

ASX Announcement

28 February 2023

1H23 Financial Results & Business Update

All figures in US\$ unless otherwise stated

Cogstate Ltd (ASX:CGS) has today released its Appendix 4D, half year report for the six months ended 31 December 2022 (1H23) and also announced an on-market buy-back of up to A\$13 million of Cogstate's ordinary share capital within the next 12 months (Share Buyback).

- Trading Conditions:** The external market for Cogstate technology and services is strong, with growth in R&D spend by pharma / biotech companies in Alzheimer's disease buoyed by recent release of positive phase 3 data and the potential impending launch of disease modifying treatments;
- 1H23 Revenue Delays:** 1H23 financial results impacted by revenue delays, caused by slower than expected recruitment of patients in a small number of large trials;
- Share Buyback:** The Board remains confident that Cogstate is well positioned for growth and has approved a Share Buyback, reflecting their belief in the business' future commercial prospects, the strong capital position, and supports the Board's ambition to improve returns for shareholders;
- Contracted Future Revenue:** Contracted future revenue has increased to \$146.7m at 31-Dec-22, of which \$19.9m is expected to be recognized as revenue in 2H23 and \$36.8m in FY24;
- FY23 Guidance:** Cogstate reported a breakeven result for 1H23 but is expecting to report:
- improved 2H23 revenue resulting in full year FY23 EBITDA in the range of 12-15% of revenue; and
 - positive operating cashflow for FY23.

Summary financial results:

	1H23 US\$m	2H22 US\$m	1H22 US\$m
Total revenue from ordinary activities	19.5	21.9	23.1
- Clinical Trials revenue	17.1	19.5	20.8
- Healthcare revenue	2.2	2.2	2.2
New sales contracts executed (net of cancellations)	27.3	28.0	54.5
Contracted future revenue	146.7	139.1	132.9
EBIT	(0.2)	4.6	6.1
Net Profit before Tax	0.0	4.6	6.1
Net Operating cashflow (excl. net customer pass-through costs)	0.4	7.3	1.8
Net operating cash flow	(0.2)	8.4	1.3

1H23 Segment Results

	1H23 US\$m	1H22 US\$m	Variance %
Total revenue from operations	19.5	23.1	(15%)
Clinical Trials			
Revenue	17.1	20.8	(18%)
Direct Cost (<i>excluding direct depreciation</i>)	(7.1)	(6.3)	(12%)
Gross Margin	10.0	14.5	(31%)
SG&A	(2.0)	(1.6)	(31%)
Clinical Trials Segment Contribution	8.0	12.9	(38%)
Contribution Margin	46%	62%	
Healthcare			
Revenue	2.2	2.2	0%
Direct Cost	(0.9)	(0.4)	(98%)
Healthcare Segment Contribution	1.3	1.8	(25%)
Contribution Margin	60%	80%	
Research			
Revenue	0.2	0.01	1,332%
Direct Cost	(0.4)	(0.4)	6%
Research Segment Contribution	(0.2)	(0.4)	50%
Contribution Margin	(108%)	(3,079%)	
Other Operating Expense	(8.1)	(7.0)	(14%)
EBITDA	1.0	7.3	(86%)
Depreciation & Amortisation	(1.3)	(1.1)	(13%)
EBIT	(0.2)	6.1	N/A
Net Interest	0.2	(0.01)	N/A
Net Profit/(Loss) before tax	0.0	6.1	(100%)
Income Tax Expense	0.1	(2.0)	N/A
Net Profit/(Loss) after tax	0.1	4.1	(99%)

Financial Results

Clinical Trials Summary

Through the half year, Cogstate managed conflicting themes of delayed revenue but increased sales opportunities.

Cogstate sales efforts in the Clinical Trials segment continue to be focused on:

- I. an increase in Alzheimer's R&D investment across the industry;
- II. the move to more decentralised trial design with Cogstate providing key technology and scientific services to support such design; and
- III. efforts by Cogstate to secure important sales contracts in indications outside of Alzheimer's disease (such as depression and other mood disorders).

Clinical Trials revenue was impacted by slower than expected enrolment of patients by pharmaceutical companies in a small number of their large Alzheimer's trials, with such enrolment rates causing delays to Cogstate's revenue recognition. In total, approximately \$3.3 million of revenue that, at 01 July 2022, was expected to be recognised in 1H23 was deferred to subsequent periods.

Staffing levels in the Clinical Trials department have been maintained in order to deliver on the large trials that Cogstate is seeking to win in future periods. In addition, additional costs were added in the form of clinicians employed to support decentralised trial design – all such clinicians working directly on ongoing clinical trials during the period. Given the relatively fixed cost base, the revenue delays have caused a decrease in clinical trials contribution margin (46% 1H23 vs. 62% 1H22) with a corresponding impact on profit before tax.

Financial analysis:

- 1H23 revenue was \$17.1m, down 18% on the previous corresponding period (pcp), with approximately \$3.3m revenue that was expected to be recognized in 1H23 delayed to subsequent periods.
 - Direct costs, associated with delivery of clinical trials, was \$7.1m (up from \$6.7m 2H22 and \$6.4m 1H22) reflecting:
 - Additional clinicians employed to deliver centralised rating activities as part of decentralised clinical trial offering;
 - Additional geographic coverage (Japan) to support increased clinical trials in that country; and
 - Increase in headcount in anticipation of upcoming workload.
 - SG&A costs, associated with sales and marketing activities directly related to clinical trials, was \$2.0m (up from \$1.6m in each of 1H22 and 2H22) reflecting:
 - Increase in the size of business development team, specifically increased science support of sales activities; and
 - Increased marketing cost.
 - Sales contracts executed during 1H23 totaled \$27.3m, (\$27.9m before cancellations), compared to \$28.0m in 2H22 and \$54.5m in 1H22 – noting that the 1H22 record result included a contract for a very large phase 3 Alzheimer's trial.
 - Of sales contracts executed in 1H23:
 - 82% were in Alzheimer's disease and 6% in Depression
 - Approx. 13% was contracted through channel partners
 - Approx. 5% were in respect of decentralised clinical trials
 - Clinical Trials contracted future revenue at 31 December 2022 was \$110.0m, up from \$100.2m at 30 June 2022, of which 87% relates to Alzheimer's disease trials.
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Healthcare Summary

The focus in Healthcare continues to be the partnership with Eisai.

- Healthcare revenue in 1H23 was \$2.2m, consistent with the previous half year periods (1H22 and 2H22). This revenue primarily reflects the amortization of deferred revenue from the Eisai licensing agreement.
- Eisai and Cogstate have previously announced the launch of Cogstate computerised assessments in Japan (branded as NouKNOW), Hong Kong and Taiwan (branded as CogMate). Since 01 July 2022, Eisai has launched Cogmate in Thailand and Korea.
- Cogstate is working with Eisai to produce an additional version of Cognigram that will be focused on identification of cognitive impairment most likely to be associated with early Alzheimer's disease, for launch in the USA. Cognigram, a class II medical device that has been cleared by the FDA in the USA, was designed as a general cognitive screener. The work on the new instance of Cognigram, which is currently underway and is being funded by Eisai, will:
 - be focused on the memory assessments that are the most relevant for identification of cognitive change associated with early Alzheimer's disease; and
 - require less time to complete an assessment (less than 10 minutes).

Operating Costs

Operating expenses increased 18% to \$8.1m, from \$7.0m pcp. Approx 50% of the additional expenditure related to software engineering and associated costs. During 1H23 work was completed on a technology application designed to decrease operational resources assigned to management of clinical trials, thereby helping improve Clinical Trials margins in future periods. Additionally, during 1H23, \$1.3m of software development costs were capitalised, which were predominantly related to the build out of new datalake infrastructure, as well as investment in smartphone based cognitive assessment.

Share Buyback

The Board of Directors has 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").

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 next 12 months.

Please refer to the Appendix 3C for further information in respect of the Share Buyback.

FY23 Full Year Guidance

Based upon current information, the Company provides the following updated guidance in respect of the full year ended 30 June 2023:

- 2H23 revenue expected to increase over 1H23, but FY23 revenue expected to be approximately 6-9% below FY22;
- EBITDA is expected to be in the range of 12-15% of revenue;
- EBIT is expected to be in the range of 6-8% of revenue; and
- Cash balance as at 31 December 2022 of \$29m; expect positive operating cash flow for 2H23.

Notwithstanding the factors which are impacting the timing of when Cogstate is able to perform its cognitive assessments, the company remains confident that it is well positioned for further growth with strong contracted future revenue, the potential launch of Alzheimer's therapies expected to drive demand for cognitive assessment in the community, and the adoption of decentralised trial designs and our channel partner strategy having the potential to create new sales opportunities. Cogstate's combination of scientifically validated digital cognitive assessments along with the specialised service offering for data quality (rater training, central rating and central monitoring services) is attractive and, in the context of the expected future growth in the amount of research and investment in potential treatments for central nervous system diseases, positions Cogstate as a valuable partner for customers and other industry partners.

This announcement has been approved for release by the Board of Cogstate Ltd.

About Cogstate

Cogstate Ltd (ASX:CGS) is a 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.

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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.
