

ASX Announcement

4 November 2022

2022 Annual General Meeting Address to Shareholders

Cogstate Limited (ASX:CGS) attaches the following Address to Shareholders, to be presented at today's 2022 Annual General Meeting:

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

This announcement was authorised for release by a sub-committee of 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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2022 Annual General Meeting Address to Shareholders

Cogstate Chairman, Martyn Myer AO

Good morning and welcome to the 19th Annual General Meeting of Cogstate as a listed company.

My name is Martyn Myer, and I am chairman of Cogstate and of this Annual General Meeting.

So to begin, let me introduce our board of directors.

As I said, my name is Martyn Myer. I have been the Chairman since the formation of Cogstate in 1999 and I have participated in every funding round that the Company has undertaken. My investment in Cogstate continues a family tradition of support of neuroscience in Australia.

I'll start by introducing our American based Directors, who are joining us online.

David Dolby, joined the Cogstate board in November 2013 and joins us today from San Francisco. David and his family have significant interests in technology and are passionate supporters of Alzheimer's disease research with a focus on both biomarkers and therapies.

Richard Mohs, joined the Cogstate Board in January 2017 and joins us today from Chicago. Richard is a former executive of Eli Lilly where, for a period of time, he oversaw their Alzheimer's R&D activities. Richard is a neuropsychologist who in 1994 prepared the first administration manual for the ADAS-Cog, the collection of cognitive assessments that has been used as the primary endpoint in pivotal Alzheimer's disease trials for many years since then.

Richard van den Broek, joined our board in August 2010 and joins us today from Connecticut. Richard has 30 years of experience in financial strategy and investment fund management in the life science industry, initially as a healthcare analyst and now as a partner in an investment fund focused on the biotech industry.

Then, here in the room with me, let me introduce our Australian directors.

Ingrid Player joined our board in August of 2019. Ingrid is an experienced Non Executive Director with Australian and international commercial and regulatory experience in mergers and acquisitions, corporate governance, risk and sustainability, as well as deep healthcare sector experience having formerly held senior executive roles with Healthscope Ltd, a leading private healthcare provider in Australia.

Kim Wenn joined our Board in November 2020. Kim has 30 years experience in innovation roles, including 14 years at Tabcorp, an ASX 50 company, where she held the role of Chief Information Officer and led a team of 1200 technology experts to drive digital transformation.

And finally, our CEO, Brad O'Connor, who has been in the role since December 2005. Brad will address the meeting shortly.

I would also like to welcome and introduce Mark Harrison from Pitcher Partners, who was the engagement partner on our external audit. Mark will be available today to answer shareholders' questions relevant to the audit and accounts.

Since the inception of Cogstate in 1999, our investment thesis has been focused on an aging population, an increasing incidence of Alzheimer's disease and other dementia-related diseases and the need to provide technology solutions that simplify the measurement of cognition for patients, their doctors and the researchers developing new and better therapies.

Throughout that journey, we have remained steadfast in our belief that, eventually, treatment options for Alzheimer's disease would come to market and, when they did, Cogstate would be ready with technology solutions that make cognitive assessment easy and accessible so that the right patients at the right time can access the right treatments.

We want to make the measurement of cognition as simple, standardized, actionable and common as the measurement of blood pressure; and we believe when we are successful at achieving that, we will have improved brain health around the globe.

Today, our business has three segments, with two major commercial focus areas.

In our clinical trials business, Cogstate supports pharmaceutical companies who are seeking to bring new therapeutic treatments to market. Today, approximately 90% of our revenue is derived from the clinical trials segment, where Cogstate provides a range of services as well as our proprietary digital assessments of cognition.

Our Healthcare business references that original investment thesis of providing technology to help doctors assess the cognition of their patients and has now extended to providing digital cognitive assessments directly to individuals. In this area, we have partnered with Japanese pharmaceutical company, Eisai, to commercialise our technology. I'll provide more detail in respect of that agreement shortly.

In addition to our commercial segments, we work extensively with academic collaborators around the world, where our technology supports their scientific ambitions, and we benefit from access to data and insights and the scientific validation that comes with their peer reviewed research.

At our 2020 AGM, we were very pleased to be able to announce a global licensing agreement with Japanese pharma company, Eisai, for Cogstate technology in all markets outside Clinical Trials. The global license followed a Japan regional license of Cogstate technology to Eisai that was executed in August 2019.

Eisai has a long and proud history in Alzheimer's disease that dates back to the launch of the drug Aricept in 1997 for the symptomatic treatment of mild-to-moderate Alzheimer's disease, and today they have a promising, multi-faceted drug development pipeline aimed at preventing and curing the disease.

The global agreement between Eisai and Cogstate provides Cogstate with certainty of cashflows, limited cost downside and significant upside with an ongoing royalty from the sale of Cogstate technology.

The 10-year term of the license provides us many options over the longer term.

The hopes for commercial success from our agreement with Eisai have been enhanced by the release of Eisai's positive trial data.

Approximately 6 weeks ago, Eisai announced that its confirmatory phase 3 Clarity AD study of experimental therapy, Lecanemab, met its primary endpoint, showing a statistically significant reduction of cognitive decline in a global study of 1,795 participants with early Alzheimer's disease.

The positive result from the lecanemab phase 3 trials, after almost 25 years since Aricept's launch, is an important milestone for Eisai but also a very important step for the scientific community and for all Alzheimer's disease patients and their families. If approved, lecanemab can potentially slow the progression of Alzheimer's disease, and provide a clinically meaningful impact on cognition and function.

Cogstate, and others, eagerly awaits the release of further data from Eisai's Clarity-AD trial at the upcoming Clinical Trials in Alzheimer's Disease conference that will be held in San Francisco later this month.

As an industry, we are also eagerly awaiting top-line data from other ongoing phase 3 trials. Roche is expected to release their phase 3 data before the end of this calendar year and Eli Lilly is expected to release top-line data from their ongoing phase 3 study in mid-2023.

Earlier this week, on Tuesday 1st November, in their quarterly earnings call, management from Lilly referenced the Eisai phase 3 data and noted, and I quote, that "these data certainly reinforces our confidence in donanemab and the forthcoming readout from our phase 3 study".

The team at Cogstate is also encouraged by Eisai's positive phase 3 data and the implications for other phase 3 trials. Given such positive data, it is possible that there could be multiple Alzheimer's therapies on market within the next 12-24 months. I make that statement aware that there is always some risk in attempting to predict how regulators and payers will interpret the data from clinical trials, but with confidence in the quality of the data that is being collected and reported.

Alzheimer's treatments, on market and widely accessible, are expected to positively impact both of Cogstate's commercial business segments.

Firstly, the release and reimbursement of the first Alzheimer's treatment is expected to lead to a substantial increase in Alzheimer's disease R&D, which provides a growing market into which Cogstate can sell our technology and services. While the topline data from Eisai's Clarity-AD trial showed a 27% slowing in cognitive decline, it is not a cure for Alzheimer's disease. With further investment, new and better therapeutic treatments can be expected over the next 10-20 years. In other areas of medicine, it has been seen that an initial breakthrough can lead to progressively improved treatment options for patients, and all of those improved treatments must complete the same clinical trial processes.

Over the next 10-20 years, we expect the market for cognitive assessment in trials of central nervous system disease therapeutics to grow. Over that time, Cogstate will seek to grow market share in that growing market.

Secondly, the availability of an effective treatment for early Alzheimer's disease is expected to increase demand for cognitive assessment in the community and in physician's offices. Through our agreement with Eisai, Cogstate is well placed to commercialise our technology in that market.

As we reported at the end of August, FY22 was another record-breaking financial year for Cogstate. The value of Clinical Trials sales contracts executed, the revenue generated, and the profit were all records.

From that strong financial foundation, we will seek to grow our business at a time when the market for our services is expanding.

I want to acknowledge the hard work of our team that has led us into this enviable position and I also want to thank the patient capital that has allowed the management team the time to build a quality business.

I'm now going to hand over to our CEO, Brad O'Connor, so that he can update you in respect of the short and longer term prospects for the business.

Cogstate CEO, Brad O'Connor

Today, there are a number of external factors that give us great confidence that Cogstate is well positioned to generate revenue growth into the future.

Firstly, a central tenet of the Cogstate investment thesis is that the launch of Alzheimer's therapies will create demand for cognitive assessment in the community. Cogstate technology is scientifically proven to be able to identify very early signs of cognitive impairment that may be associated with Alzheimer's disease and therefore our tests are well placed to meet that demand.

Additionally, we expect that the approval of the first Alzheimer's disease modifying therapies will create a path to market for future therapies and thereby lead to an increase in overall research & development expenditure focused on this terrible disease.

Secondly, the increased adoption of decentralized trial designs, where testing is conducted at-home, is providing Cogstate with increased sales opportunities. Cogstate has been able to expand our service offering to meet demand for decentralized clinical trials with telehealth style assessments, thereby increasing the average value of such contracts to Cogstate. And, of course, Cogstate's digital assessments are well suited and proven to be effective for remote at-home administration or even self-administration.

Finally, our channel partner strategy--focused on both technology platforms for electronic data collection and contract research service providers--is generating an increase in sales opportunities and, as stated earlier, providing opportunities to expand beyond Alzheimer's disease trials.

Looking at the September quarter clinical trials sales contracts, there is evidence of the positive macro forces impacting our business.

Clinical Trials sales contracts executed during the September quarter were \$17.9m, our 3rd strongest sales quarter ever. Alzheimer's disease research was again an important factor in our commercial success, making up 89% of the total value of sales contracts executed.

While the total value of sales contracts executed was down compared to the same quarter last year, it is important to remember that last year's September result was impacted by one very large Alzheimer's trial.

The positive Clinical Trials sales result, took our contracted revenue backlog to \$148.3m at 30 September 2022, which is another record.

Clinical Trials contracted future revenue at 30 September was over US\$110m, up 26% from the same time last year and up 162% from the same time 2 year ago.

Despite the strong sales result and the record contracted future revenue, September quarter revenue was down compared to recent quarters.

In a couple of large Alzheimer's trials, the pharmaceutical companies running the studies are dealing with slower than forecast enrolment of patients. The slow enrolment is unrelated to any Cogstate activity

but relates to issues with both identification of patients and also supply chain issues relating to availability of certain necessary biological tests.

The slower enrolment has meant that Cogstate is performing our assessments at a rate that is slower than expected and therefore our revenue recognition has been slower than we forecast at the beginning of these studies.

There is no risk that these trials will be cancelled – they are continuing to enroll patients, but just at a slower rate. This is a timing issue only and the revenue will be recognized as the cognitive assessments are performed. We have seen acceleration in enrolment over the last couple of months and the pharmaceutical companies involved are confident that they will continue to accelerate enrolment in the coming months.

While the revenue delays are impacting the first half of FY23 results, analysis of contracted future revenue for FY24 and FY25 indicates significant revenue growth in those coming years.

Contracted revenue for the next financial year is 17% higher than the same time last year, and contracted revenue for year 3, in this case FY25, is up 77% compared to this time last year. Separating out the Clinical Trials contracted revenue from Healthcare revenue for FY25 shows clinical trials revenue of \$28.2m, up 100% from the same time last year.

The contracted revenue base for FY24 and FY25 provides a springboard for future revenue growth if the market expands, as we expect.

I want to spend some time now talking to recent data points that support our view of a growing market for Cogstate services.

For some time now, we have stated that we expect that the market for trials in Alzheimer's disease, and more generally in central nervous system indications, will grow substantially in the coming years.

I am happy to report that, following the release of the positive data from Eisai, we are already seeing the first shoots of that new growth. Our largest customers are already planning expansion of their existing Alzheimer's clinical trials programs and therefore we expect that we will execute additional sales contracts to further support those ongoing programs during this financial year.

Cogstate is working with customers that are developing monoclonal antibodies to lower amyloid in early Alzheimer's disease with delivery of drug via an infusion. Those same customers are now planning trials that will seek to provide for subcutaneous injection as an easier delivery model than infusion. In addition, our customers are planning to run trials to determine what happens when patients come off drug and whether a maintenance regimen of further treatment will be required.

In addition, in the trials that are ongoing in the pre-clinical Alzheimer's population, the companies will not only seek to explore subcutaneous injection, but they are also planning to expand the ongoing studies geographically to help speed recruitment. All of this additional work is expected to result in additional contracts, and therefore additional revenue, for Cogstate.

Away from Alzheimer's disease, we continue to expand our offering and gain further reach through our channel partner strategy.

Mood disorders, such as major depressive disorder, are an area where we're seeing growing interest in Cogstate services from our contract research and technology platform channel partners. In a step that takes us closer to broader support of mood disorder trial solutions, Cogstate has been awarded a new project in a phase 2 Major Depressive Disorder trial.

Separately, our cognitive testing technology solutions are being sought after in new configurations and new deployment modalities. The digital innovation group within a large pharmaceutical company has engaged Cogstate in a multi-study research collaboration, using Cogstate digital assessments via remote web-based assessment, to monitor thousands of healthy adults with the aim of establishing a self-administered early dementia screening system for identification of patients for a number of clinical trials.

From a scientific perspective, in July we had strong participation at the annual Alzheimer's Association International Conference in San Diego, with 23 scientific presentations and meetings with over 20 different customers. Looking forward, we will have a similarly strong participation in the upcoming Clinical Trials in Alzheimer's Disease conference in San Francisco later this month.

Turning our attention to the expected financial results for this FY23 year, we see two contrasting events impacting our expectations:

Firstly, 1H23 revenue and profit are expected to be impacted by slower than forecast enrolment of patients in a couple of large Alzheimer's trials, which will cause delays to revenue recognition.

However, over recent weeks, we have become more confident in respect of Clinical Trials sales that are expected to positively impact revenue and profitability in the 2nd half of FY23.

Therefore, whilst we are anticipating that 1H23 Clinical Trials revenue will decrease 10-12% from the 2H22 result, we expect a stronger result in the second half of the financial year. As 2H23 revenue will be significantly impacted by sales contracts executed between today and 30 June 2023, we are unable to provide specific revenue guidance at this time.

Given a decrease in revenue, the margins for the Clinical Trials segment are expected to be lower for 1H23 as we resource for the expected increase in trial activity in coming months. We expect that the clinical trials margin for 1H23 will be in the range of 48%-51%, compared to 57% for 2H22.

As a result, 1st half profit for the group will be negatively impacted, but we anticipate a stronger profit result in the 2nd half of the financial year on the basis of an expected increase in clinical trials sales and an associated increase in clinical trials revenue.

We continue to target group FY23 EBITDA in the range of 27-29% of revenue. Group FY23 EBIT, based on current revenue forecast, is expected to be at the bottom end of the range of 20% - 24% of revenue. Again, the actual result will vary with the level of sales contracts executed between now and 30 June 2023.

We remain confident that short term revenue delays will be resolved in the normal course of operations and therefore we are more focused on the increased trial activity that we expect following the positive phase 3 data from Eisai and the impact of that increased activity on the financial performance of Cogstate through the 2nd half of FY23 and into FY24 and beyond.

In Summary, as we stand here today, Cogstate is well positioned for growth.

Cogstate's disruptive digital assessments are clinically validated and accepted by regulators. With the adoption of decentralized trial design over recent years, the market for well validated digital assessments has grown as pharma companies and regulators both seek to ensure that assessments are well suited to the environment in which they are delivered.

Cogstate has significant leverage to the breakthroughs in Alzheimer's disease treatment that are expected to be available to patients in the near future. We expect to see an increase in the level of Alzheimer's disease research & development expenditure, which is positive for our Clinical Trials business. Of course, the partnership with Eisai provides much upside beyond contracted minimum payments as new Alzheimer's treatments result in a growing need for ease of access to accurate and reliable assessments of cognition.

Cogstate has developed channel relationships with a number of contract research and technology platform providers to the clinical trials market. These channel partners rely on Cogstate to provide complimentary specialized services and solutions for optimized clinical outcomes assessment, as well as to help inform their technology and service roadmap as they refine their solutions for greater penetration in central nervous system trials. This channel strategy is beginning to prove to be a source of new sales opportunities and awarded contracts— giving Cogstate more shots on goal.

Of course, Cogstate is in a very strong financial position, with over \$148m of contracted future revenue, almost \$30m of net cash and a profitable cashflow positive business at a time when debt and capital markets are negatively impacting many other businesses.

And, while we are experiencing some short term issues associated with revenue recognition, we expect those issues to begin to resolve in 2H23.

All in all, Cogstate has never been better positioned and the executive team that I work with daily are all very excited about our future.

To conclude, I take this opportunity to thank all Cogstate shareholders for your patience over a number of years as we have awaited a therapeutic landscape in Alzheimer's disease that creates demand for large scale brain health assessment and sought to secure the commercial opportunities that will provide long term returns for our shareholders.