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We are on a mission to democratize brain health assessment across clinical research and clinical care... combining proven science with disruptive digital innovation to make the measurement of cognition as simple, standardized, actionable and common as the measurement of blood pressure.

Company Snapshot

Cogstate is a leading neuroscience technology company optimising brain health assessments to advance the development of new medicines and to enable earlier insights in healthcare.

After more than 20 years spent developing and scientifically validating our technologies, Cogstate is a leading provider of digital brain health assessments:

- Selected to support world's top 10 pharma*
- More than 2,000 academic and clinical research trials
- More than 2 million tests administered

Cogstate tests are highly automated, easy to use, sensitive to change and accepted by global regulators.

Cogstate is growing rapidly. For the calendar year ended 31 December 2021, Cogstate recorded revenue of US\$42m and EBIT of US\$10m.



Cogstate was founded in Melbourne, Australia, where approx. 25% of our workforce is based. We have a small presence in the UK, but most of our staff are based in the USA.



- ~ 255 team members, comprised of 185 employees
- + global network of consulting neuropsychologists



Our largest customer base is pharma / biotech companies developing new drugs or other treatments. Global clinical trials is a \$40B+ industry that seeks tools for better go/no-go decisions that can speed new therapies to market.



In the next decade, better solutions for screening, diagnosing, and treating brain disorders will be imperative. Cogstate is a leader and uniquely positioned to support this need for clinical evaluation and self-assessment at scale.



Market Dynamics





Brain Health

An aging population and an increased focus on brain health

World's population aged 60+ will double to 2.1 billion by 2050¹



Investment

Increase in investment in the neuroscience sector, particularly in Alzheimer's

Biotech investors predict 2020s to be decade of neurology renaissance akin to 2010 for oncology²



Disruption

Clinical trials industry ripe for disruption with a desire to leverage digital assessments

85% of CNS drugs fail in trials and digital endpoints address many data quality issues that contribute³



New Drugs

The launch of Alzheimer's therapeutics will create a lucrative market for screening and diagnosis

Modern AD drug candidates focus on prevention, so early detection of cognitive decline is central⁴



Cogstate Positioning



Customer Base

72 pharma/biotech customers over the last 21 months; Trusted partner relationships



Financial Strength

Profitable and cashflow positive with \$143.5m revenue backlog



Product Offering

Disruptive innovation Clinically validated

Accepted by regulators
Supported by data



Growth

Direct and Indirect sales channels delivering growth in expanding markets



Blue Sky

Eisai agreement underpins push into lucrative Healthcare market



3Q22 Financial Highlights

(All figures in US\$)

Clinical Trials Sales Contracts



\$73.6m YTD

\$19.2m 3Q22, record 3Q result

Group Revenue



\$32.3m YTD

\$9.3m in 3Q22

Cashflow From Operations*



\$2.3m 3Q22

\$4.1m YTD

Contracted Future Revenue



\$143.5m

Increased \$10.6m during 3Q22

FY22 EBIT Guidance



\$8.8m - \$11.3m

20%-24% EBIT Margin

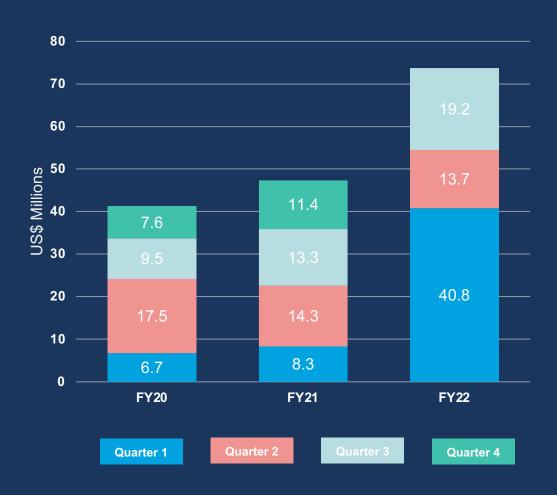
Net Cash Balance



\$26.1m

\$17.6m net cash at 31-Mar-21

Clinical Trials Sales Contracts

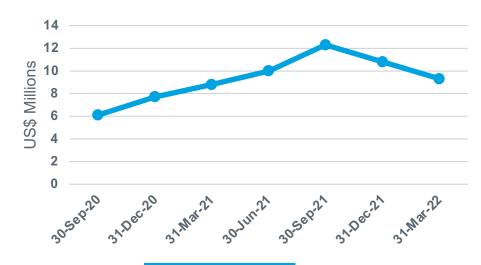


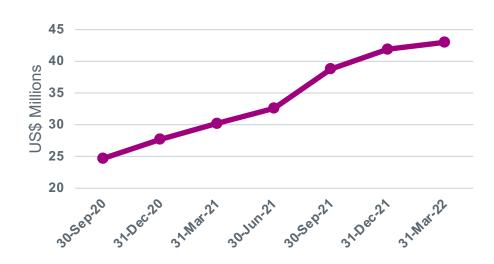
Record sales contracts FY22 YTD

- \$73.6m executed year to date, up 105% compared to PCP
- \$19.2m 3Q22 is the 2nd best ever quarterly result, behind only the 1Q22 result
- Alzheimer's disease clinical trials:
 - 87% of 3Q22 sales contracts
 - 89% of FY22 YTD sales contracts

Group Revenue

- 3Q22 revenue of \$9.3m, down from recent guarters reflecting delays in revenue recognition in Clinical Trials
 - slower than expected patient enrolment in a key Alzheimer's study has delayed recognition of revenue during 3Q22. Expected to be a timing issue only with deferred revenue expected to be recognised in the June quarter.
 - A large percentage of the \$19.2 million of Clinical Trials sales contracts executed during 3Q22 occurred during the last two weeks of March. Therefore, only minimal revenue from those new contracts was recognised during 3Q22
 - Maintain guidance of full year revenue in the range of \$44m \$47m, implying 4Q22 revenue range of \$11.6m \$14.6m
- Trailing 12-month revenue of \$43.0m, up 42% from 3Q21





Quarterly Revenue

Trailing 12 Months Revenue

Revenue Yield From Clinical Trials Sales Contracts

On average:

- 17% of contract value is recognised as revenue in the same quarter as a sales contract is executed
- 51% contract value is recognised within 4 quarters of contract execution

but timing can vary according to the specifics of the trial.

Revenue Yield = speed by which revenue is recognised, may vary according to many factors:

- Timing of contract execution contracts executed late in quarter have minimal in-quarter revenue impact
- Length of the trial revenue from larger phase 3 trials is recognised over a longer time period
- Time between contract execution and trial initiation longer planning phase can delay revenue recognition
- Software license mix software revenue is recognised earlier than services revenue
- Patient enrolment slow enrolment may delay revenue recognition
- Contract scope the mix of activities can impact timing of revenue

	Revenue In- Quarter	Revenue Quarter +1	Revenue Quarter +2	Revenue Quarter +3
High Case	28%	1%	8%	7%
Low Case	4%	26%	11%	11%
Average	17%	14%	10%	10%



Year-On-Year Growth in Revenue Backlog

The long-dated contractual nature of Cogstate revenue provides revenue predictability and insight into future revenue performance.

\$143.5m Backlog at 31-Mar-22, up 80% year-on-year

- Clinical Trials Backlog \$103.6m
 - Up 86% year on year
- Healthcare Backlog \$39.9m
 - Up 66% year on year

Contracted Revenue Run-Off



Revenue to be Recognised from Backlog in Future Periods is Growing

This time last year, FY22 contracted revenue was \$23.5m (of which \$19.2m related to Clinical Trials), whereas today our FY23 contracted revenue is \$33.9m (of which \$29.7m relates to Clinical Trials)

Year-on-Year Growth in Contracted Revenue

	Current As at Mar-22 US\$	PCP As at Mar-21 US\$	Growth US\$	Annual Change %
Yr 1	FY22 44.1	FY21 30.0	14.1	47%
Yr 2	FY23 33.9	FY22 23.5	10.4	44%
Yr 3	FY24 30.5	FY23 20.9	9.6	46%
Yr 4	FY25 24.5	FY24 9.7	14.8	153%
Yr 5	FY26 16.8	FY25 7.2	9.6	133%

Clinical Trials Business Update

Alzheimer's Driving Growth

Cogstate has calculated 13.3% market share of Alzheimer's disease trials, based on historical data (based on number of trials, rather than value of trials). Throughout FY22, Cogstate has won significant work in Alzheimer's disease (89% of the value of sales contracts), including important contracts with new customers; an important indicator of market share growth.

Channel Sales Showing Benefit

3Q22 sales contracts include two sizeable joint awards for both Cogstate and one of our industry partners. The awards were with top 15 pharmaceutical companies (as measured by revenue). There is a growing pipeline of opportunities that we are progressing through channel partners.

Decentralised Trials Adoption

The industry shift towards decentralised trials continues. Cogstate's computerised tests are ideal for remote administration and we have significant and growing experience supporting tele-health style (virtual) assessment of non-Cogstate tests, which is a trend we expect to continue. Through the first three quarters, Cogstate has executed multiple sales contracts with a decentralised offering and we have multiple additional sales opportunities in play across rare diseases and Alzheimer's disease.

Industry Association

Cogstate has joined the Decentralized Trials & Research Alliance (DTRA) whose 100 member organisations work to accelerate the adoption of patient-focused, decentralised clinical trials and make research participation accessible to everyone.

Reimbursement of Alzheimer's Treatments Expected To Result In More Trials

The status of reimbursement in the USA of monoclonal antibodies targeting amyloid in Alzheimer's disease has been clarified following release of medicare coverage policy by the Centers for Medicare and Medicaid Services (CMS). If approved by FDA for the treatment of Alzheimer's disease based upon evidence of efficacy from a direct measure of clinical benefit, reimbursement may be covered in CMS-approved prospective comparative studies. Study data for CMS-approved prospective comparative studies may be collected in a registry. We note that Cogstate's offering aligns well with collection of cognitive data via both virtual and in-person assessment as part of a registry.

Healthcare Business Update

Exciting Industry Dynamics

There are multiple promising potential Alzheimer's therapies with pivotal data to be released soon. The launch of Alzheimer's therapeutics will increase demand for easy-to-use, accurate brain health assessments.

Progress in Japan

In Japan, over 26,000 NouKNOW assessments (nouknow.jp) have been performed through initial engagements with municipalities and businesses seeking to offer their employees, residents, and customers easy-to-use digital solutions for understanding their brain health. Cogstate and Eisai will share profits 50/50 from activities in Japan once activities are profitable.

Positive Data on Selftesting Feasibility

>90% of NouKNOW testing sessions initiated were successfully completed, which is an excellent result for unsupervised assessment.

New Sales Channel

In Japan, from February 2022, the Raku-Raku smartphone (developed by FCNT LIMITED) will be shipped with a version of NouKNOW, pre-installed on the device. The Raku-Raku smartphone is marketed to the senior population in Japan and has shipped more than 7 million units. It has been designed with a primary focus on the essential features that enable easy-to-use, easy-to-hear, and easy-to-read functionality.

New Markets in Asia

In January 2022, Eisai announced that Cogstate technology, branded as CogMate, will be marketed directly to consumers in Taiwan and in Hong Kong targeting municipalities and corporations. This will be the first release of Cogstate technology in the Asian region (excluding Japan). Similar launch in additional countries (including USA, Singapore and others) is expected in 2022. Launch of CogMate in Taiwan and Hong Kong has gone well, with first sales contracts executed during the quarter.

Improved and Localized Product

CogMate is a global multilingual version of NouKNOW®, a digital tool (non-medical device) for self-assessment of brain performance, developed and distributed by Eisai using the cognitive function test Cogstate Brief BatteryTM (CBB) created by Cogstate. For the Asian region, CogMate is equipped with multilingual functions such as Chinese (Traditional Chinese) and English. CogMate can be deployed via a PC, tablet or smartphone.



Clinical Trials

Revenue:

- 2H22 range of \$19m \$22m. Full year FY22 range of \$40m \$43m
 - Notwithstanding the 3Q22 revenue result, revenue for the 2nd half expected to be in the range of \$19-\$22m
 - Assumes a pick-up in patient enrolment for the large Alzheimer's trial that has been delayed, but that risk is somewhat off-set by a positive expectation for in-quarter revenue recognition from sales contracts that we expect to execute in 4Q22

Contribution Margin:

2H22 in the range of 54% - 57%. Full year FY22 in the range of 58% - 61%.

Healthcare

- 2H22 Revenue \$2.2m. Full year FY22 Revenue \$4.4m
- 2H22 and full year FY22 gross contribution margin in the range of 75% 80%

Group Earnings

- 2H22 revenue range of \$21m \$24m. Full year FY22 revenue in the range of \$44m \$47m
- FY22 Research segment loss of \$0.7m
- FY22 Operating Expenses expected in the range of 31% to 33% of revenue, an improvement of 5% to 7% percentage points on prior year FY21
- FY22 EBIT margins expected to increase and be in the range of 20-24%, providing for FY22 EBIT in the range of \$8.8m \$11.3m due to stronger 1H22 performance and improved outlook for 2H22 gross contribution margin.
- Operating cash flow for 2H22 expected to be at least \$4m, taking operating cashflow for the full year FY22 to at least \$5m

Positive Business Outlook

Clinical Trials Growing

Growth in sales contracts represents positive macro dynamics as well as expansion in sales channels.

Increased revenue backlog provides visibility of continued revenue growth.

Half year results demonstrate sustainable segment profit margins.

Improving Margins

Fixed costs in the range of 31%-33% of revenue in FY22, but that will decrease as revenue increases.

Therefore, EBIT margins are expected to expand as revenue increases.

Healthcare Upside

Short-term revenue will predominantly represent amortisation of Eisai contractual minimum payments.

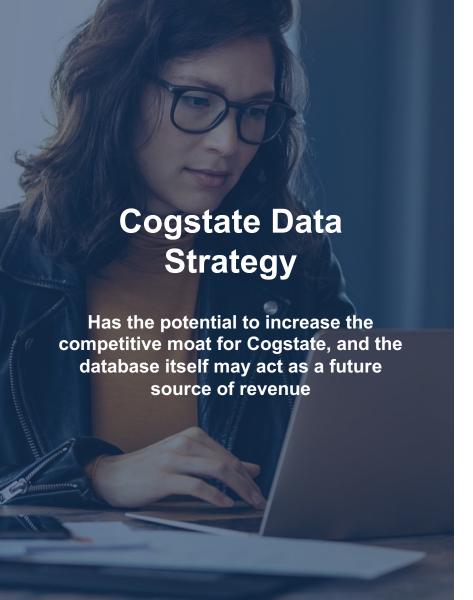
Substantial upside exists if and when disease modifying treatments for Alzheimer's disease become available.

Growth in Earnings and Cash

As revenue grows, Cogstate expects to grow both profit and cashflows







A Unique Opportunity to Drive Insights from Data

Vision: Enable greater decision-making capabilities for researchers, doctors and patients – decisions that will speed the development of a cure or help identify the right patients for treatment.

Mission: Create best-in-class digital interactions with our technology, supported by a holistic data solution leveraging AI/ML, data visualization and self-service capability.

Data Platform: Investment ongoing to develop a new data platform, that will act as a central hub, where insights are derived through advanced analytics such as predictive and prescriptive solutions.

Data Sources: Data is derived from a variety of sources, including industry trials, academic research, patient registries, in-clinic assessment by physicians and direct-to-consumer applications (such as NouKNOW and CogMate).

Why Cogstate: Cogstate's access to cognitive and meta data provides a unique dataset from which to extract insights.

Outcome: Improved data analysis may increase sensitivity of existing tests and/or allow for earlier identification of impairment – leading to better health outcomes.



Cogstate is working on 117 Ongoing Clinical Trials

Cogstate Clinical Trials revenue backlog (%), by phase



Phase 1 studies represent 26% (31 of 117) of ongoing studies but only 4% of backlog. Phase 2 studies represent 38% (45 of 117) of ongoing studies and 35% of backlog. Phase 3 studies represent 21% (24 of 117) of ongoing studies and 58% of backlog.

- later stage studies usually have a much higher contract value.

The 76 phase 1 & 2 trials form part of Cogstate's future sales pipeline. As drugs progress through development stages, successful early phase studies may generate later phase contracts.

Wide range of indications

Of 117 ongoing clinical trials, 26% are in Alzheimer's disease, but other indications include:

IU	ications include.		
•	Healthy volunteers	•	Angelman syndrome
•	Autism	•	Autoimmune Disorder
•	Depression	•	CDKL5
•	Batten disease	•	Charcot Marie Tooth Disease
•	Epilepsy		Chronic Heart Failure
•	Migraine		CNS Neoplasms (other)
•	Mild Cognitive Impairment		Dravet Syndrome
•	Mitochondrial disease	•	End Stage Renal Failure
•	Phenylketonuria (PKU)	•	Familial
•	Cognitive Disorder		Hypercholesterolemia
	Hemophilia	•	Fragile X
	Narcolepsy	٠	Friedreich's ataxia
	Parkinson's Disease	•	Frontotemporal Dementia (FTD)

Primary

Immunodeficiencies

Acute Lymphocytic-ALL



Glioblastoma Multiforme

Insomnia

Cogstate Share of Alzheimer's Trial Market

All Ongoing Alzheimer's Trials

There are 127 ongoing industry sponsored P1-3 AD trials listed in clinicaltrials.gov.

Of the Alzheimer's trials that Cogstate is supporting, we were able to map 17 trials to the clinicaltrials.gov dataset. That represents a 13.3% market share of ongoing AD studies

Trials initiated Since 01-Jul-2019

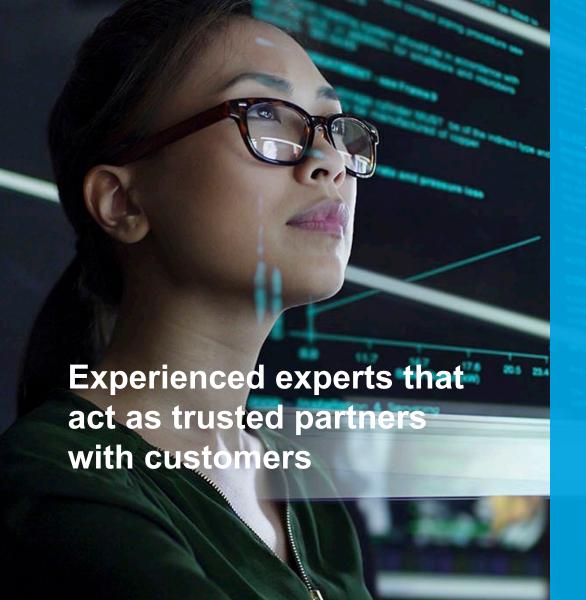
Since 01-Jul-2019, 90 Alzheimer's trials have been posted to clinicaltrials.gov.

Of the Alzheimer's trials that Cogstate is supporting, we were able to map 12 trials to the clinicaltrials.gov dataset. That represents a 13.3% market share of ongoing AD studies started since 01 July 2019, broken down as follows:

	Total Alzheimer's Trials clinicaltrials.gov	Cogstate Alzheimer's Trials Mapped to clinicaltrials.gov	Cogstate Market Share
Phase 1	26	4	15.4%
Phase 2	42	6	14.3%
Phase 3	22	2	9.1%
Total	90	12	13.3%

Not All Trials Posted to clinicaltrials.gov

It is important to note that Cogstate is working on Alzheimer's trials that are not posted to clinicaltrials.gov. Results submission is not required under FDAAA 801 for a clinical trial that is not an Applicable Clinical Trial. For example, a trial conducted entirely outside the USA is not an Applicable Clinical Trial.



Supported 440+ Industry-Sponsored Clinical Trials

115,000

patients tested globally

19,000

test supervisors and raters trained

10,000

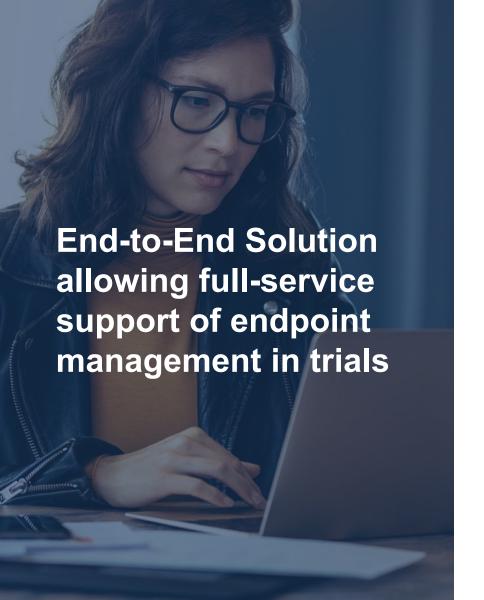
sites supported globally

115

biopharma customers

100

languages & dialects







Lower patient burden

- Brief and user-friendly assessments
- Delivered in-clinic or at-home

Heightened sensitivity

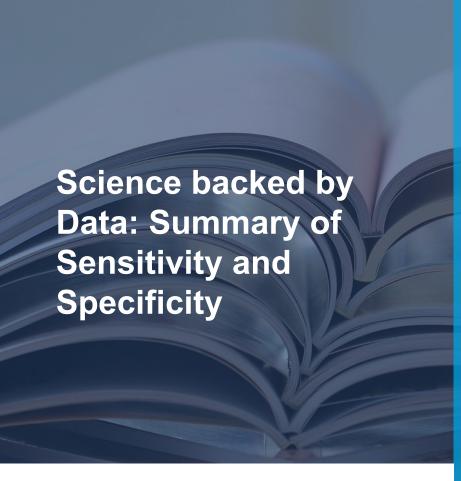
- Digital automations prevent errors
- Culturally-neutral stimuli with many alternate forms
- Hundreds of published studies

Operational ease for reduced site burden

- Can be delivered on a single device with eCOA partners
- Highly automated assessment, scoring and upload

Avoid trial delays from start to finish

- Rapid start-up timelines
- Accurate data from the start speeds database lock





Index of published studies available for review

- Extensive library of peer reviewed publications in international scientific journals demonstrate the Cogstate tasks are sensitive to the cognitive impairment associated with dementia due to Alzheimer's disease, Parkinson's disease, Schizophrenia, Lewy Body Disease and HIV
- Data from use in clinical trials shows the Cogstate tests are sensitive to cognitive change associated with CNS sedative and alerting drugs, putative cognitive enhancers and to the secondary effects on the CNS of drugs targeted at systemic disease (e.g. breast cancer, anemia, endocrine disorders)
- Cogstate tests are also sensitive to increases in biomarkers of degenerative disease (e.g. amyloid, tau), allelic variation in cognitive genes (Apoe4, BDNF val66met, COMT) and to increasing severity of neurodegenerative and neuropsychiatric diseases in both children and adults
- Data from use in clinical medicine demonstrate the utility, acceptability and sensitivity of Cogstate tests to cognitive impairment and change in individuals with dementia (and MCI), HIV, head injury and surgery

Case Study: Selecting the Appropriate Patients for Global AD Programs

Challenge

- A sponsor of two large Phase 3 global studies evaluating a treatment in early Alzheimer's Disease (AD) sought an effective screening assessment.
- Verbal list learning tests are a common paradigm for testing episodic memory in early AD but can be difficult to translate/globalize without impacting validity.
- The study team needed a verbal list learning tests with cross-cultural validity appropriate for use in their large 29-country program.



The study teams ensured the right patients entered the trial by selecting a verbal memory screening measure with proven cross-culture validity across 29 countries and 35 languages

- They selected the Cogstate International Shopping List Test (ISLT), a measure of verbal episodic memory uniquely designed for use across different cultural backgrounds and available with validated stimulus sets in 90 languages.
- In a sample of 8,711 subjects in 35 languages from the study, published data demonstrated that different language versions of the ISLT provided equivalent performance in learning trajectory and memory decay in older adults with memory impairment seeking entry to the study.

Case Study: Demonstrating Cognitive Safety of NMDA Modulator Antidepressant Medications

Challenge

- A sponsor sought to evaluate the effects of intranasal esketamine on cognitive functioning for their global pivotal clinical trials in treatment resistant depression.
- Given the drug mechanism (compound acts on NMDA neurotransmission) and known cognitive impacts, it was critical the cognitive assessment be robust, sensitive to drug-related change and acceptable to regulators.



The sponsor successfully **characterized cognitive effects** as part of first-in-class drug approval: demonstrated that **2 hours post-dose** cognitive impairment returned to placebo levels

- Esketamine was studied in five pivotal Phase 3 trials in more than 1,700 adults with treatment-resistant depression (TRD), and a battery including Cogstate computerised tests was selected as a primary safety outcome measure.
- Esketamine was associated with significant cognitive impairment at 40 min post-dose for all Cogstate tests. In contrast, performance on these tests did not differ significantly between esketamine and placebo at 2, 4, or 6 hours post-dose.
- FDA granted approval for esketamine administered inclinic with 2-hour observation period post-dose for adults with TRD.

Case Study: At-home, Web-based Computerised Testing



The sponsor achieved **remote monitoring of cognitive change** using CBB: **28,000 study** participants collected longitude data on cognitive performance

Challenge

- The Brain Health Registry is a webbased, observational study to capture data to more efficiently identify, assess, and longitudinally monitor the cognitive changes associated with neurodegenerative diseases.
- They needed a rapid, reliable and repeatable assessment of memory that could be self-administered at-home on the patients own computer.

- The Cogstate Brief Battery (CBB) was specifically configured for independent selfadministration, which participants complete athome every 3-6 months.
- 75,491 participants have tested using CBB to date.
- Published data has demonstrated the feasibility of remote/unsupervised testing with extensive longitudinal data collection and ability to sensitively discriminate individuals with a diagnosis of MCI.

Case Study: Measuring Neurocognitive Effects of Oncology Treatments in Children

Challenge

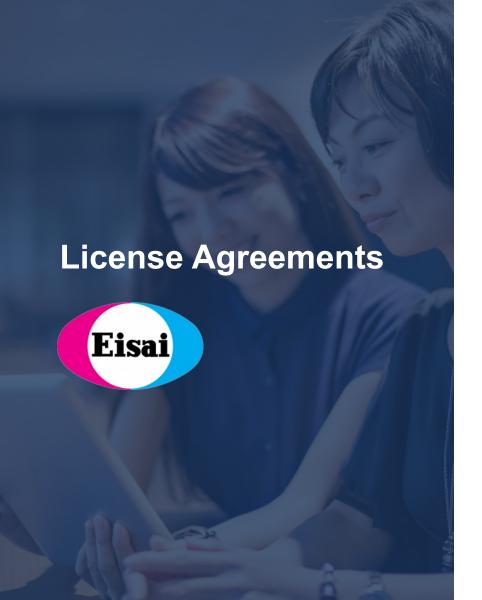
- A multi-national consortium conducting research on childhood cancers wanted to understand the neurocognitive effects of treatments on developmental trajectories
- Previous attempts saw high rates of missing data due to:
 - Sites lacking neuropsychologists
 - Batteries were lengthy, difficult and not designed for frequent assessment in broad age ranges

Sponsors experienced improved data collection and participant satisfaction as demonstrated by:

>86% of acute lymphoblastic leukemia patients successfully completed the full schedule of tests

- Cogstate provisioned validated, brief and gamelike computerised cognitive assessments to a large trial in pediatric leukemia, spanning 30 countries, participants ages 4-11, and duration of 37 months
- Published study completion rates soared compared to conventional assessments
- Sponsors were able to efficiently generate conclusive study results while dramatically reducing participant burden





Who is Eisai?

- Listed on Tokyo Exchange
- Market Cap approx. ¥1.7Tn (A\$21bn)
- Total Assets (31-Dec-21) ¥1.17Tn (A\$14bn)
- Revenue (year to 31 Mar 2020) ¥646bn (A\$7.7bn)
- Profit before tax: ¥52bn (A\$621m)
- Focusing on dementia as global pioneer since Aricept launch in 1997
- Partnered with Biogen to jointly develop and commercialise Alzheimer's disease treatments, including key assets:
 - Aduhelm (Aducanumab): FDA approval Jun-21
 - Lecanemab (BAN2401): granted breakthrough therapy designation by the FDA in Jun-21.
 Currently in phase 3 trials



- The parties began discussions in 2018
- Japan agreement executed 27 August 2019
 - 10-year license from execution
 - NouKNOW (nouknow.jp) product launch occurred 31-Mar-20 initially targeting (i) municipalities providing health services to local residents and (ii) corporations providing health checks for employees.
- Rest-of-World license executed 25 October 2020
 - 10-year license from first commercial sale, which must occur within 12 months of execution
- Eisai committed to launch within:
 - USA: 1 year, EU: 3 years, China: 4 years

Eisai Commercial Terms

License	Commercials
 2 x 10-year licenses (Japan & Rest-of-World) No longer has right to terminate ROW after year 5 Includes all Cogstate technology (existing and future) Excludes Clinical Trials market 	Japan: \$1m upfront (received 1Q20) and 50/50 profit split Rest-of-World (ROW): US\$15m upfront – received in 2Q21 Royalty on all revenue Minimum cumulative royalty over 10 years \$10m over years 1-5 \$20m over years 6-10
Eisai Responsibilities	Data Ownership

Eisai: Revenue vs Cash



2 Rest of World

Revenue

\$1m treated as deferred revenue to be recognised on a straight-line basis over 10yrs.

50/50 profit split recognised as realised.

Cashflow

Upfront

\$1m cash payment received in 1H20

Ongoing

50/50 profit split to be received as realised

Revenue

\$45m treated as deferred revenue to be recognised on a straightline basis over 11yrs (10yr term + 12mths to commence)

Royalties in excess of minimums will be recognised as received

Cashflow

Upfront

\$15m cash payment received in 1H21

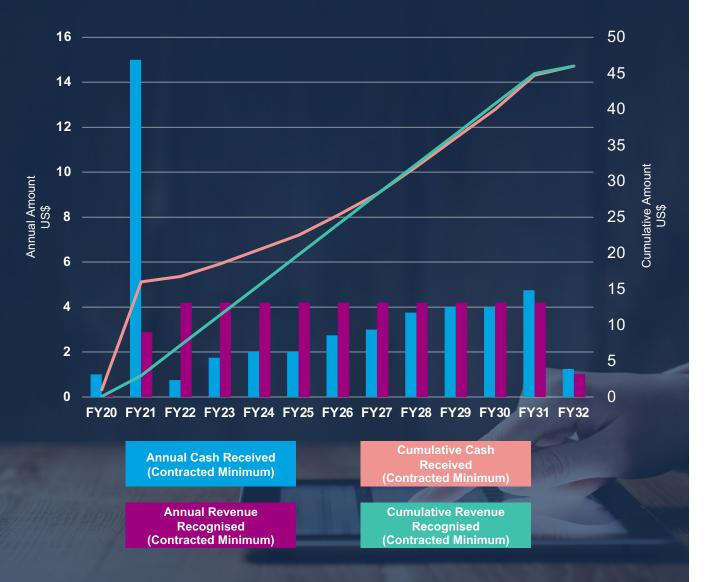
Ongoing

Cash received quarterly from first commercial sale, which must occur within the first 12 months.

Amount received will be the greater of

(i) royalty based on actual sales or (ii) guaranteed minimums





Eisai Minimum Payments Revenue vs Cash

US\$46m minimum contracted payments (including Japan and Global Agreements)

Cash

- Lump sums
 - \$1m received FY20
 - \$15m received FY21
- Quarterly minimum payments
 - First quarterly minimum invoiced 2Q22
 - Minimum payments increase year-on-year

Revenue

- Amortised over 11 years
- \$4.2m p.a.

