

ASX Announcement

22 August 2023

FY23 Financial Results & Business Outlook

All figures in US\$

Reporting Period: 30 June 2023. Prior Corresponding Period (PCP): 30 June 2022

Cogstate Ltd (ASX:CGS) has today released its Appendix 4E and Annual Report to Shareholders for the year ended 30 June 2023 (FY23). A summary of the FY23 result is provided below.

- **Group Revenue** of \$40.5m, down 10% on PCP (*vs. guidance of \$39m - \$41m*).
- **Group Earnings:** Profit Before Tax (PBT) before non-recurring restructuring costs of \$3.5m and PBT including non-recurring restructuring costs of \$3.0m (*vs. guidance of \$0.6m - \$1.6m and PCP \$10.7m*). Net Profit After Tax (NPAT) of \$3.6m (*PCP \$7.5m*).
- **Clinical Trials – Impacted by trial delays and low second half new contract sales.**
 - Clinical Trials sales contracts executed in FY23 was \$34.0m, down 59% on PCP (\$82.5m)
 - o 1H23 \$27.3m : 2H23 \$6.7m
 - Clinical Trials revenue was down 11% on PCP to \$35.7m, due to delays associated with specific issues for a small number of clinical trials as well as lower Clinical Trials Sales contracts executed during 2H23.
 - At 30 June 2023, Clinical Trials contracted future revenue was US\$98.0m, with \$27.7m of contracted Clinical Trials revenue expected to be recognised in FY24 (PCP: \$29.7m).
- **Healthcare**
 - Revenue for the Healthcare segment, primarily reflecting the recognition of the Eisai agreements, decreased by 1% compared to the prior year.
 - At 30 June 2023, contracted future revenue for the Healthcare segment was US\$34.7m, with \$4.2m of contracted revenue expected to be recognised in FY24.
- **Cash Flow/Balance Sheet:** Net cash in-flow from operations of \$1.7m during FY23, compared to PCP of \$9.0m (excluding movement in net pass-through expenses). Net cash balance at 30 June 2023 of \$27.8m (gross cash less cash received in advance for future pass-through costs).
- **Contracted future revenue:** Future contracted future revenue of \$132.6 million, down 5% on PCP (\$31.9m expected to be recognised in FY24).
- **FY24 outlook:** With a growing addressable market, a well-validated offering, strong commercial partnerships with the relevant drug developers, and a strong balance sheet, Cogstate is well positioned to return to growth quickly.

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Summary of FY23 Results (All figures are stated in US\$)

	30 June 2023 US\$	30 June 2022 US\$	MOVEMENT	
			US\$	%
Total revenue from ordinary activities	40,451,123	44,980,356	(4,549,233)	(10)
- Clinical Trials revenue	35,729,909	40,328,147	(4,598,238)	(11)
- Healthcare revenue	4,400,970	4,456,700	(55,730)	(1)
- Research revenue	320,244	195,509	124,735	64
EBITDA	5,291,797	13,009,201	(7,717,404)	(59)
Profit Before Tax before non-recurring restructuring charge	3,515,226	10,692,600	(7,177,374)	(67)
Restructuring Charge	(490,520)	-	(490,520)	n/a
Profit Before Tax before non-recurring restructuring charge	3,025,111	10,692,600	(7,667,489)	(72)
Net Profit After Tax	3,567,733	7,519,734	(3,952,001)	(53)
EPS	0.021	0.044	(0.023)	(52)
Net operating cash flow	654,129	9,726,133	(9,072,004)	(93)

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FY23 Segment Reporting

Proforma segment report excluding non-recurring costs

	Half Year 31 Dec 22 US\$	Half Year 30 June 23 US\$	Full Year 2023 US\$	Full Year 2022 US\$
Revenue from operations	19,544,710	20,906,413	40,451,123	44,980,356
Clinical Trials				
Revenue	17,134,599	18,595,310	35,729,909	40,328,147
Direct Cost (excluding direct depreciation)	(7,130,854)	(6,591,218)	(13,722,072)	(13,059,409)
Gross margin	10,003,745	12,004,092	22,007,837	27,268,738
SG&A	(2,040,724)	(1,423,313)	(3,464,037)	(3,143,519)
Clinical Trials Contribution	7,963,021	10,580,779	18,543,800	24,125,219
Contribution Margin	46%	57%	52%	60%
Healthcare				
Revenue	2,218,651	2,182,319	4,400,970	4,456,700
Direct costs	(886,330)	(367,729)	(1,254,059)	(1,214,266)
Healthcare Contribution	1,332,321	1,814,590	3,146,911	3,242,434
Contribution Margin	60%	83%	72%	73%
Research				
Revenue	191,460	128,784	320,244	195,509
Direct costs	(397,840)	(386,079)	(783,919)	(833,470)
Research Contribution	(206,380)	(257,295)	(463,675)	(687,961)
Other operating costs	(8,052,962)	(7,882,277)	(15,935,239)	(13,670,491)
EBITDA*	1,036,000	4,255,797	5,291,797	13,009,201
Depreciation and amortisation	(1,271,183)	(1,323,759)	(2,594,942)	(2,324,175)
Profit before tax, interest and other income	(235,183)	2,932,038	2,696,855	10,685,026
Net interest	235,588	430,452	666,040	7,574
Other Income	-	152,736	152,736	-
Net profit before tax	405	3,515,226	3,515,631	10,692,600
Non-recurring Restructuring Charges	-	(490,520)	(490,520)	-
Net profit before tax	405	3,024,706	3,025,111	10,692,600

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Explanatory Notes

- 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.
- 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 pre-determined milestones throughout the clinical trials. The contracted future revenue figure provides insight into future revenue performance.
- 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.

FY23 Analysis

Clinical Trials

- Clinical Trials revenue in FY23 decreased 11% on PCP to \$35.7m (FY22 \$40.3m), impacted by revenue delays on specific trials, and low second half new contract sales.
- Contribution margin in FY23 decreased to 52% (PCP 60%), impacted by the revenue delays, with resource levels maintained before a reduction in staff numbers via a restructure in May 2023.
- The value of sales contracts executed in FY23 was \$34m, down 59% on the \$82.5m achieved in FY22. Sales contracts in 2H23 were impacted by large customers focused on completion of phase 3 trials, regulatory submissions for drug approvals, and access to capital for biotechs.
- Cogstate continues to win work across a number of different indications but Alzheimer's disease and associated dementias represent the bulk of revenue backlog -14% of Clinical Trials revenue backlog as at 30 June 2023 related to indications other than Alzheimer's disease.
- As at 30 June 2023, Cogstate had Clinical Trials contracted revenue backlog of \$98.0m, with \$27.7m expected to be realised as revenue in FY24 (PCP \$29.7m).

Healthcare

- Healthcare revenue, primarily representing revenue recognised in relation to Eisai royalty payments, decreased in FY23 by 1% on PCP (\$4.5m) to \$4.4m.
- The earnings contribution declined 3% on PCP to \$3.1m, representing a contribution margin of 72%, the decline in margin resulting from activities undertaken to assess the go-to-market opportunities for the Healthcare market.

Future Revenue Backlog

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

	FY23	FY22	VARIANCE FAV/(UNFAV)	
	US\$	US\$	US\$	%
Contracted Clinical Trials Revenue	97,951,714	100,242,981	(2,291,267)	(2)
Eisai Licence – Global (commercial years 1-10)	34,035,590	38,123,444	(4,087,854)	(11)
Eisai Licence – Japan (10 year licence)	615,658	715,576	(99,918)	(14)
Total Contracted Future Revenue	132,602,962	139,082,001	(6,479,039)	(5)

Profit Before Tax

- Revenue decline in the Clinical Trials segment, combined with the mostly fixed nature of costs, resulted in a decline in PBT, before non-recurring restructuring charges, to \$3.5m, compared to PCP of \$10.7m. The half to half comparison shows much improved financial performance in 2H23.
- Staff costs increased 7% to \$26.1m, with staff levels maintained before a reduction in staff numbers via a restructure in May 2023. Full time equivalent staff numbers reduced to 162.3 at 30 June 2023, down from 191.1 at 30 June 2022. During FY23 \$0.9m of software development costs were capitalised and \$0.2m product development costs were reimbursed (FY22 \$2.6m).
- Depreciation and amortisation expense of \$2.5m in FY23, a 12% increase on PCP (\$2.3m), reflecting the ongoing investment in Cogstate technology.

Net Profit after tax

- The Company reported a net profit after tax in FY23 of \$3.6m compared to PCP of \$7.5m.
- A tax benefit of \$0.5m was recognised in FY23 compared to a tax expense of \$3.2m in FY22.

Cash Flow/Balance Sheet

- The Company reported a positive Net Operating Cash Flow of \$1.7m in FY23 (excluding pass-through expenses), a decrease from the \$9.0m reported in FY22. Operating cash flow included:
 - Cash receipts from customers totalled \$39.6m for FY23, down \$1.1m from FY22.
 - Payment of FY22 employee bonuses, higher employee costs (up 7% year to year) and restructuring costs of \$0.5m.
 - Net cash outflow of \$1.0m associated with timing of pass-through charges to Clinical Trial Clients. 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 FY23 result included recognition of approximately \$4.2m of revenue associated with the Eisai licencing agreements; Global and Japan. Cogstate has been invoicing Eisai for minimum quarterly royalty payments under the Global Agreement (excl. Japan) since the second quarter of financial year 2022. Total royalties invoiced to Eisai during FY23 were \$1.75m. Total software development costs invoiced to Eisai were \$0.2m.
- As at 30 June 2023, Cogstate had gross cash of \$28.7m, which included \$0.9m 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 \$27.8m.

Share Buy-Back

On 28 February 2023, the Company announced that the Board of Directors had approved an on-market share buy-back of up to A\$13 million of Cogstate's issued ordinary share capital within the next 12 months ("Share Buyback"). To date, the Company has acquired 331,966 shares on market, for total consideration of A\$520,543.94 (average price of \$1.568).

The implementation of the Share Buyback program reflects the Cogstate Board's belief in the business' future commercial prospects, the business' strong capital position, and supports the Board's ambition to improve returns for shareholders.

The timing and number of shares to be purchased under the Share Buyback will depend on the prevailing share price, market conditions and the capital position and requirements over the buy-back period.

Following this release, the restrictions governed by Cogstate's Share Trading Policy have been removed and the Company will recommence the Share Buyback.

FY24 Outlook

Successful Alzheimer's disease phase 3 trial results over the last 12 months, and subsequent approval of new therapies, are expected to drive increased R&D spend over coming periods. Growth in R&D spend is expected to come from:

- trials in the pre-symptomatic stage of the disease (where Cogstate currently enjoys 100% market share);
- line extension of approved therapies into areas such as Lewy body dementia, frontal temporal dementia, and Alzheimer's disease in Down syndrome;
- trials targeting tau in combination with approved amyloid therapies; as well as
- exploration of new mechanisms in Alzheimer's disease.

With strong partnerships already in place with key large pharmaceutical companies and developing opportunities with a number of additional large pharmaceutical companies, Cogstate is well placed to capture opportunities not only in Alzheimer's but in other indications such as Parkinson's disease, Depression, Sleep disorders, Obesity and others.

Execution of sales contracts within the Clinical Trials segment will be critical to revenue growth in FY24. The timing of execution of those sales contracts will impact the level of revenue that can be recognised in FY24.

Since May 2023, the volume of requests for proposal from Cogstate customers has increased substantially, both in terms of total number of trials and total value of sales pipeline – to such an extent that it is now back to 2022 levels.

Cost base reductions enabled by technology efficiency gains, which were executed in May 2023, position the company for profitable revenue growth.

Management expects to grow revenue and profit in FY24, but no specific guidance is provided at this time, pending execution of sales contracts to provide greater certainty in respect of timing of revenue.

A further update will be provided at the company's AGM on Wednesday 25 October 2023.

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 22 August 2023, 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://register.gotowebinar.com/register/4892357684922300507>

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:

Brad O'Connor, Chief Executive Officer, boconnor@cogstate.com

Important Notices

Past performance

Past performance is given for illustrative purposes only and should not be relied upon as (and is not) an indication of Cogstate's views on its future financial performance or condition. Past performance of Cogstate cannot be relied upon as an indicator of (and provides no guidance as to) the future performance of Cogstate. Nothing contained in this announcement nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee, whether as to the past, present or future.

Future performance and forward-looking statements

This announcement contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "should", "could", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this announcement are based on assumptions and contingencies that are subject to change without notice and involve known and unknown risks and uncertainties and other factors that are beyond the control of Cogstate, its directors and management. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance.

Actual results, performance or achievements may differ materially from those expressed or implied in such statements and any projections and assumptions on which these statements are based. These statements may assume the success of Cogstate's business strategies, including the that the results of any of those strategies will be realised in the period for which the forward-looking statement may have been prepared or otherwise. For example, Cogstate's performance in any one financial period is sensitive to whether or not contracts are signed in that period, or a subsequent period, and the rate of enrolment in trials of its customers which are influenced by factors that are outside of Cogstate's control.

Readers are cautioned not to place undue reliance on forward-looking statements and except as required by law or regulation, none of Cogstate, its representatives or advisers assumes any obligation to update these forward-looking statements. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in this announcement. The forward-looking statements are based on information available to Cogstate as at the date of this announcement. Except as required by law or regulation (including the ASX Listing Rules), none of Cogstate, its representatives or advisers undertakes any obligation to provide any additional or updated information, whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements.

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