

ASX Announcement

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2021 Annual General Meeting Address to Shareholders

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Cogstate (ASX:CGS) provides the following Address to Shareholders, to be presented at the 2021 Annual General Meeting today:

- 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 over 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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2021 Annual General Meeting Address to Shareholders

Cogstate Chairman, Martyn Myer AO

Good morning and welcome to the 18th 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.

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.

Ingrid Player joined our board in August of 2019 and joins us today from Melbourne. 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.

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.

Kim Wenn joined our Board in November 2020 and, although she is Australian, she joins us today from Europe. 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 and joins us today from Melbourne. 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 the need to provide technology solutions that simplify the measurement of cognition for patients, their doctors and the companies 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 there to provide technology solutions that make cognitive assessment easy and accessible.

Our goal has always been to play a small but important role in delivering better brain health to all. Within the context of our original ambitions, the last 12 months have been a watershed for Cogstate.

At this meeting last year, 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. Today, Eisai is one of very few companies that are targeting several key areas in Alzheimer's disease research.

Over the last two years, the Cogstate team has found Eisai to be a highly committed partner, and we are excited about the impending launch of Cogstate technology solutions through Eisai. We look forward to sharing more news shortly in respect of the Eisai partnership, with the launch of Cogstate's digital assessments imminent in a number of countries, including the USA and countries through the Asia region.

After years of waiting patiently for Alzheimer's treatments to come to market, suddenly there has been a rush of activity over the last few months. The introduction of treatment options is encouraging for all patients and families suffering under the weight of this terrible disease.

On 7 June 2021, the US Food & Drug Administration approved the first ever disease modifying treatment for early Alzheimer's disease. The treatment, branded as Aduhelm, was developed by Eisai and their development partner Biogen.

Then, later in June, the FDA announced that two other potential treatments had been given breakthrough therapy designation, which aims to expedite the development and review of drugs. Those potential treatments are being developed by Eisai and Eli Lilly respectively.

As a result of being awarded breakthrough therapy designation, on 28 September 2021, Eisai announced that it had initiated a rolling submission to the FDA of a Biologics License Application for Lecanemab, Eisai's investigational treatment of early Alzheimer's disease.

Eli Lilly's investigational treatment of early Alzheimer's disease, donanemab, has also been granted breakthrough therapy designation and Lilly has announced that it expects to lodge an application with the FDA before the end of this calendar year.

With so much activity, it is possible that, by the time we meet again next year, there could be three interventional treatments for early Alzheimer's disease on the market. A situation that seemed incredibly remote not so long ago.

Throughout a year when Cogstate generated record financial results, nearly all Cogstate staff were working 100% remotely. Cogstate committed to a "virtual-first" working environment throughout the year and will commit to this working model going forward. Cogstate staff have overwhelmingly expressed their appreciation for the flexibility afforded them by the virtual working model that still provides opportunities for in-person collaboration and team building.

External to Cogstate, the global health pandemic has changed behaviour and led to adoption of technology solutions at a rate previously unseen, including remote clinical trials, known as decentralised trials. Decentralised trials are an emerging trial design that threatens to disrupt the traditional site-centric model of clinical trials. Cogstate digital cognitive assessments offer the ability for remote or unsupervised assessment, which is essential in the context of decentralised trials.

These changes to trial design represent a new and significant opportunity for Cogstate as digital assessments become a more central element of assessment, due to the changed nature of the trial design.

2021 was a record-breaking financial year for Cogstate. The value of Clinical Trials sales contracts executed, the revenue generated, and the profit and the cash flow from operations were all records for Cogstate. The financial results reflect not only the emerging commercial opportunities but also effective management of expenditure by the management team.

Cogstate generated revenue growth of \$9.9 million compared to the prior year. That revenue increase generated a profit before tax from ordinary operations of \$3.9 million, a profit increase of \$6.9 million compared to the prior year. That level of financial leverage should please all shareholders as we look forward to another year of revenue and profit growth in the 2022 financial year.

I'm now going to hand over to our CEO, Brad O'Connor, so that he can update you in respect of the start of this 2022 financial year.

Cogstate CEO, Brad O'Connor

As Martyn has mentioned, the 2021 financial year was a watershed year for Cogstate and, pleasingly, the 2022 financial year has started positively.

In the first quarter, Cogstate has executed almost a year's worth of clinical trials sales contracts. This result was underpinned by the award of a large phase 3 Alzheimer's disease study, which is being conducted as a completely virtual, decentralized trial. That trial will use Cogstate proprietary digital assessments as key endpoints in the trial.

Through Cogstate's history, we have seen large trial opportunities such as this from time to time, but never quite this large. So, while a large phase 3 opportunity is not unusual, they are irregular in nature.

Group revenue for the September quarter was \$12.3m, a record quarterly result that was up almost 100% against the same period last year and up 23% compared to the most recent June quarter.

Clinical Trials revenue has been increasingly steadily over the last two years as the level of sales contracts executed has converted into revenue. For the September quarter, Clinical Trials revenue was \$11.1 million.

Trailing 12-month revenue was approximately \$39m.

Contracted revenue is the amount of revenue that will be generated in future periods, by sales contracts that are already in place. This is an important metric for both the management team and all shareholders, as it provides insight into secured revenue that will be generated in future periods.

As a result of the record sales bookings in the clinical trials segment through the first quarter for FY22, the amount of contracted future revenue has increased by 209% since the same time last year and is up 28% since the end of June this year.

If we focus on just the clinical trials segment, the revenue backlog is \$88m, which is up 109% since the same time last year and up 51% since the end of June this year.

Contracted revenue in the Healthcare segment represents the minimum revenue from Eisai under both the Japan and the global agreements.

Revenue for the remainder of the 2022 financial year will be a product of two factors: firstly, how much revenue is contracted now, and secondly, our ability to execute new sales contracts in clinical trials throughout the rest of this financial year.

In total, including the revenue generated during the first quarter plus the revenue contracted for the rest of fiscal 22, we have just over \$38m of revenue secured for this financial year. As we execute new sales contracts throughout the rest of this financial year, we will generate additional revenue.

As we look forward to next financial year, we see that we are in a good position to be able to record revenue growth again into FY23, with more than \$30m of revenue already secured by contract for that financial year.

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.

Secondly, through our relationship with Eisai, Cogstate technology is about to launch in a number of countries, where we will seek to capture the expected increase in demand for easy to use, quick, non-invasive but scientifically accurate measures of cognition.

Thirdly, 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.

Finally, the increased adoption decentralized trial design is expected to provide additional sales opportunities for digital assessments such as Cogstate's.

Turning our attention to the expected financial results for this FY22 year, at this time, we reiterate guidance provided only 8 weeks ago.

Clinical Trials revenue under contract for FY22 has increased since we issued our guidance and will continue to increase as we execute sales contracts between now and the end of the financial year. All other aspects of guidance provided on 24 August 2021 remain unchanged.

The FY22 year has of course started well, the business fundamentals are sound, and we have a clear path to revenue and profit growth from FY21 to FY22.

In Summary, the last 2 years have seen significant growth in the commercial opportunities available to Cogstate.

At 30 September, Cogstate has contracted future revenue in excess of \$130 million. Our momentum in clinical trials continues to build and the Eisai partnership will deliver at least \$43 million of revenue over the course of the next 10 years.

For the FY22 year, we expect to grow both revenue and profit and, if we look forward, we have already secured more than \$30m of revenue for the FY23 year.

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.

Our technology has excellent scientific validation and the market for that technology is large and growing.

We have a strong balance sheet, with \$23.4 million of net cash, no debt and we expect to be cashflow positive through FY22.

To conclude, I take this opportunity to thank all Cogstate shareholders for your patience over a number of years as we have sought to secure the commercial opportunities that will provide long term returns for our shareholders.

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