

# ASX Announcement

30 August 2022

## FY22 Financial Results & Business Outlook

All figures in US\$

Reporting Period: 30 June 2022. Prior Corresponding Period (PCP): 30 June 2021

Cogstate Ltd (ASX:CGS) has today released its Appendix 4E and Annual Report to Shareholders for the year ended 30 June 2022 (FY22). A summary of the FY22 result is provided below.

- **Record Group Revenue** of \$45.0m, up 38% on PCP.
- **Record Group Earnings:** Profit Before Tax (PBT) of \$10.7m (vs. *guidance of \$10.3m - \$10.8m and PCP - \$5.8m*) and Net Profit After Tax (NPAT) of \$7.5m (*PCP \$5.2m*)\*.
- **Clinical Trials - Another record-breaking year**
  - Clinical Trials sales contracts executed in FY22 was up 74% on PCP to a record of \$82.5m.
  - Clinical Trials revenue was up 41% on PCP to a record \$40.3m, benefitting from the substantial increase in Clinical Sales contracts executed during both FY22 and FY21.
  - At 30 June 2022, Clinical Trials contracted future revenue was US\$100.2m, with \$29.7m of contracted Clinical Trials revenue expected to be recognised in FY23.
- **Healthcare**
  - Revenue for the Healthcare segment increased by 19% compared to the prior year, reflecting the first full year under the Eisai global agreement.
  - At 30 June 2022, contracted future revenue for the Healthcare segment was US\$38.8m, with \$4.2m of contracted revenue expected to be recognised in FY23.
- **Strong Cash Flow/Balance Sheet:** Net cash in-flow from operations of \$9.7m during FY22 (PCP \$16.1m, including an upfront \$15m payment from Eisai) and a net cash balance at 30 Jun 2022 of \$28.7m (gross cash less cash received in advance for future pass-through costs).
- **Record high contracted future revenue:** Future contracted future revenue increased to \$139.1 million, up 37% on PCP (\$33.9m expected to be recognised in FY23).
- **FY23 outlook**
  - \$16.6m Clinical Trials contracts executed in the 2 months since 01 July 2022
  - Clinical Trials revenue
    - 1H23 expected to be consistent with 2H22
    - 2H23 will vary with level of sales contracts and therefore unable to be accurately forecast at this time
  - Healthcare revenue and segment contribution expected to be consistent with FY22
  - EBITDA targeted to be in the range of 27% - 29% of revenue
  - EBIT, based on current revenue forecast, expected to be at the bottom end of the target range of 20% - 24% of revenue
  - operating cashflow approximately 75% of EBITDA

**Summary of FY22 Results** (All figures are stated in US\$)

	30 June 2022 US\$	30 June 2021 US\$	MOVEMENT	
			US\$	%
Total revenue from ordinary activities	44,980,356	32,686,396	12,293,960	37.6
- Clinical Trials revenue	40,328,147	28,667,707	11,660,440	40.7
- Healthcare revenue	4,456,700	3,758,790	697,910	18.6
- Research revenue	195,509	259,899	(64,390)	(24.8)
EBITDA**	13,009,201	5,711,737	7,297,464	127.8
Profit Before Tax**	10,692,600	5,820,270	4,872,330	83.7
Underlying Profit Before Tax**	10,692,600	3,880,270	6,812,330	175.6
Net Profit After Tax**	7,519,734	5,233,283	2,286,451	43.7
EPS**	0.044	0.031	0.013	41.9
Net operating cash flow***	9,726,133	16,114,410	(6,388,277)	(39.6)

\* PCP 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 fees associated with the Eisai global agreement.

\*\*\* FY21 includes upfront royalty receipt from Eisai Co., Ltd (\$15m).

## CEO Commentary

Commenting on the result, Cogstate's CEO, Brad O'Connor, said: "FY22 was a year of continued momentum for Cogstate. The company delivered record sales, record earnings and strong operating cash flow, has a record level future contracted revenue backlog of \$139.1m, and a net cash balance of \$28.7m."

"A record performance in Clinical Trials new contract sales of \$82.5m has laid the foundation for a strong financial performance for the year, with revenue growing to \$45m, up 38% on FY21. This, combined with continuing improvement in productivity across the business has resulted in a profit before tax result at the top end of the guidance provided in our July business update."

Mr O'Connor continued, "The year included several key milestones:

- The formation of a Scientific Advisory Board which comprises world-class neuroscience experts in cognitive assessment and drug development. This Board has begun working with our scientific leadership team to support the advancement of the Cogstate strategy, innovation roadmaps and research & development activities.
- The expansion of our partnership with clinical trial data management leader, Clario, to enhance our joint support of Central Nervous System research. This collaboration expands our previously announced partnership to deliver Cogstate's digital cognitive assessments together with Clario's platform for a streamlined customer experience.
- Expansion of Cogstate technology to consumers across the Asia region through our partnership with Eisai Co, Ltd. This includes launches in Taiwan and Hong Kong, and in Japan, the inclusion of Cogstate technology was offered as a pre-installed application on the Raku-Raku smartphone, a model marketed to the senior population in Japan that has shipped more than 7 million units.
- Expanded involvement with major industry initiatives and consortia including participation in the Davos Alzheimer's Collaborative, joining the Digital Medicine Society's Alzheimer's Disease and Related Dementia's Digital Measures Development Project and also joining the Decentralized Trials & Research Alliance which focuses on the acceleration and adoption of patient-focused, decentralized clinical trials.

These developments continue to enhance 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."

## FY22 Segment Reporting

	Half Year 31 Dec 21 US\$	Half Year 30 June 22 US\$	Full Year 2022 US\$	Full Year 2021 US\$
<b>Revenue from operations</b>	23,075,459	21,904,897	44,980,356	32,686,396
<b>Clinical Trials</b>				
Revenue	20,846,863	19,481,284	40,328,147	28,667,707
Direct Cost (excluding direct depreciation)	(6,359,442)	(6,699,967)	(13,059,409)	(9,876,793)
<b>Gross margin</b>	<b>14,487,421</b>	<b>12,781,317</b>	<b>27,268,738</b>	<b>18,790,914</b>
SG&A	(1,556,337)	(1,587,182)	(3,143,519)	(3,336,900)
<b>Clinical Trials Contribution</b>	<b>12,931,084</b>	<b>11,194,135</b>	<b>24,125,219</b>	<b>15,454,014</b>
Contribution Margin	62%	57%	60%	54%
<b>Healthcare</b>				
Revenue	2,215,228	2,241,472	4,456,700	3,758,790
Direct costs	(447,852)	(766,414)	(1,214,266)	(799,871)
<b>Healthcare Contribution</b>	<b>1,767,376</b>	<b>1,475,058</b>	<b>3,242,434</b>	<b>2,958,919</b>
Contribution Margin	80%	66%	73%	79%
<b>Research</b>				
Revenue	13,368	182,141	195,509	259,899
Direct costs	(424,934)	(458,536)	(883,470)	(731,788)
<b>Research Contribution</b>	<b>(411,566)</b>	<b>(276,395)</b>	<b>(687,961)</b>	<b>(471,889)</b>
<b>Other operating costs</b>	<b>(7,033,852)</b>	<b>(6,636,639)</b>	<b>(13,670,491)</b>	<b>(12,229,307)</b>
<b>EBITDA*</b>	<b>7,253,042</b>	<b>5,756,159</b>	<b>13,009,201</b>	<b>5,711,737</b>
Depreciation and amortisation	(1,126,549)	(1,197,626)	(2,324,175)	(2,299,010)
<b>Profit before tax, interest and other income</b>	<b>6,126,493</b>	<b>4,558,533</b>	<b>10,685,026</b>	<b>3,412,727</b>
Net interest	(10,929)	18,503	7,574	(36,657)
Other income (non-operating)	-	-	-	2,444,200
<b>Net profit before tax</b>	<b>6,115,564</b>	<b>4,577,036</b>	<b>10,692,600</b>	<b>5,820,270</b>

\* 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.
3. **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 pre-determined milestones throughout the clinical trials. The contracted future revenue figure provides insight into future revenue performance.
4. **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™, 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.

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 cash royalty, which ramp up over the contract period.

## FY22 Analysis:

### Clinical Trials - a strong result with momentum building.

- Clinical Trials revenue in FY22 increased 40.7% on PCP to \$40.3m (FY21 \$28.7m), benefitting from the substantial increase in Clinical Trials sales contracts executed in recent periods.
- Contribution margin in FY22 increased to 60% (PCP 54%), benefitting from a strong SW license revenue mix as well as continuing productivity improvements within the business segment and maintaining cost control. Of the \$11.7m increase in Clinical Trials FY22 revenue, 74% flowed through to an increase in the segment earnings contribution.
- The value of sales contracts executed in FY22 totalled \$82.5m, up 74% on the \$47.3m achieved in FY21. Sales contracts executed in FY22 were with both existing and new customers, and included sales through our partnership with Clario.
- Cogstate continues to win work across a number of different indications, with 18% of Clinical Trials revenue backlog as at 30 June 2022 related to indications other than Alzheimer's disease.
- As at 30 June 2022, Cogstate had recorded Clinical Trials contracted revenue backlog of \$100.2m, with \$29.7m expected to be realised as revenue in FY23.

### Future Backlog Revenue:

The revenue backlog for both the Clinical Trials and Healthcare segments are highlighted in the table below.

	FY22	FY21	VARIANCE FAV/(UNFAV)	
	US\$	US\$	US\$	%
Contracted Clinical Trials Revenue	100,242,981	58,424,721	41,818,260	71.6
Eisai Licence – Global (commercial years 1-10)	38,123,444	42,211,299	(4,087,855)	(9.7)
Eisai Licence – Japan (10 year licence)	715,576	815,494	(99,918)	(12.3)
<b>Total Contracted Future Revenue</b>	<b>139,082,001</b>	<b>101,451,514</b>	<b>37,630,487</b>	<b>37.1</b>

### 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 FY22 increased 18.6% on PCP (\$3.8m) to \$4.5m, with approximately \$4.2m of revenue recognised in relation to Eisai royalty payments. This leaves \$38.8m to be realised over the remaining Japan and global licence periods (global royalty revenue will be recognised on a straight-line basis over 11 years = 10 year term + 12 months to commence). With respect to the global licensing agreement, 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 9.6% on PCP to \$3.2m, representing a contribution margin of 73%. The margin was lower than the 79% achieved in the PCP due to costs incurred in respect of further investments made and the management of the Eisai relationship.

## Profit before tax

- Group revenue growth combined with improved productivity and cost management saw the business achieve a consecutive positive PBT of \$10.7m in FY22. This was at the upper end of the guidance range provided in the company's July trading update of \$10.3-\$10.8m and compared to a PBT \$5.8m recorded in the PCP.
- Staff costs increased 17% to \$24.4m reflecting (i) an increase in full-time equivalent (FTE) headcount from 161.4 in FY21 to 191.1 in FY22 and (ii) increases in staff bonus payments accrued at 30 June 2022, reflecting the improved financial results. During FY22 \$2.0m of software development costs were capitalised and \$0.6m product development costs were reimbursed (FY21 \$2.1m).
- Depreciation and amortisation expense of \$2.3m in FY22, consistent with PCP (\$2.3m).

## Net Profit after tax

- The Company reported a net profit after tax in FY22 of \$7.5m vs \$5.2m in FY21.
- A tax expense of \$3.2m was incurred in FY22 compared to a tax expense of \$0.6m in FY21.

## Cash Flow/Balance Sheet

- The Company reported a positive Net Operating Cash Flow of \$9.7m in FY22 compared to PCP \$16.1m. Operating cash flow included:
  - Cash receipts from customers totalled \$40.6m for FY22, down \$2.1m from FY21.
  - Net receipts of \$0.7m associated with pass-through charges to Clinical Trial Clients. This represents a timing difference for Cogstate. In many contracts, Cogstate charges up front for pass-through costs that will be incurred in future periods. These cash inflows are fully offset by cash outflows as the expense is incurred.
- The FY22 result included recognition of approximately \$4.2m of revenue associated with the Eisai licencing agreements; Global and Japan. Cogstate has commenced invoicing Eisai for minimum quarterly royalty payments under the Global Agreement (excl. Japan) in 2Q22. Such invoices will be issued quarterly for the 10-year life of the license agreement.
- As at 30 June 2022, Cogstate had gross cash of \$30.6m, which included \$1.9m of cash held on behalf of customers for future pass-through payments. Excluding cash held for pass-through payments, Cogstate had a net cash balance of \$28.7m.

## FY23 Outlook

Over the last two years, an increase in Alzheimer's disease research and development as well as the move to more at-home and virtual assessment, has positively impacted on Cogstate's business. In addition, Cogstate has had recent success in growing Clinical Trials sales through channel partnerships, such as the recently announced partnership with Clario. We expect that these trends will continue.

External catalysts for Cogstate's business over the next 12 months include important phase 3 data from key Alzheimer's trials. Specifically, phase 3 data is expected from Eisai Co. Ltd at the end of September 2022 and Eli Lilly & Co in mid-2023 calendar year. We expect that the release of this data could impact short term sales opportunities in our Clinical Trials business, either positively or negatively, depending on the trial results.

Similarly, the phase 3 data from those key Alzheimer's trials is expected to impact our Healthcare business. Cogstate has consistently stated that the upside revenue opportunity for the Healthcare business, beyond the contracted minimum payments from Eisai, is expected to be dependent upon the release, reimbursement, and availability of proven Alzheimer's therapeutics.

In respect of Clinical Trials sales contracts, Cogstate has started the FY23 year with \$16.6 million of sales contracts executed since 1 July 2022 (up from \$8.8m in the most recent Jun-22 quarter, but still substantially less than the \$40.8m executed in the Sep-21 quarter).

FY23 Clinical Trials revenue will be a function of both the contracted revenue expected to be recognised in FY23 and revenue yield from contracts executed during the financial year. FY23 contracted revenue at 1 July 2022 was \$29.7 million (PCP \$24.5m). As noted previously, contracted revenue at 1 July 2022 has been impacted by studies on hold pending FDA reviews and slower than expected enrolments into a key Alzheimer's study, which total approximately \$4m. Resolution of these challenges would yield incremental revenue in FY23.

Based on our current forecasts, Clinical Trials revenue for 1H23 (half year ending 31 December 2022) is expected to be consistent with the 2H22 result (2H22 \$19.5m), which was a decrease from the 1H22 Clinical Trials revenue of \$20.8m. Clinical Trials revenue for 2H23 will be more reliant on sales contracts executed during FY23 (and particularly those executed in 1H23) and, at this time, we cannot accurately forecast that result.

Healthcare revenue and segment contribution for FY23 is expected to be consistent with the FY22 result.

In respect of forecast earnings, Cogstate continues to target EBIT margins in the range of 20% - 24% over the coming years. Based on current revenue forecast, FY23 EBIT margins are expected to be at the bottom end of that range. Target EBITDA range is 27% - 29% of revenue.

Cogstate is expected to be cashflow positive, with operating cashflow expected to be approximately 75% 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 FY22.

A further update will be provided at the company's AGM on Friday 4 November 2022.

### **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, Tuesday 30 August 2022, 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: <https://www.cogstate.com/investors/>.

This announcement was authorised for release by the Board of Directors of Cogstate Ltd.



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**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](http://nouknow.jp)). For more information, please visit [www.cogstate.com](http://www.cogstate.com).

**For further information contact:**

Brad O'Connor, Chief Executive Officer, [boconnor@cogstate.com](mailto:boconnor@cogstate.com)