-5, and at least US\$20 million in years 6-10. Eisai currently has the option to terminate the agreement after completion of year 5 under specific conditions.
- Healthcare revenue in 1H21 increased 245% on pcp to US\$1.1m (as previously noted, revenue in the prior period was restated down from \$1.3m to \$0.3m to reflect the change in revenue recognition policy). During 1H21, \$0.8m of revenue was recognised in relation to Eisai Global (ex Japan) Royalty payments, leaving \$24.2m to be realised over the remainder of the 6-year initial term.
- A very low cost base for the Healthcare segment, resulting from the restructure of operations undertaken in FY19, provided for the \$0.8m positive Healthcare segment contribution in 1H21 (\$0.3m in pcp), representing a margin of 65.5%.

Profit before tax

- Cogstate reported a loss before tax in 1H21 of -\$0.4m vs a loss of -\$3.9m in 1H20.
- Staff costs increased 8% to -\$11.4m reflecting an increase in full-time equivalent (FTE) headcount from 158.1 in 1H20 to 163.8 as at 1H21.
- Depreciation and amortisation expense increased from -\$0.9m in 1H20 to -\$1.1m in 2H20 due to amortisation of a new database platform.
- Direct costs in Research reduced from -\$0.5m in 1H20 to -\$0.3m in 1H21.
- The result also included -\$0.5m one-off Advisor fees relating to the Eisai Global agreement.

Net Profit after tax

- The Company reported a net loss after tax in 1H21 of -\$0.4m vs a loss of -\$2.7m in 1H20.
- A tax expense of -\$0.06m was incurred in 1H21 compared to a \$1.13m tax benefit in 1H20.

Cash Flow/Balance Sheet

- The Company reported a positive Net Operating Cash Flow of \$13.2m in 1H21 compared to an outflow of -\$1.2m in pcp. Operating cash benefited during the period from the upfront Royalty payment from Eisai. Net proceeds from this payment totalled \$13.8m after accounting for withholding tax levied in Japan of 5% and direct advisory costs.
- As at 31 December 2020, Cogstate had gross cash of \$21.3m and borrowings of \$2.9m, resulting in a net cash position of \$18.5m pre lease liabilities (or \$16.4m after lease liabilities).

FY21 Outlook:

Clinical Trials Sales Contracts and Revenue Expectations

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 at 31 December 2021, Cogstate had \$49.7m 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, over \$10.1m is expected to be recognised in 2H21, a record start to any half-year period.

However, the full impact of COVID on Cogstate's business operations and revenue remains unclear. Cogstate's ability to secure new Clinical Trials contracts and realise revenue from existing Clinical Trials contracts will be somewhat dependent upon the ongoing impact of COVID, particularly in Cogstate's key offshore markets.

Healthcare Revenue

During 2H21 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 2H21 result will also see a full 6 month contribution from Eisai Global (ex Japan) Royalties (\$2.06m) compared to just 2 months' in 1H21 (\$0.78m).

Earnings Expectations

The ongoing COVID pandemic creates a higher degree of uncertainty, particularly in respect to Clinical Trials revenue and therefore 2H21 earnings.

Based on the assumption that the COVID pandemic does not materially impact the initiation of new clinical trials or the conduct of ongoing clinical trials over the balance of 2H21, the Company is targeting positive profit before tax for FY21.

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, Thursday 25 February 2021, at 10:30am Australian eastern daylight savings 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: <https://www.cogstate.com/investors/>.

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 www.cogstate.com.

For further information contact:

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