ASX Announcement
24 February 2022

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Cogstate Investor Briefing

Cogstate Ltd (ASX:CGS) has today released an Investor Briefing that provides a summary of the financial results for the half-year ended 31 December 2021 and also provides commentary in respect of the business and financial outlook.

The presentation material is attached to this announcement.

Additionally, a video recording of Cogstate CEO, Brad O'Connor and CFO, Darren Watson, presenting the materials will be available in due course and can be viewed on the Cogstate Investor Centre homepage:

https://www.cogstate.com/investors/

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 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 in March 2020 (nouknow.jp) and recently expanded to Taiwan and Hong Kong in January 2022, branded as CogMate™. For more information, please visit www.cogstate.com.

For further information contact:
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Investor Update

Financial results for the half-year ended 31 December 2021
Presented February 2022

Cogstate

Disclaimer

This presentation has been prepared by Cogstate Limited ('Cogstate'). The information in this presentation is of a general nature and does not purport to be complete, nor does it contain all the information which would be required in a prospectus prepared in accordance with the requirements of the Corporations Act. This presentation may contain statements, opinions, projections, forecasts and other material (forward looking statements), based on various assumptions. Those assumptions may or may not prove to be correct. None of Cogstate, its respective officers, employees, agents, advisers or any other person named in this presentation makes any representation as to the accuracy or likelihood of fulfilment of any forward looking statements or any of the assumptions upon which they are based.

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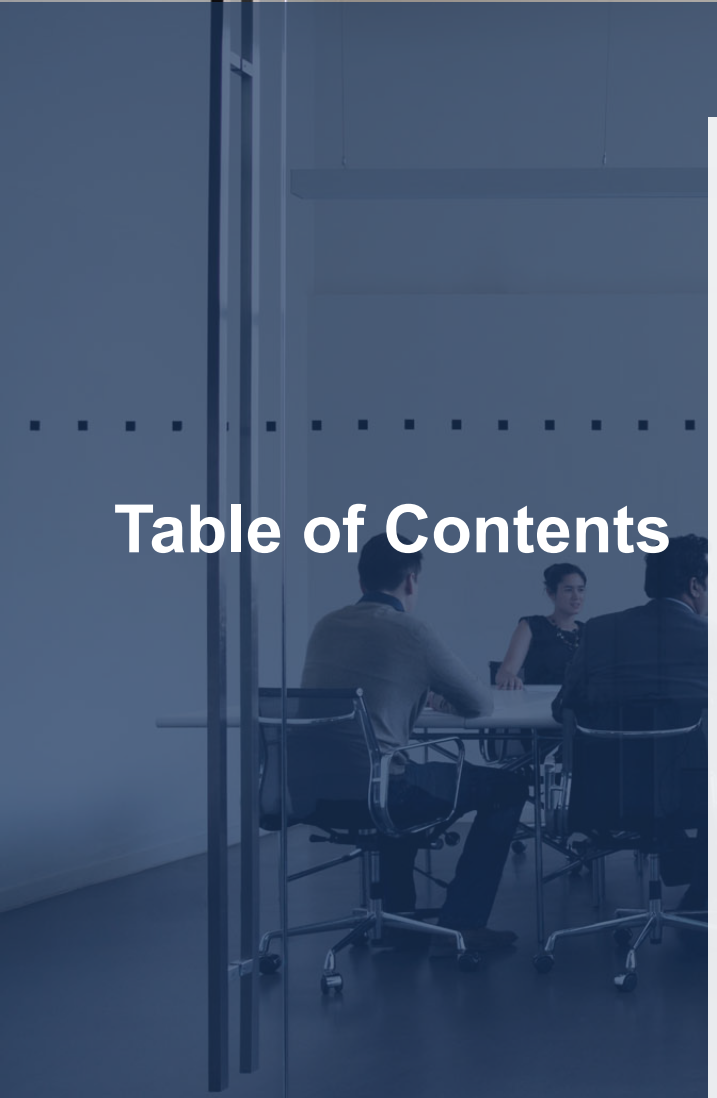

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We are on a mission to democratize brain health assessment across clinical research and clinical care...

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 optimizing 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.

*Ranked by revenue, as at Dec 2021

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 2050[1]

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 oncology[2]

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 contribute[3]

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 central[4]

1. https://bit.ly/369Ta6N, 2. https://bit.ly/3LzLA5M , 3. https://bit.ly/3rQEvpF, 4. https://bit.ly/3uOxdV5

Cogstate Positioning

1H22 (Jul-Dec 2021) Financial Highlights

(All figures in US$)

Record Clinical Sales Contracts Executed

$54.5m

Alzheimer's disease represented 90% of the value of contracts executed in 1H21

Record Contracted Future Revenue

$132.9m

Strong contracted revenue pipeline

Record Group Revenue

$23.1m

Clinical Trials revenue of $20.8m, up 66%
Healthcare revenue of $2.2m, up 93%

Margin Expansion in Clinical Trials

62%

1H21: 49%, up 13pts
2H21: 58%, up 4pts

EBIT

$6.1m

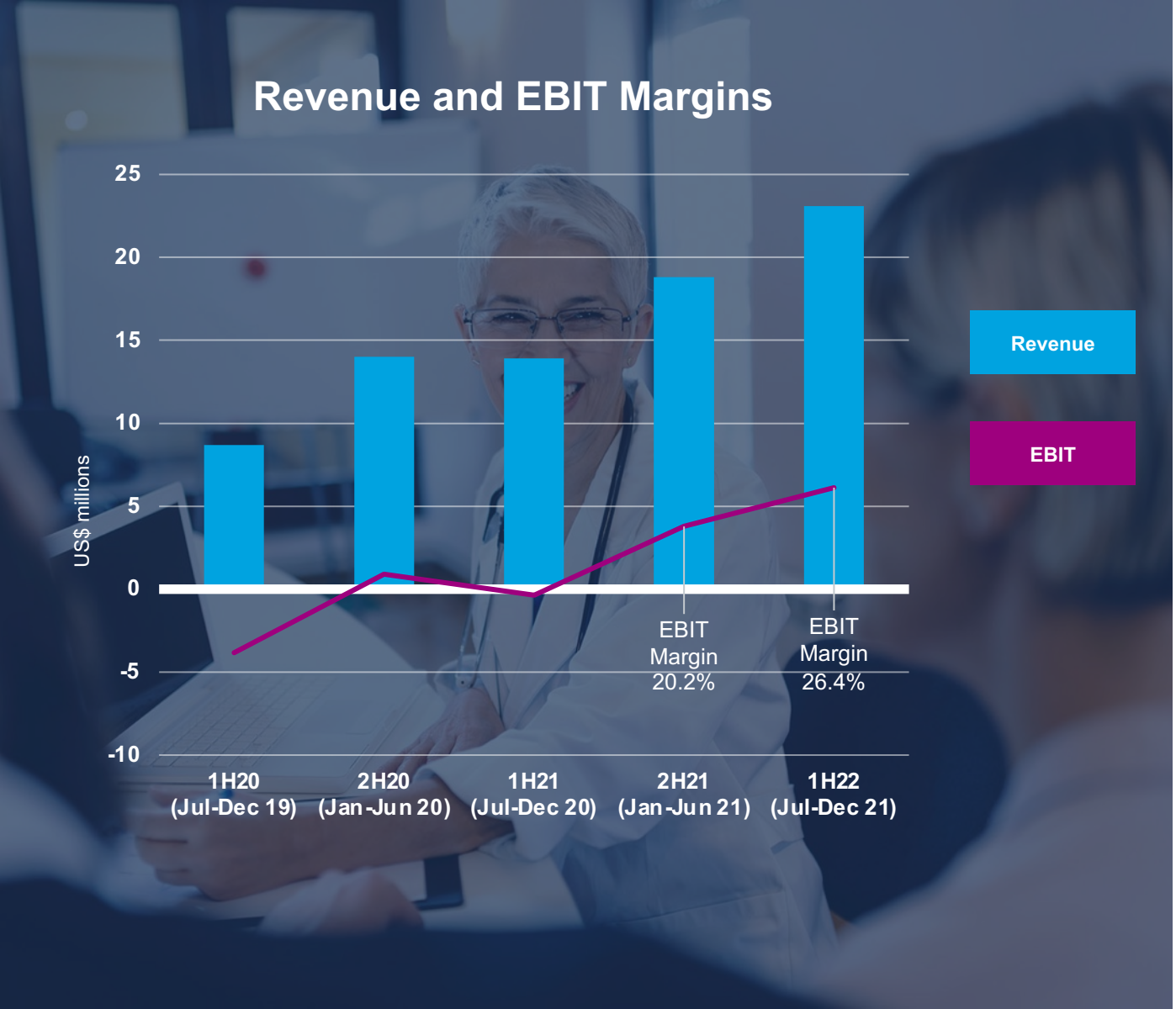
PCP loss of $0.4m
1H22 EBIT margin 26%

Net Cash Balance

$24.6m

An increase of $6.1m from a year ago, including $4.2m operating cash inflow

PCP: Previous Corresponding Period
EBIT: Earnings Before Interest & Tax



Operating Leverage

Growth in Clinical Trials sales contracts has resulted in increased revenue, especially over the last two half-year periods.

At the same time, Healthcare revenue has increased following the execution of the global agreement with Eisai.

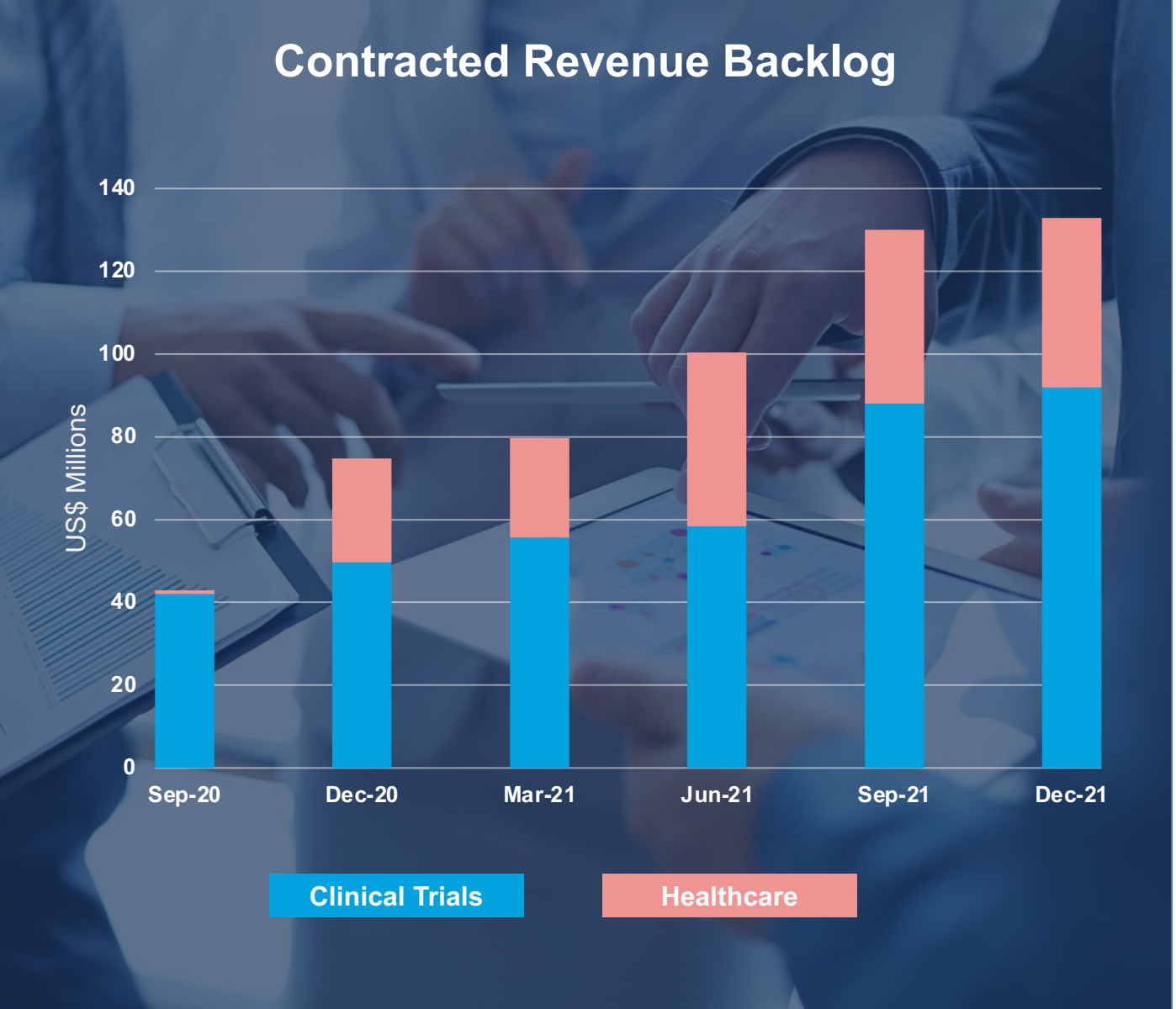
Margin expansion in 1H22 reflected features of the Clinical Trials business, such as:

- Higher software license revenue mix in total revenue;
- Existing staffing capacity; and
- Focus on efficiency.

(see page 12 for further detail)

EBIT margin in coming periods is expected to normalise in a range of 18% - 24%, depending upon software license revenue mix in each period.

Longer term margin expansion will be possible when Healthcare revenue exceeds contracted minimums.

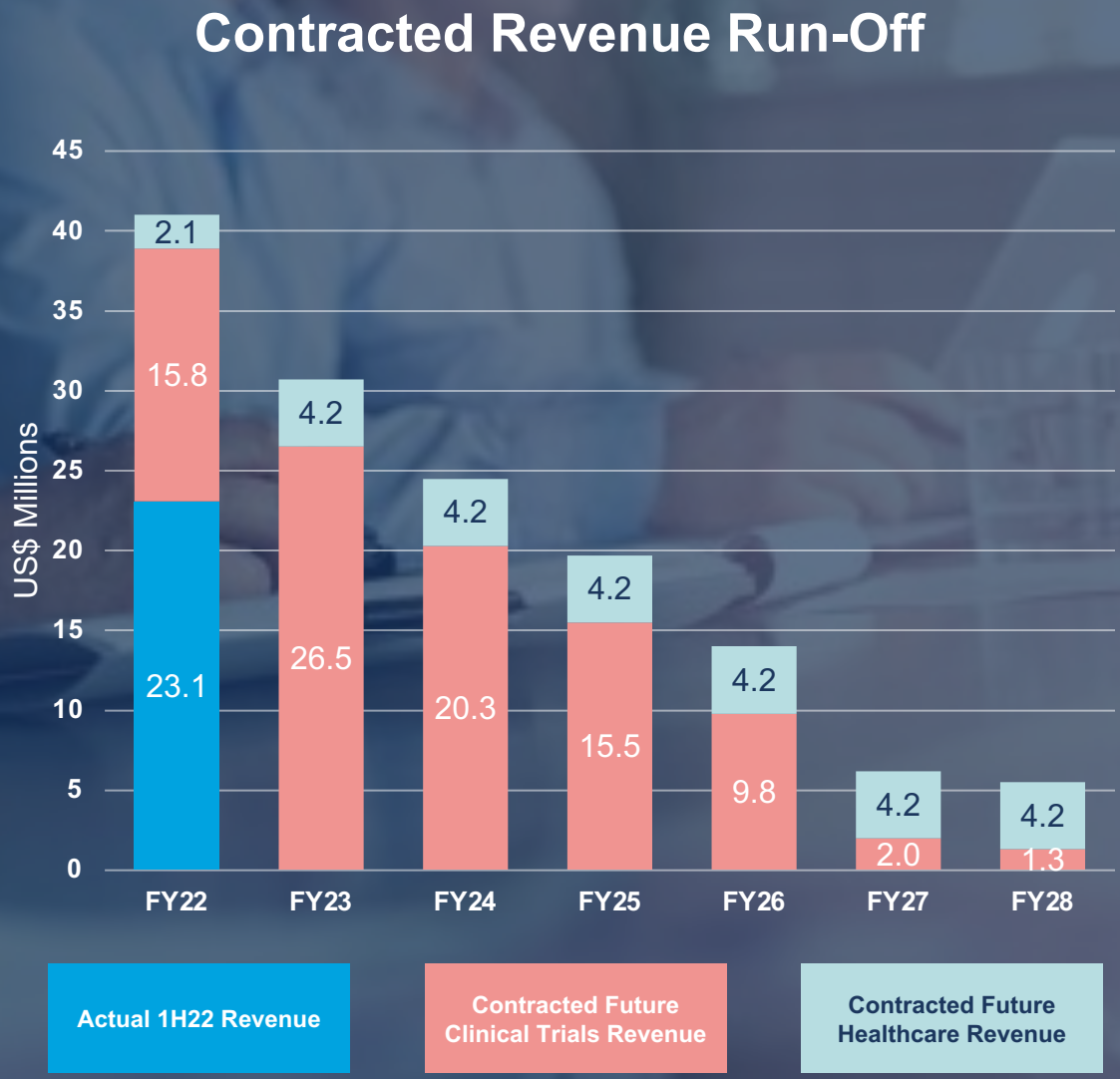


Year-On-Year Growth in Revenue Backlog

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

$132.9m Backlog at 31-Dec-21, up 78% year-on-year

- Clinical Trials Backlog $92.0m
  - Up 85% year on year
- Healthcare Backlog $40.9m
  - Up 63% year on year



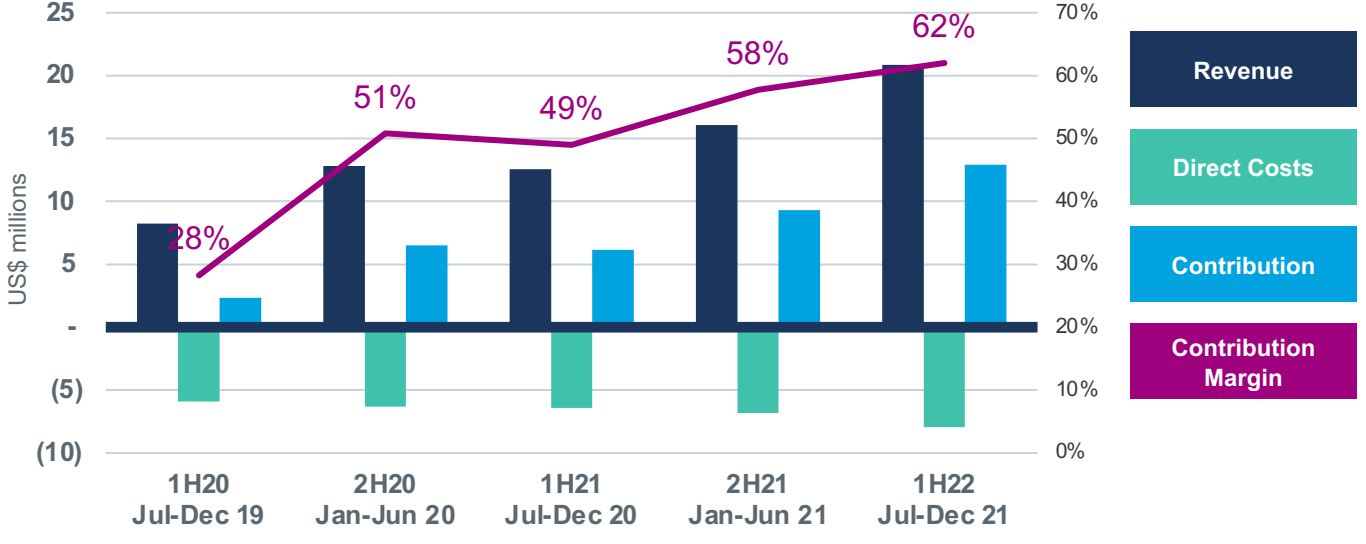
With Sales Growth, Revenue to be Recognised from Backlog in Future Periods is Growing

This time last year, FY22 contracted revenue was $20.1m *(of which $15.8m related to Clinical Trials)*, whereas today our FY23 contracted revenue is $30.7m *(of which $26.5m related to Clinical Trials)*

	Current As at Dec-21 US$	PCP As at Dec-20 US$	Growth US$	Annual Change %
Yr 1	41.0	26.1	14.9	57%
Yr 2	30.7	20.1	10.6	53%
Yr 3	24.5	14.9	9.6	64%
Yr 4	19.7	9.6	10.1	105%
Yr 5	14.0	6.5	7.5	115%

Clinical Trials – Our Established Business

US$ millions	1H20	2H20	1H21	2H21	1H22
Revenue	8.25	12.82	12.58	16.09	20.85
Direct Costs	(4.22)	(4.56)	(4.92)	(4.97)	(6.36)
SG&A Costs	(1.70)	(1.75)	(1.50)	(1.83)	(1.56)
Contribution	2.33	6.51	6.16	9.29	12.93
Contribution Margin	28%	51%	49%	58%	62%



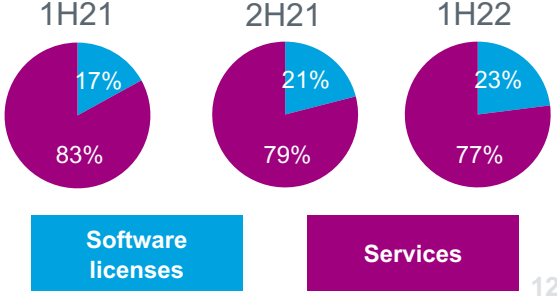
Revenue growth and improved margin

Growth in sales contracts over recent years is providing increased revenue.

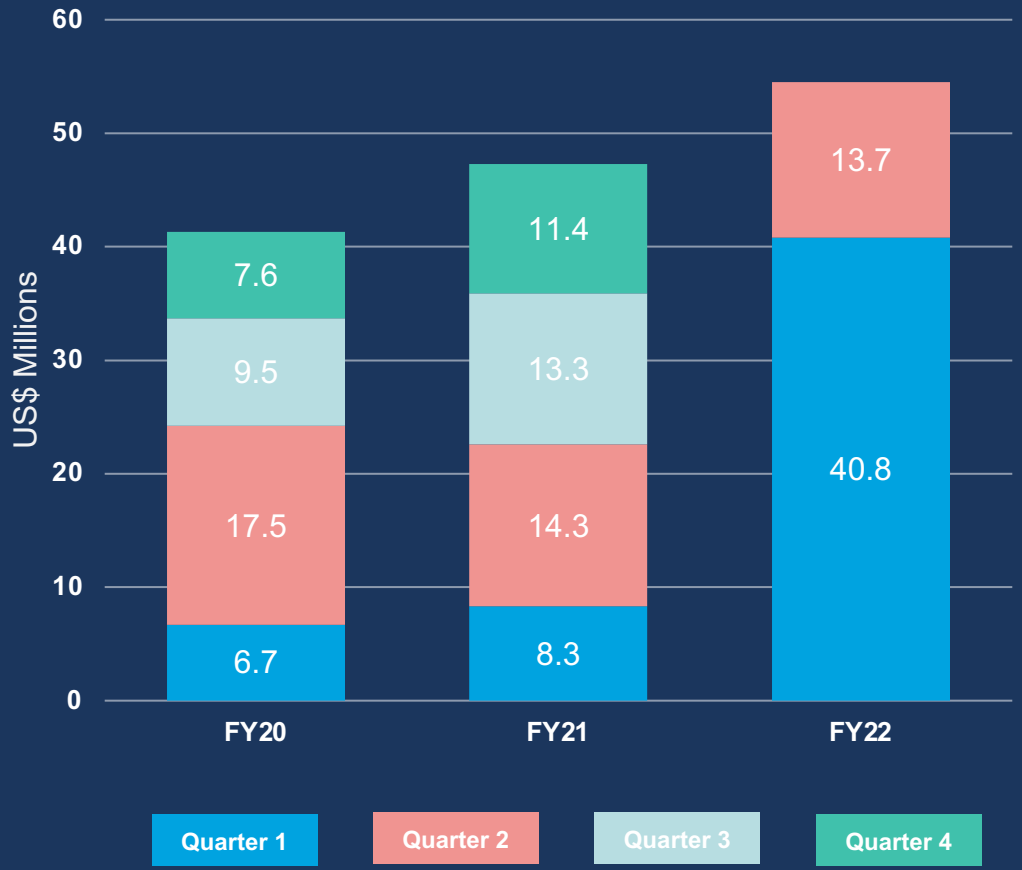
Contribution margin benefitting from increased software license mix and improved utilization of existing capacity within the segment, allowing management to maintain tight cost control.

Contribution margin in coming periods is expected to normalise in a range of 54% - 60%, depending upon software license revenue mix in each period.

Software License mix:



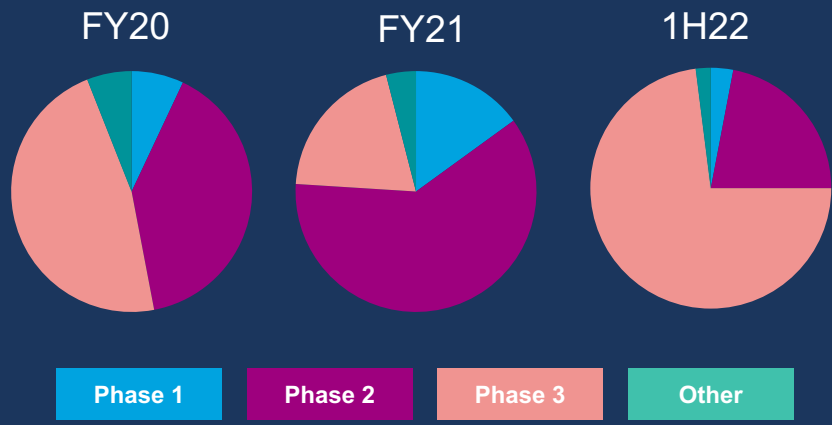
Clinical Trials Sales Contracts



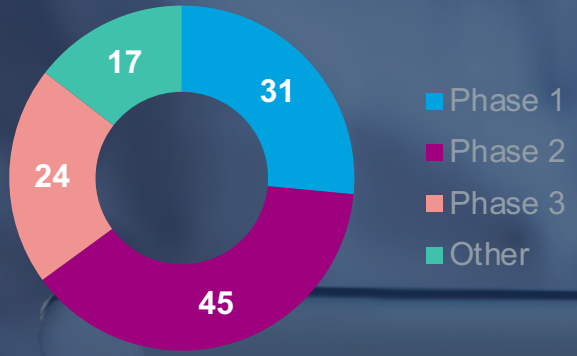
Record 1H sales contracts

- 141% increase over the same period last year
- 90% of the value of 1H22 sales contracts relate to Alzheimer's

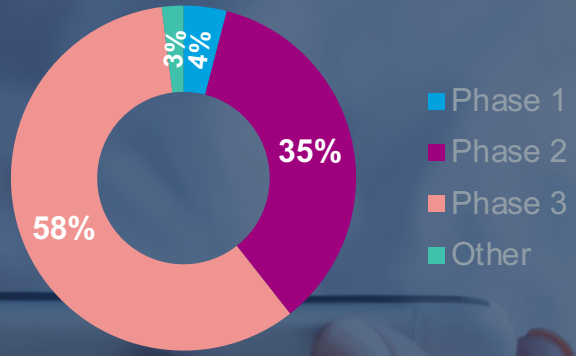
Value of contracts signed, by study phase



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:

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

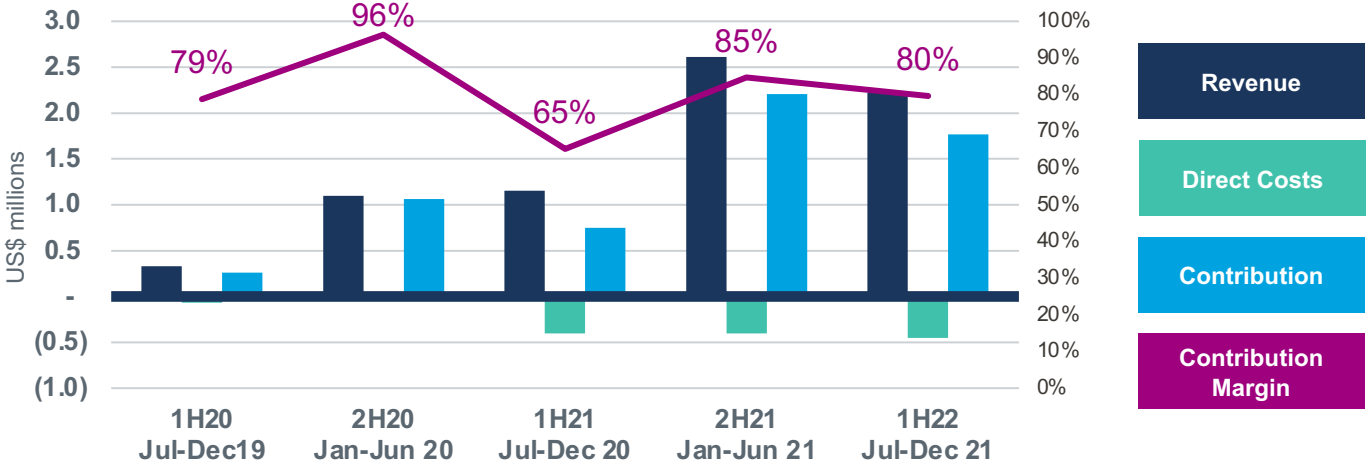
It is important to note that Cogstate is working on Alzheimer's trials that are not posted to clinicaltrials.gov.
Results submission is not required under FDAAA 801 for a clinical trial that is not an Applicable Clinical Trial.
For example, a trial conducted entirely outside the USA is not an Applicable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

Clinical Trials Business Update

Growing and Diverse Portfolio	Currently running 117 clinical trials with a revenue backlog of US$92.0 million across more than 30 different indications and more than 70 customers.
Improved Regulatory Landscape	Recent decisions by the FDA neurology division are indicative of a more favorable regulatory backdrop.
Alzheimer's Disease Foothold	Continuing to see new Alzheimer's disease trials in the sales pipeline, including new studies for existing and new compounds (from both existing and new customers). Positive comments from large pharma companies (such as Eli Lilly & Eisai) in respect of upcoming trials in their most recent quarterly presentations.
Decentralised Trials Adoption	Existing decentralised trials progressing well in multiple indications, demonstrating utility of Cogstate assessments and central rating solutions in virtual trial environment. New opportunities in discussion with increased marketing push in this area, including upcoming webinar on 09-Mar.
Sales Strategy Execution	In addition to direct sales via Cogstate business development team, channel sales strategy has become more formalised with the appointment of a dedicated Channel Manager focused on CROs and eCOA providers. New sales for Cogstate generated in conjunction with and via Clario (previously known as ERT) support the channel sales strategy.
Tech Improvements Focused on Sales	Investment is being made in improved integration into channel partners, including improved API (application programming interface). Better and easier integration results in an improved experience for the customer and less operational burden for Cogstate and its channel partner.
Tech Improvements Focused on Efficiency	Work is ongoing in respect of release of technology-enabled processes that will further drive efficiency in the support of clinical trials. As the size of the portfolio grows, there will be opportunities for economies of scale.

Healthcare – Our Next Frontier

US$ millions	1H20	2H20	1H21	2H21	1H22
Revenue	0.33	1.10	1.15	2.61	2.22
Direct Costs	(0.07)	(0.04)	(0.40)	(0.40)	(0.45)
Contribution	0.26	1.06	0.75	2.21	1.77
Contribution Margin	79%	96%	65%	85%	80%



Eisai product launch stage begins

Revenue represents amortisation of contractual minimum payments from Eisai.

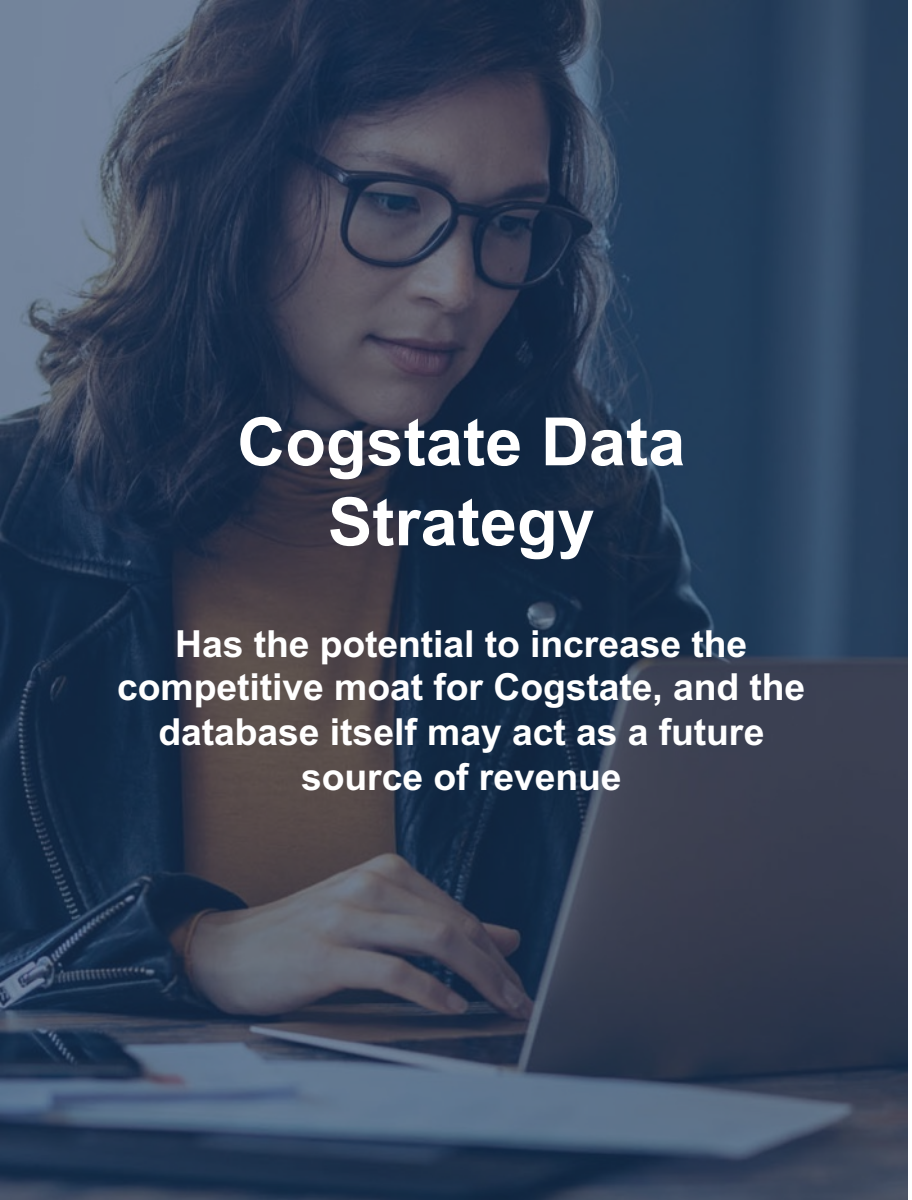
First invoice of quarterly minimum cash payments began in 2Q22.

Revenue change between 2H21 and 1H22 represents change in treatment of Eisai reimbursement of costs

- Treated as revenue in 2H21
- Treated as reduction in software development (overhead) costs in 1H22

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.
Positive Data on Self-testing 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.
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.



Cogstate Data Strategy

Has the potential to increase the competitive moat for Cogstate, and the database itself may act as a future source of revenue

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.

FY 2022 Outlook

Clinical Trials

Revenue:

- 2H22 range of $19m - $22m. Full year FY22 range of $40m - $43m
  - 2H22 revenue dependant on the value of new sales contracts executed in 2H22, but supported by strong sales pipeline

Contribution Margin:

- 2H22 in the range of 54% - 57%. Full year FY22 in the range of 58% - 61%. *(upgrade from prior guidance of 54% for FY22)*
  - Possible upside to gross contribution margin depending upon software license revenue mix in 2H22

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 *(Downgrade from previous guidance of $0.5m loss)*
- FY22 Operating Expenses expected to remain in the range of 31% to 33% of revenue, an improvement of 5% to 7% percentage points on prior year FY21 *(Guidance unchanged)*
- 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 *(Upgrade from previous guidance of 15%-18%)* 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


Financial Charts

Financial Summary – Income Statement

	1H21 Jul-Dec 2020 US$ Million	2H21 Jan-Jun 2021 US$ Million	1H22 Jul-Dec 2021 US$ Million	Calendar Year 2021 US$ Million
Group Revenue	13.9	18.8	23.1	41.9
Clinical Trials Revenue	12.6	16.1	20.8	36.9
Clinical Trials Contribution	6.2	9.3	12.9	22.2
Clinical Trials Contribution Margin	49.2%	57.8%	62.0%	60.2%
Healthcare Revenue	1.1	2.6	2.2	4.8
Healthcare Contribution	0.8	2.2	1.8	4.0
Healthcare Contribution Margin	72.7%	84.6%	81.8%	83.3%
Research Contribution	(0.2)	(0.3)	(0.4)	(0.7)
Operating Expenses	(6.0)	(6.2)	(7.0)	(13.2)
EBITDA	0.7	5.0	7.3	12.3
EBITDA Margin	5.0%	26.6%	31.6%	29.4%
EBIT	(0.4)	3.8	6.1	9.9
EBIT Margin	(2.9%)	20.2%	26.4%	23.6%

Strong revenue growth driven by the significant increase in new Clinical Trial contracts over recent periods.

Improved contribution margin, with higher license fee mix and improved utilisation of capacity in Clinical Trials increasing overall gross margin by 2.2% (compared to 2H21 - the most recent half year period).

Improved EBIT margin as operating expenses decreased to 31% of revenue (vs 43% in 1H21 and 33% in 2H21).

Capitalisation of employee development expenditure reduced due to focus on development of Eisai product through 1H22 and reimbursement of those costs by Eisai:

- 1H22 $0.06m
- 2H21 $1.45m
- 1H21 $1.19m

This reflects work focus areas during 1H22, not a change in capitalisation policy.

EBIT growth $6.1m for 1H22, an increase in EBIT margin to 26.4% compared to 20.2% for 2H21.

Financial Summary – Balance Sheet

	31 Dec 2020 US$ Million	30 Jun 2021 US$ Million	31 Dec 2021 US$ Million
Cash	21.3	23.6	25.3
Trade Receivables	5.5	7.9	8.8
Property, Plant & Equip	1.2	1.2	1.1
Intangibles	8.3	8.7	8.6
Other Assets	10.7	10.0	8.4
TOTAL ASSETS	47.0	51.4	52.2
Trade payables	7.7	8.7	6.8
Deferred revenue	16.1	16.0	12.1
Employee provisions	2.1	2.5	2.3
Other liabilities	5.7	2.4	2.8
TOTAL LIABILITIES	31.6	29.6	24.0
NET ASSETS	15.4	21.8	28.2

Net cash balance of $24.6m, which is an increase of $6.1m compared to the same time last year.

Net Cash calculated as gross cash less borrowings and less cash receipts received in advance for future pass-through charges.

Intangibles decreased, reflecting changes to software development focus during the half year.

Deferred revenue relates to amounts received from customers, but not yet recognised as revenue:

- Clinical Trials $ 0.9m
- Healthcare (Eisai payments) $11.2m

Trade Receivables increased due to the timing of new contract signings and completion of contract deliverables.

Net Assets of $28.2m compared to $15.4m at the same time last year.

Financial Summary – Cash Flow

	1H21 31 Dec 2020 US$ Million	2H21 30 Jun 2021 US$ Million	1H22 31 Dec 2021 US$ Million
EBIT	(0.4)	3.8	6.1
Adjustments:			
Deferred Income	15.0	(0.1)	(3.9)
Working Capital	(1.9)	(2.1)	(2.5)
Depreciation & Amortisation	1.1	1.2	1.1
Non-cash employee benefits	0.3	0.2	0.9
Tax Paid	(0.8)	(0.1)	(0.5)
Other	(0.1)	0.0	0.1
Net Operating Cash Flow	13.2	2.9	1.3
Total Cash Flow	11.0	2.3	1.7
Net Cash Balance	18.5	22.4	24.6

Net operating cash flow of $1.3m for 1H22, continuing positive cashflow trend over recent periods.

Working capital increased, reflecting an increased receivables balance, increased prepayments (specifically relating to insurance) and increased payables.

Deferred revenue largely relates to amortisation of the Eisai upfront payment.

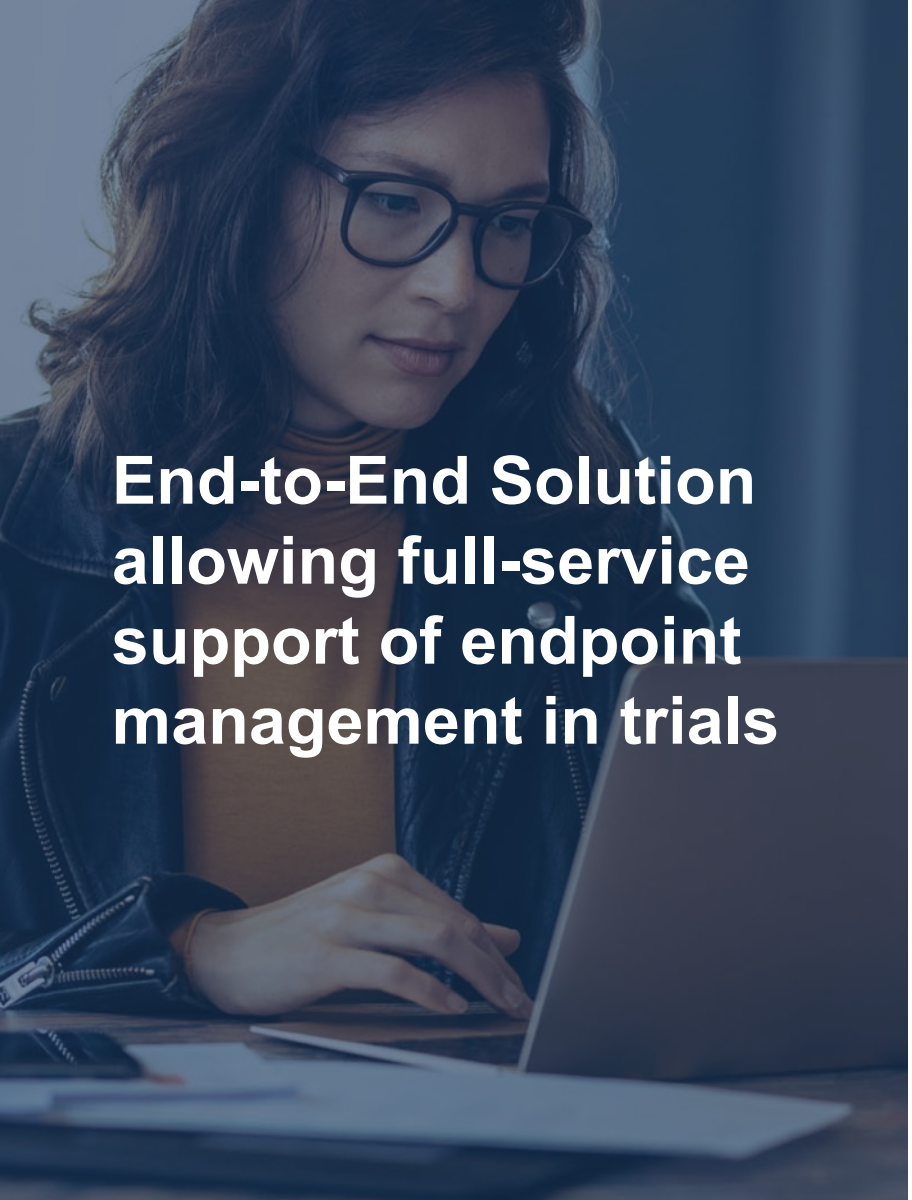

Additional Materials


Clinical Trials

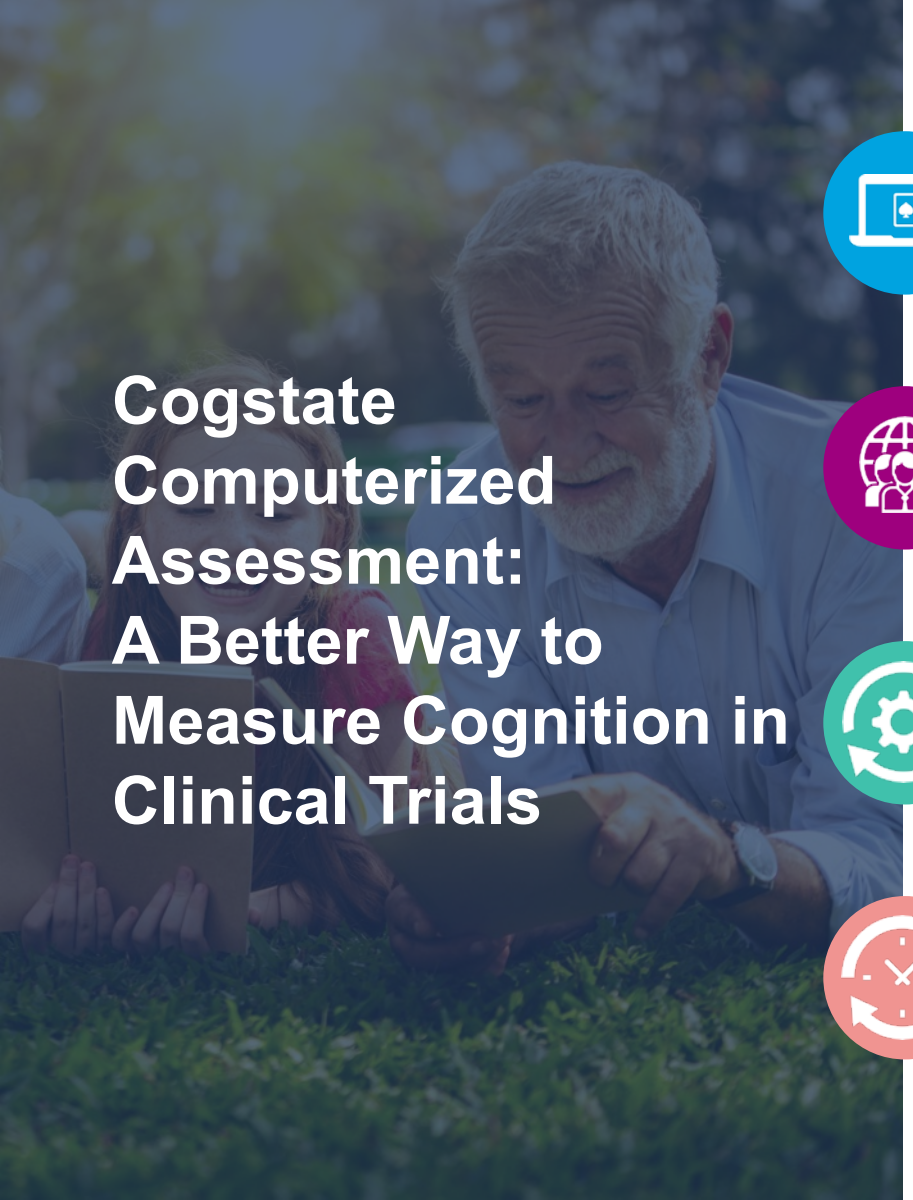
Experienced experts that act as trusted partners with customers

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



End-to-End Solution allowing full-service support of endpoint management in trials



Cogstate Computerized Assessment: A Better Way to Measure Cognition in Clinical Trials

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

Science backed by Data: Summary of Sensitivity and Specificity

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

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**

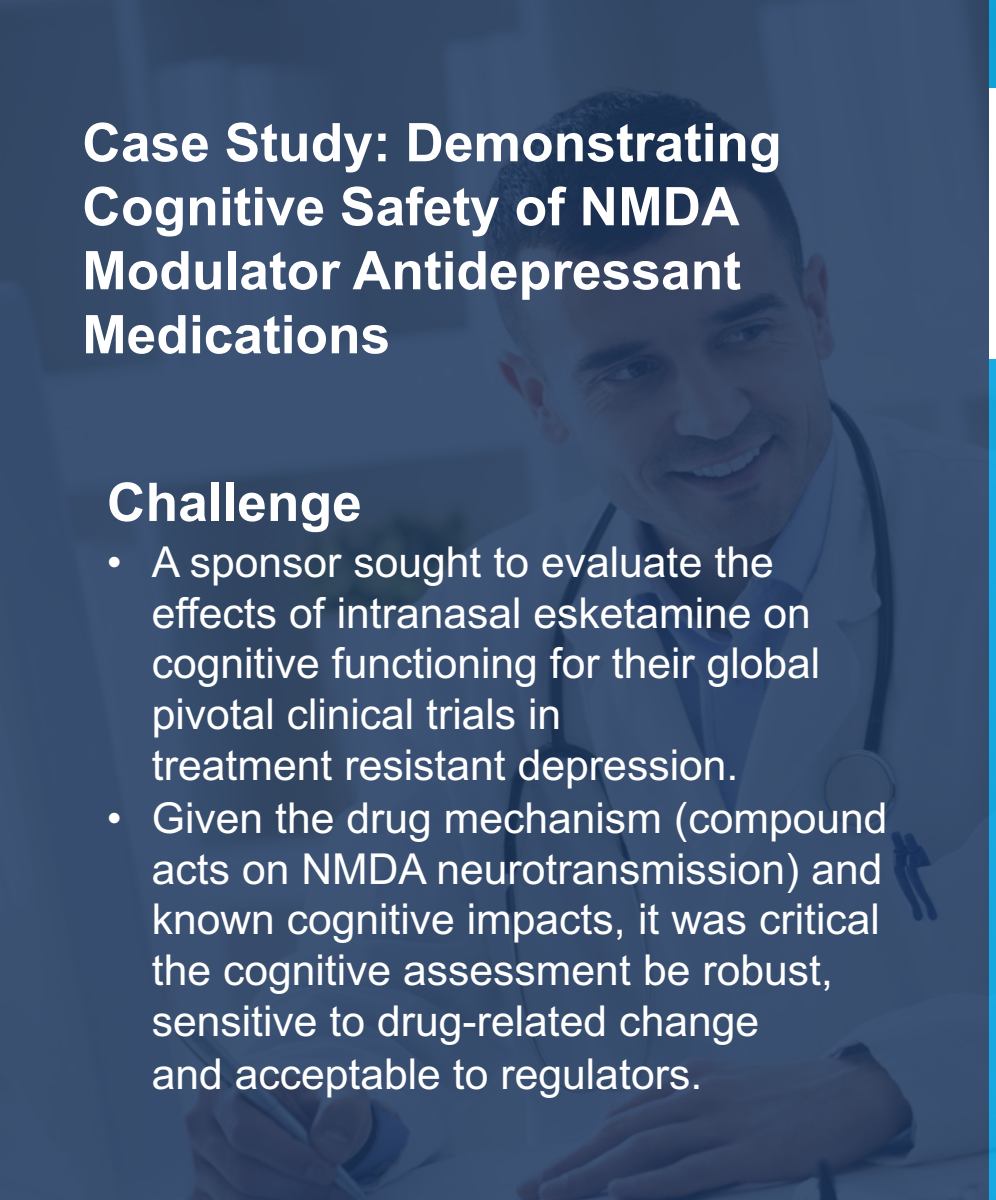
Challenge

- 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.

Outcome

- 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



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

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.

Outcome

- 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 in-clinic with 2-hour observation period post-dose for adults with TRD.

Case Study: At-home, Web-based Computerized 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 web-based, 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.

Outcome

- The Cogstate Brief Battery (CBB) was specifically configured for independent self-administration, which participants complete at-home 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

Outcome

- Cogstate provisioned validated, brief and game-like computerized 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


Healthcare

License Agreements

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

Global License

- 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

- 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

Commercials

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

- Fund any software development work required under the collaboration
- Manage all regulatory clearances and issues
- Responsible for all sales and marketing activities

Data Ownership

- All jointly owned (by Cogstate and Eisai)
- Including all data inputs by the user

Eisai: Revenue vs Cash

1 Japan

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

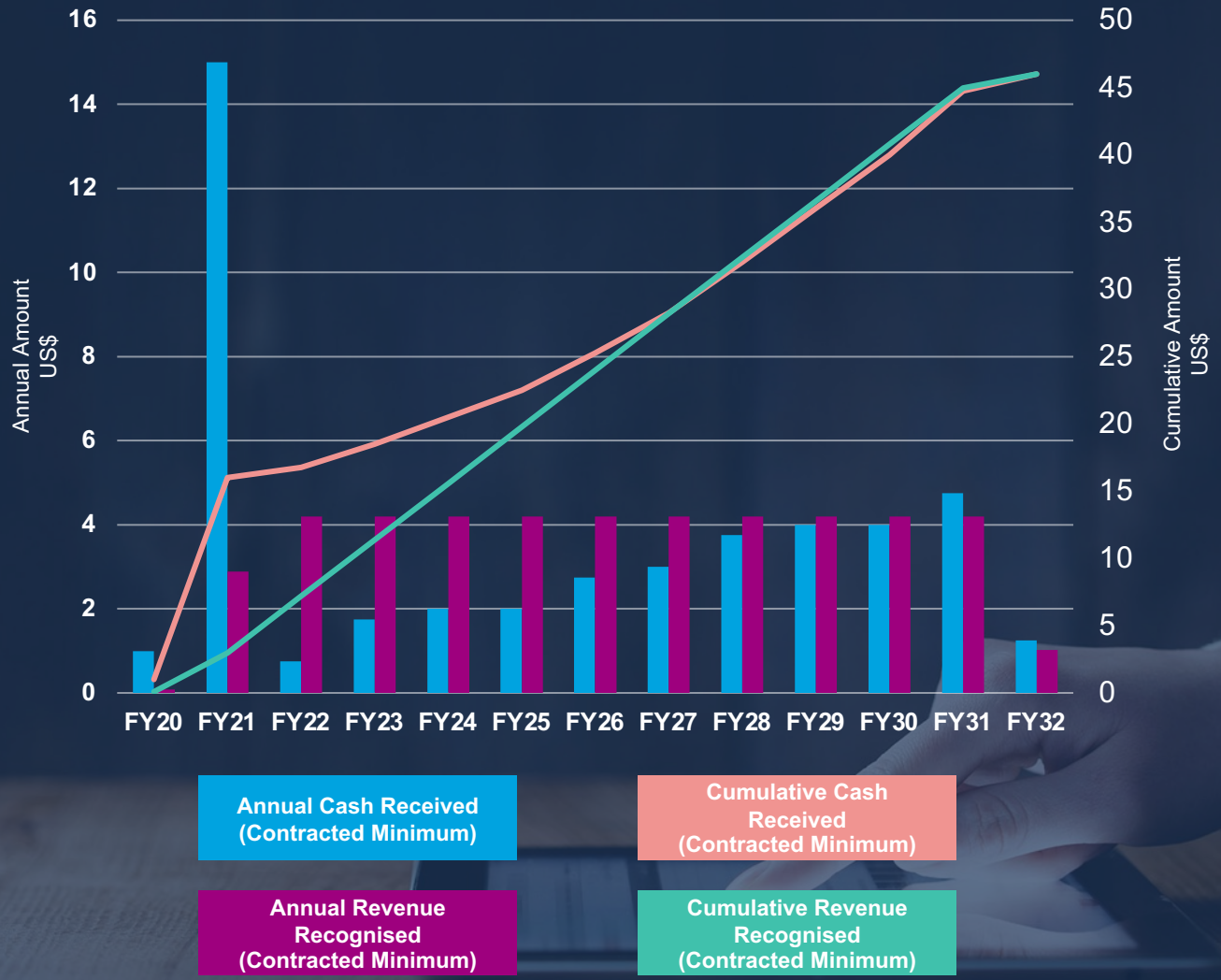
2 Rest of World

Revenue
$45m treated as deferred revenue to be recognised on a straight-line 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.

Cogstate