

ASX Announcement

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2023 Annual General Meeting Address to Shareholders

Cogstate Limited (ASX.CGS) attaches the following Address to Shareholders, to be presented at today's 2023 Annual General Meeting:

- Mr Martyn Myer AO, Cogstate Chairman; and
- Mr Brad O'Connor, Cogstate CEO.

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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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.

2023 Annual General Meeting

Address to Shareholders

Cogstate Chairman, Martyn Myer AO

Cogstate was formed more than 20 years ago with an investment thesis that doctors and researchers required better diagnostic tools in the context of an aging population and an increasing incidence of Alzheimer's disease and other forms of dementia.

Today, across the globe, at least 55 million people are believed to be living with Alzheimer's disease or other dementias. Worldwide dementia care is estimated to cost upwards of US\$1 trillion; much of the care is provided by unpaid family and loved ones.

Since our inception, Cogstate has supported more than 100 Alzheimer's disease trials and we have developed leading technology, expertise and operational delivery systems that enable our customers to gather reliable data to determine the effectiveness of their investigational treatments. Our work in Alzheimer's disease is critical to our financial results. In our Clinical Trials business, Alzheimer's disease trials represented over 70% of the value of sales contracts executed over the last 2 years.

Over the last 12 months, there have been tremendous breakthroughs in Alzheimer's disease, with two companies presenting statistically significant phase 3 data that shows that their treatment slowed cognitive decline in patients with early Alzheimer's disease.

First, Eisai presented their data from their Clarity AD phase 3 trial of lecanemab. Eisai received regulatory approval in the USA from the FDA on 06 July this year, with the drug to be sold under the brand name, Leqembi. Cogstate did not work on the Clarity AD program, but we are working on Eisai's phase 3 trial of Leqembi in pre-symptomatic Alzheimer's disease – referred to as the Ahead trial.

In addition, Cogstate has partnered with Eisai to provide Cogstate technology to primary care doctors and consumers so that they might identify the first cognitive changes that could be associated with Alzheimer's disease – we refer to this as our Healthcare market and we report that segment separately from our Clinical Trails business. Now that new treatments are available, we believe that it is crucial that the right diagnostic tools are available to primary care physicians so that they can find patients who can benefit from the treatments as soon as possible. The Healthcare license agreement with Eisai has generated over \$19m in cash receipts since it was executed in October 2020.

The second potential treatment came from pharmaceutical giant, Eli Lilly, when in June this year they presented positive data from their phase 3 trial of donanemab in patients with early Alzheimer's disease. Cogstate has been proud to work with Lilly throughout the development of donanemab; from phase 1 all the way to phase 3. Across the donanemab program, known as the Trailblazer trials, Cogstate has worked on 8 trials testing the safety and efficacy of donanemab - 1 phase 1 trial, 4 phase 2 trials and 3 phase 3 trials. Total Cogstate contract value, to date, across the donanemab program is almost US\$87m. Lilly has submitted the data from the successful phase 3 trial to the FDA and they are expecting to hear the outcome of their submission in this current quarter. Should donanemab receive

approval, as expected, Cogstate anticipates involvement in potential future donanemab trials, such as post-marketing (or phase 4) trials, line extension studies into indications such as Lewy body Dementia as well as possible combination therapies with the approved treatment and other treatments such as tau therapies.

Cogstate works across a range of disease areas, with a particular focus on diseases that impact the central nervous system. In the context of Cogstate's business, Alzheimer's disease has a larger financial impact than any other condition. Over the last two financial years, 24% of new sales opportunities were in Alzheimer's disease; other significant disease areas include Depression, Parkinson's disease, and a number of rare diseases. However, as I mentioned earlier, 70% of the value of sales contracts executed over that same period related to Alzheimer's disease trials, reflecting the size and complexity of Alzheimer's disease trials relative to other indications.

Several studies have identified that most older adults with dementia are either undiagnosed or unaware of the diagnosis, suggesting shortcomings in detection and communication of dementia. Timely diagnosis is critically important to improved health outcomes, either from new treatments or other changes in care. Cogstate technology has demonstrated sensitivity to the cognitive changes present in the earliest stages of Alzheimer's disease and other dementias. Further, Cogstate technology can provide ease of assessment via computer, tablet, or smartphone—without the need for supervision by highly trained physicians.

Recent drug approvals are bringing hope to millions, but the breakthrough treatments from Eisai and Lilly only act to slow the rate of cognitive decline in early Alzheimer's disease – those patients will continue to decline over time, even when on drug. Therefore, substantial areas of unmet medical need remain in Alzheimer's, providing ample room for continued and more diverse research. At the start of 2023, there were 141 different potential treatments for Alzheimer's disease being explored across 187 clinical trials, with a wide variety of investigational agents. This represents a 23% increase in the number of clinical trials since 2021, as well as huge diversity in the exploration of biological targets, demonstrating growth and innovation in this field.

In other disease areas, following successful clinical trials and approved commercial release of a therapy, there is typically a de-risking of investment that results in substantial increase in R&D by pharmaceutical and biotechnology companies. There is no reason to believe Alzheimer's will be any different. Cogstate scientific expertise and technological excellence mean our team is well placed to assist companies seeking to advance new treatments and better health outcomes.

Given the launch of the first disease modifying treatments of Alzheimer's disease and the expanding and diverse research landscape, the addressable market for Cogstate—in both its Clinical Trials and Healthcare businesses—is expected to grow across coming years.

Less than 2 weeks ago, the Cogstate management team presented a deep dive into our Clinical Trials business for investors – a recording of that webinar can be found on the investor page of the Cogstate website.

During that presentation, Cogstate VP Science, Dr Pam Ventola, presented on the work of her team in supporting biotech company, Acadia, which recently received the first ever approval of a treatment for a rare genetic neurological disease in the USA.

For more than 7 years now, Pam has been growing Cogstate's business in rare disease. Over that time, Cogstate has run more than 40 clinical trials across 25 rare disease indications.

Rare disease trials, given their relatively small size, will never compete with Alzheimer's disease in terms of revenue generation for Cogstate. However, this breakthrough approval is another example of how Cogstate is contributing to important scientific advancement and helping biotech and pharmaceutical companies bring new treatments to patients in need.

All shareholders should be incredibly proud of the work that the Cogstate team is doing. Every day they strive to bring technology and expertise to assist with the development of new treatments and identification of the patients who can benefit from those treatments.

Late in 2022, the Cogstate Board was approached by a potential purchaser of the business.

These discussions substantially commenced in late December 2022, with access to due diligence granted in late January 2023. At all times, the Company considered that the discussions were and remained confidential, non-binding, incomplete and insufficiently definite to warrant disclosure. On 18 February 2023, it was determined that the potential transaction would not proceed, and accordingly, all such discussions ceased.

The potential strategic buyer saw value in the revenue synergies that Cogstate could bring to their business, particularly as they sought to grow revenue in central nervous systems disease trials.

While the discussions ceased without a formal proposal put to shareholders, we believe that the positive nature of the negotiations reflects well on the long-term strategic value we are creating at Cogstate.

Reflecting Cogstate's strong cash position, as well as the Board's view of Cogstate's strategic value, in February 2023 we announced that we would initiate a share buy back.

To date, we have bought-back just over 2 million shares at an average cost of \$1.50 per share – with much of the activity occurring during this most recent quarter.

We plan to re-initiate the buy-back following this meeting.

I note that, at 30 September 2023, our cash balance is US\$27.3m. During the most recent quarter, we used approximately US\$1.4m to acquire shares.

I will now hand over to CEO, Brad O'Connor, who will discuss the FY23 financial results and also provide a business update at the completion of the first quarter of FY24.

Cogstate CEO, Brad O'Connor

Notwithstanding the very positive macro factors that Martyn discussed, the FY23 year did not deliver the financial results we were expecting. In addition to the revenue delays associated with ongoing clinical trials, we also experienced a significant decline in Clinical Trial sales contracts, particularly through the second half of FY23. The decline in the value of sales contracts executed during the period resulted in lower than expected in-period revenue yield from new sales contracts.

However, the financial results improved in the second half of FY23 when we recorded EBITDA of \$4.3 million and profit before tax of \$3.5 million for the half year, excluding non-recurring restructure charges.

As part of a restructure announced in May 2023, Rachel Colite was promoted into the role of Executive Vice President, Clinical Trials, a role in which she will take full P&L responsibility for the Clinical Trials division. The restructure created opportunities for promotion and change of responsibility for other high-performing and high-potential individuals, as part of our talent identification and development program.

The restructure resulted in staff reduction of approximately 13% of full-time employees from the business. This reduced annual costs by \$2.6 million. All restructure costs were taken to account in the June 2023 half year period. The decision to reduce staff was only made after significant consideration of our ability to deliver on current and new projects. Important to the restructure planning were efficiency gains seen in the second half of FY23 that resulted from investment through FY22 and FY23 in improved technology solutions for management of clinical trials.

As mentioned, clinical trials sales contracts in the second half of FY23 disappointed against expectations. There were multiple reasons for this. Certainly, general market issues and increasing interest rates seemed to impact all eClinical vendors in the pharma services space during that time. More specific to Cogstate was the uncertainty caused by pending drug approvals for the new Alzheimer's therapies combined with uncertainty related to reimbursement of the therapies, which have now been resolved.

Today, our largest customers are still in the planning stage for their next trials. During 1Q24, less than 1% of the value of sales contract executed came from our two largest customers, reflecting their transition from regulatory submission to planning for new trials. Nonetheless, we have delivered a solid start to the FY24 year in terms of sales contracts executed.

Gross sales contracts for the quarter were \$9m – the net result was \$8m after negative reconciliations of \$1m. This result is an improvement from the \$3.1m and \$3.6m of sales contracts recorded in each of the last two quarters respectively.

In line with prior periods, Alzheimer's disease again represented over 70% of the value of sales contracts. We were pleased to be selected by a new Alzheimer's customer to manage their phase 2 trial in pre-symptomatic Alzheimer's disease. Sales contracts were also executed for trials in rare disease, schizophrenia, depression, migraine and sleep. In total, we executed 24 contracts with 19 unique sponsors – some of these trials were quite small, but we have seen previously how small trials can grow into large programs.

Looking forward, we expect growth in sales contracts, revenue and profit in FY24.

All of the internal metrics that we track in respect of sales pipeline have increased through the first quarter. One such metric is proposal deliverables, which includes statements of work, request for proposals, and request for information. During the September quarter, the proposals team delivered 109 pieces of work, compared to just 64 in the previous quarter. As a result of this activity, the value of sales opportunities that we are tracking is at a record high.

1Q24 revenue, at \$9.2m, was consistent with 1Q23. This reflects sales contracts in March and June quarters that were less than expectations. There was also very little in-period revenue recognition from contracts executed in 1Q24 as more than half of that value was executed in the last weeks of the quarter.

Looking forward then, Cogstate's ability to increase revenue in the coming quarters will be dependent upon our ability to turn the sales activity into executed sales contracts. However, the short-term revenue impact of sales opportunities will be dependent on the timing of execution of sales contracts. Presently we believe that most of the opportunities we are tracking are likely to close between now and March 2024. If a large amount of sales contracts are executed in 3Q24, or even if they push into 4Q24, that could have a negative impact on our revenue expectations due to the limited time before 30 June 2024 to recognize revenue under such contracts.

Notwithstanding this timing uncertainty, we remain confident of revenue growth from FY23 to FY24 and with that revenue growth, we expect to grow profit.

In the Healthcare business, we expect Eisai to launch Cognigram in the US market during FY24. Revenue from the US launch is not expected to exceed the minimums payable under the global license agreement in FY24. At this stage, due to confidentiality, we are unable to provide more specific information in respect of Eisai's launch plans.

As we have mentioned throughout this presentation, Cogstate works across a range of disease areas but, from a financial perspective, Alzheimer's disease has a substantial impact on our financial results.

Even though Cogstate has generated \$40m and \$45m of revenue in each of the last two years respectively, our business has, to now, remained relatively small with a concentration of revenue in Alzheimer's disease and the few pharmaceutical companies that have been pushing ahead aggressively in that space in the face of decades of failed trials.

With the approval of breakthrough therapies that Martyn discussed earlier in this presentation, the landscape is changing rapidly. We are seeing the predictable increase in pharmaceutical companies entering the space, along with new trials being planned by those companies with positive phase 3 data. Cogstate's ability to leverage our existing relationships and success in running global phase 3 Alzheimer's trials to win new work from existing and new customers will be critical to our future growth.

As the new therapies are being launched in the US, we are intrigued by a healthcare system that is seemingly not set up to identify patients that could benefit from those new treatments. We believe that Cogstate technology has an exciting role to play in identifying the first signs of cognitive impairment. Additionally, all of the market research work that we have done convinces us that people want to be able to accurately measure their own brain health.

Finally, we are confident that we can grow our business over the coming years and that the growth we deliver will be strategically important within the industry in which we operate.

I want to thank all of our shareholders for your continued support of the Board and management of Cogstate and I look forward to delivering you improved financial results in the coming periods.

- Presentation Concludes -