

ASX Announcement

30 August 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 year ended 30 June 2022 (FY22) 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 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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Investor Update

Including Results For The Financial Year Ended 30 June 2022
Presented August 2022

BRAIN HEALTH FOR ALL



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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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, has long dated contracted revenue, is earnings and cashflow positive, and has a strong net cash balance.

*Ranked by revenue, as at Dec 2021



Cogstate was founded in Melbourne, Australia, where approx. 22% of our workforce is based. We have a small presence in each of the UK and Japan, but most of our staff (74%) are based in the USA.



~ 387 team members, comprised of 203 employees + global network of consulting neuropsychologists

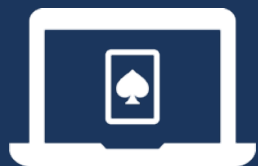


Our largest customer base is pharma / biotech companies developing new drugs or other treatments. Global clinical trials is a \$40B+ industry that seeks tools for better go/no-go decisions that can speed new therapies to market.



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

Cogstate Digital Assessments

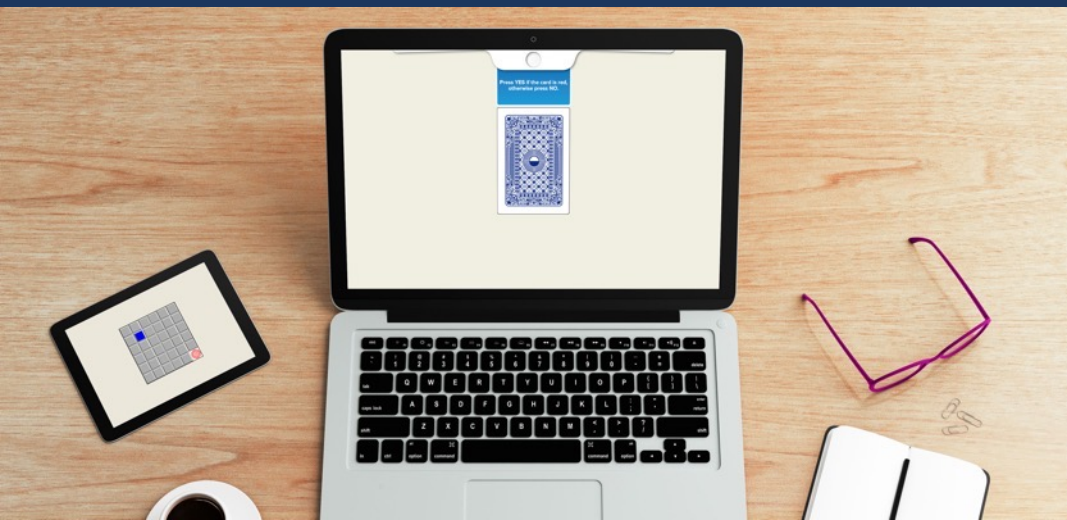


Computerized Cognitive Assessments

Traditional measures can be long, biased, and error prone, making it difficult to successfully conduct CNS trials.

Cogstate's proprietary computerized tests cover many domains of interest to drug developers and deliver heightened sensitivity:

- Standardized administration with automated scoring
- Brief assessment with high usability
- Tests designed to minimize the impact of practice, language or culture
- Strong scientific validation as demonstrated through hundreds of peer-reviewed studies




Published data
sets in hundreds
of journals
spanning 65+
indications

Bipolar disorder
Mild cognitive impairment **Haemophilia**
Schizophrenia Genetic disorders
Major depressive disorder **Narcolepsy**
Diabetic peripheral neuropathy **Insomnia** **Angelmans Syndrome**
Alzheimer's disease Multiple sclerosis (MS)
Obsessive compulsive disorder Hyponatremia **Tourette's syndrome**
Attention deficit hyperactivity disorder (ADHD) Prostate cancer
Glioblastoma Familial Hypercholesterolemia **Epilepsy**
Safety Migraine **Dementia** Hepatitis C
Parkinson's disease Lung carcinoma
Autism spectrum disorders Anemia
Cognition disorders
Down syndrome **HIV**
NSCLC
Phenylketonuria
Fragile X
Depression
Stroke



**In Clinical Trials,
Cogstate provides an
End-to-End Solution for
assessments in central
nervous system disease
trials**





FY22 saw a number of strategic initiatives and further penetration of our products

Strategic developments in FY22

- **Formation of a Scientific Advisory Board (SAB)**, comprising world-class neuroscience experts in cognitive assessment and drug development.
- **Expansion of our partnership with clinical trial data management leader, Clario**, to enhance our joint support of Central Nervous System research.
- **Inclusion of Cogstate digital assessments as part of the primary endpoint in the Ascend-LB study**, a phase 2 clinical trial in Dementia with Lewy Bodies (DLB) conducted by EIP Pharma Inc.
- **Expansion of Cogstate technology to consumers across the Asia region, through our partnership with Eisai Co., Ltd (Eisai)**. This includes launches in Taiwan and Hong Kong, marking the first release in the region outside of Japan.
- **Expanded involvement with major industry initiatives and consortia:**
 - Continued participation on the Davos Alzheimer's Collaborative (DAC)
 - Joined the Digital Medicine Society's (DiMe) Alzheimer's Disease and Related Dementias (ADRD) Digital Measures Development Project alongside partners including Biogen, Eli Lilly, Eisai, Merck, the Alzheimer's Drug Discovery Foundation (ADDF)
 - Joined the Decentralized Trials & Research Alliance (DTRA)
- **Increased adoption of decentralised clinical trial design** throughout the industry

Decentralised Clinical Trials Experience



Disease Areas

Cogstate has supported remote cognitive assessment in AD, MCI, FTD, PD, MS, PTSD, oncology, cardiovascular disorders, hypoparathyroidism, and a range of rare neurodevelopmental disorders



Assessments

Vineland Scales, Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS), Clinical Global Impression (CGI), CDR, MoCA, ADCS-ADL, NPI, FAQ, QoL-AD, C-SSRS, Category Fluency Test (CFT), and Cogstate tests in different configurations, such as the Cogstate Brief Battery (CBB), C3 Battery, ISLT, iDSST, and CPAL



Geographies

Cogstate has experience supporting central ratings and remote testing in North America (US and Canada), Europe (Italy, Spain, Netherlands), Asia (Japan), and Australia

FY22 Financial Highlights (All figures in US\$)

Strong earnings growth and solid cash position

Record clinical sales contracts executed


+74%

\$82.5m

Alzheimer's disease represented 84% of the value of contracts executed in FY22

Record contracted future revenue


+37%

\$139.1m

Strong contracted revenue pipeline

Record Group Revenue


+38%

\$45.0m

Clinical Trials up 41% to \$40.3m
Healthcare up 19% to \$4.5m

Record PBT


+84%

\$10.7m

Updated guidance in July 2022 was \$10.3m-\$10.8m.

Strong operating net cash flow


-46%

\$9.0m

Excl. customer pass-through costs.
FY21 included \$13.8m net proceeds from Eisai upfront license fee payment

Net Cash balance

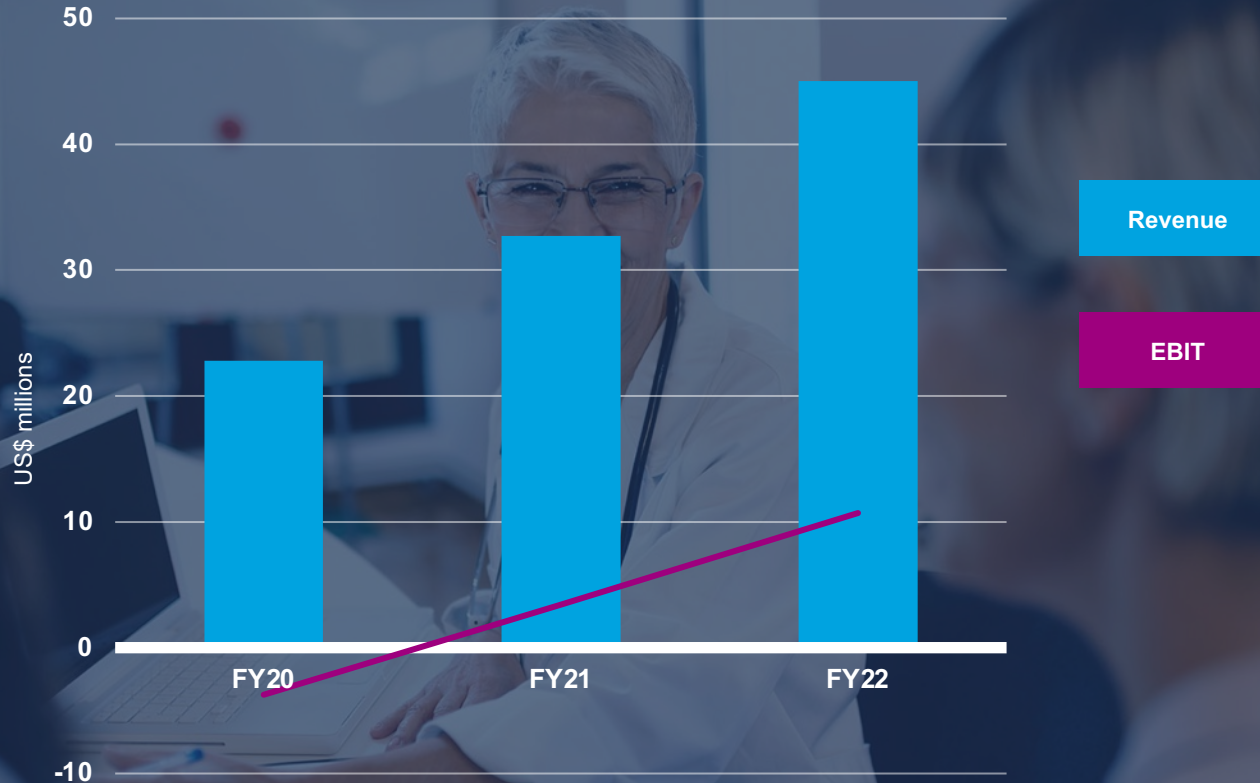

+28%

\$28.7m

An increase of \$6.3m during the year



Revenue and EBIT Margins 30 June Financial Year



Operating Leverage

Growth in Clinical Trials sales contracts has resulted in increased revenue.

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

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

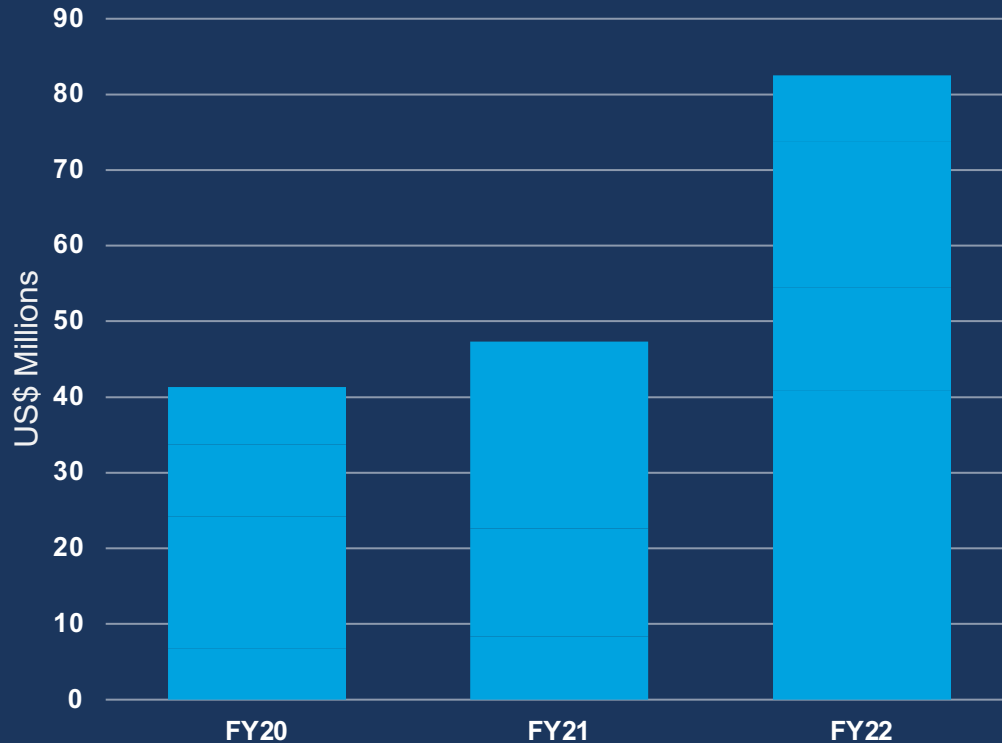
- Higher software license revenue mix in total revenue;
- Existing staffing capacity; and
- Focus on efficiency.

Our financial model provides for EBIT margins in the range of 20-24%. The margin in any given period will vary according (i) the revenue mix, and (ii) investment decisions that may impact shorter term results.

In general, as revenue increases, margins should increase.

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

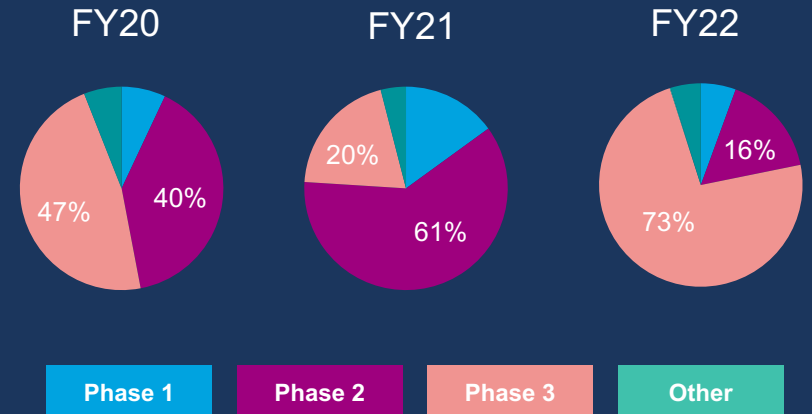
Clinical Trials Sales Contracts



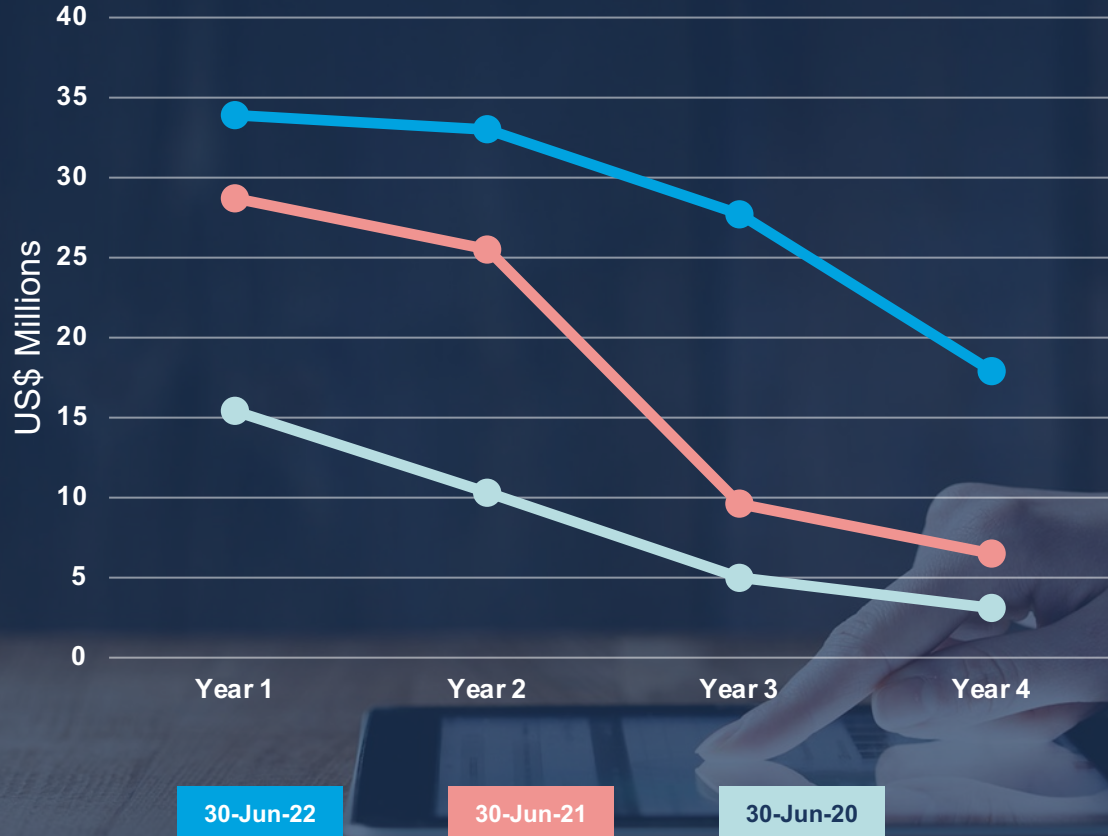
Record FY22 sales contracts

- 74% increase over the prior year
- 84.2% of the value of FY22 sales contracts relate to Alzheimer's (65.3% in PCP)
- 73% of the value of FY22 sales contracts relate to phase 3 trials

Value of contracts signed, by study phase



Contracted Revenue At 30 June



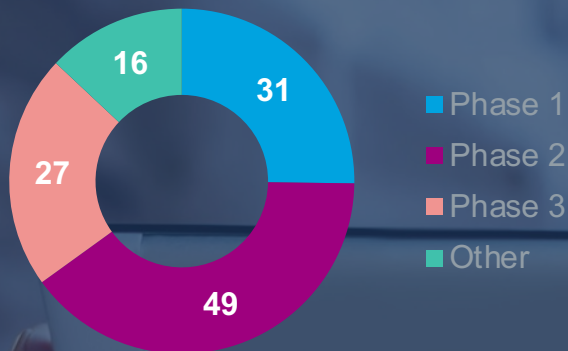
Growing Momentum

Analysis of contracted revenue over the last 3 years, at 30 June, demonstrates the future revenue growth, especially as we look forward to years 2-4.

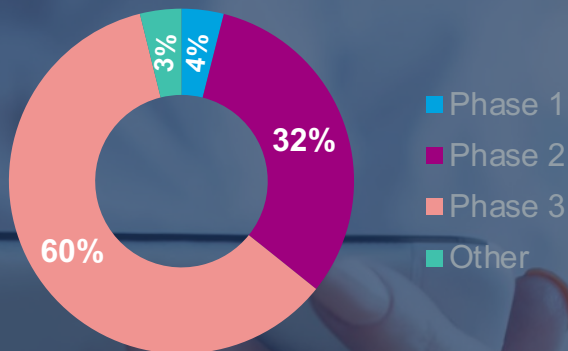
This analysis provides insight to continued revenue growth for the business in future years.

Data as at 30 June 2022

Cogstate is working on 123 Ongoing Clinical Trials



Cogstate Clinical Trials revenue backlog (%), by phase



Phase 1 studies represent 25% (31 of 123) of ongoing studies but only 4% of backlog.

Phase 2 studies represent 40% (49 of 123) of ongoing studies and 32% of backlog.

Phase 3 studies represent 22% (27 of 123) of ongoing studies and 60% of backlog.

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

The 80 phase 1 & 2 trials form part of Cogstate's future sales pipeline.

Follow-On Revenue From Existing Trials

As drugs progress through the development pathway they may generate later phase contracts for Cogstate, which are generally significantly larger in value

Alzheimer's Importance

Of 123 ongoing clinical trials, a total of 30 (or 24%) are in Alzheimer's disease.

>80% of revenue backlog relates to Alzheimer's disease due to large phase 3 trials.

Cogstate Share of Alzheimer's Trial Market

Analysis as at 30 June 2022

All Ongoing Alzheimer's Trials

There are 130 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 19 trials to the clinicaltrials.gov dataset. That represents a 14.6% market share of all ongoing AD studies

Trials initiated Since 01-Jul-2019

Since 01-Jul-2019, 94 Alzheimer's trials have been posted to clinicaltrials.gov that are still ongoing. Of the Alzheimer's trials that Cogstate is supporting, we were able to map 16 trials to the clinicaltrials.gov dataset. That represents a 17% market share of ongoing AD studies started since 01 July 2019 – up from 13.3% as at 31-Dec-21. This data is broken down as follows:

	Total Alzheimer's Trials clinicaltrials.gov	Cogstate Alzheimer's Trials Mapped to clinicaltrials.gov	Cogstate Market Share
Phase 1	22	4	18%
Phase 2	45	9	20%
Phase 3	27	3	11%
Total	94	16	17%

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.

A man with glasses and a blue striped shirt is sitting at a desk, looking thoughtful. He has a green pen in his mouth. The background is a blurred office setting with whiteboards. The text "Financial Performance" is overlaid in the center in a large, white, sans-serif font.

Financial Performance

Profit & Loss

US\$ Million	1H22	2H22	FY22	FY21	YTY%
Revenue	23.1	21.9	45.0	32.7	37.6%
Gross Contribution	14.3	12.4	26.7	17.9	48.7%
Contribution margin	61.9%	56.6%	59.3%	54.9%	4.4% pts
EBITDA	7.3	5.8	13.0	5.7	127.8%
EBITDA margin	31.4%	26.3%	28.9%	17.5%	11.4% pts
EBIT	6.1	4.6	10.7	3.4	216.7%
EBIT margin	26.5%	20.8%	23.8%	10.4%	13.4% pts
Profit before Tax	6.1	4.6	10.7	5.8	83.7%
Profit after Tax	4.1	3.4	7.5	5.2	43.7%
Underlying Profit before Tax*	6.1	4.6	10.7	3.9	175.9%
Underlying Profit before Tax margin	26.5%	20.9%	23.8%	11.9%	11.9% pts

* Underlying PBT is a non-statutory measure that excludes one-off items in FY21: US PPP loan forgiveness +\$2.4m and Advisor fees in relation to the Eisai Global Partnership -\$0.5m.

Strong revenue growth driven by record Clinical Trial contract sales in FY22 and continued contributions from both the Eisai Global and Japan partnerships

Increase in contribution margin, highlighting the higher SW license mix and improved productivity in Clinical Trials

Staff Costs (direct & indirect) increased 17% to \$24.4m

Depreciation & Amortisation consistent with PCP as amortisation of intangible assets continues

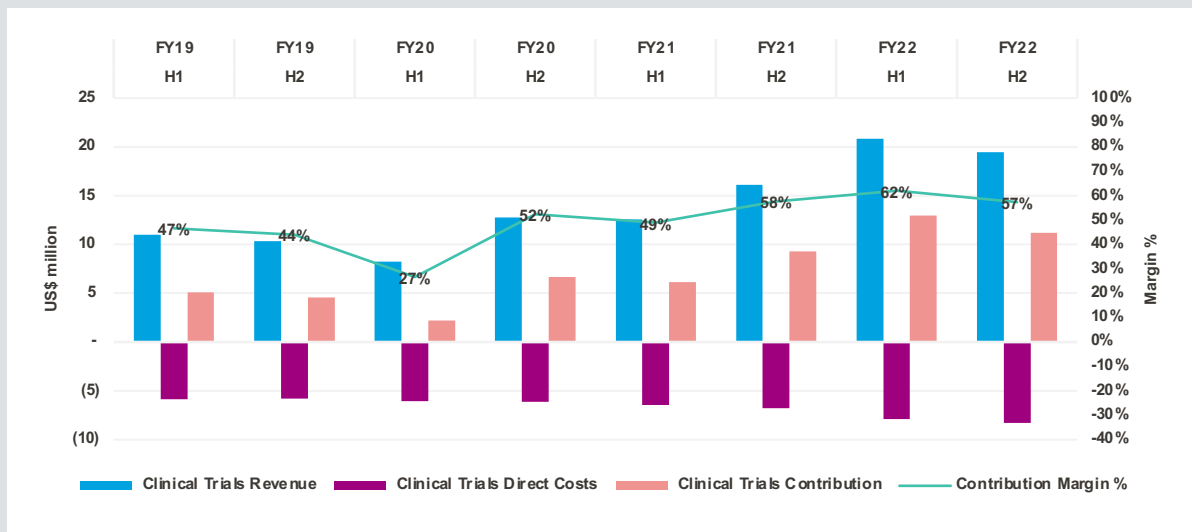
PBT growth: up 84% to \$10.7 million





Clinical Trials – our established business

US\$ millions	1H22	2H22	FY22	FY21	YTY%
Revenue	20.8	19.5	40.3	28.7	40.7%
Direct Costs	(7.9)	(8.3)	(16.2)	(13.2)	(22.6%)
Contribution	12.9	11.2	24.1	15.5	56.1%
Contribution margin	62.0%	57.5%	59.8%	53.9%	5.9% pts



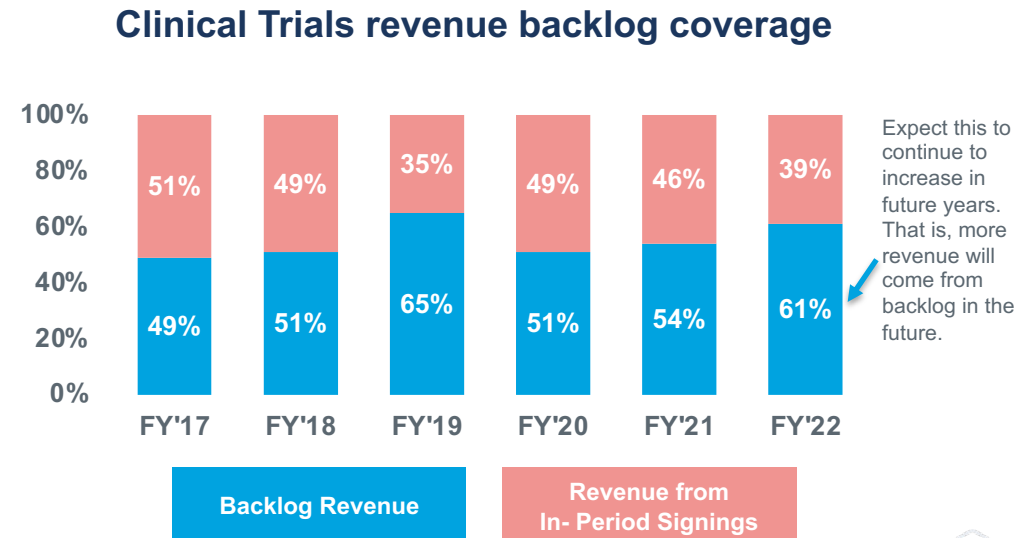
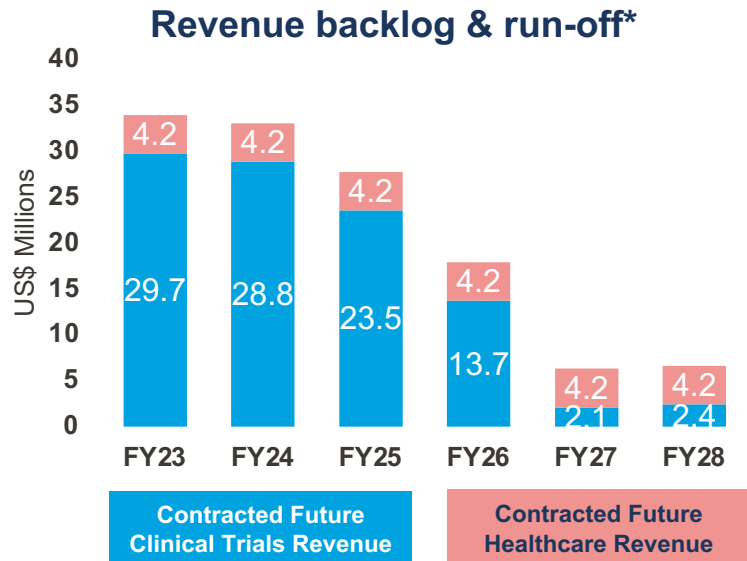
Another record-breaking year

- Record revenue driven by the substantial increase in Clinical Trials sales contracts executed in recent periods and during FY22.
- Contribution margin in FY22 increased to 60% (PCP 54%), benefitting from higher SW license mix and continued productivity improvements.
- Study delays, completely outside Cogstate control, have resulted in lower Clinical Trials revenue and therefore lower gross margins in 2H22. This currently continues into 1H23 but anticipated to be resolved going into 2H23
- Expect FY23 Clinical Trials contribution margins to be stabilize at 2H22 levels – 57%-58% with potential upside depending on level of SW license mix.



Revenue Backlog run-off and coverage

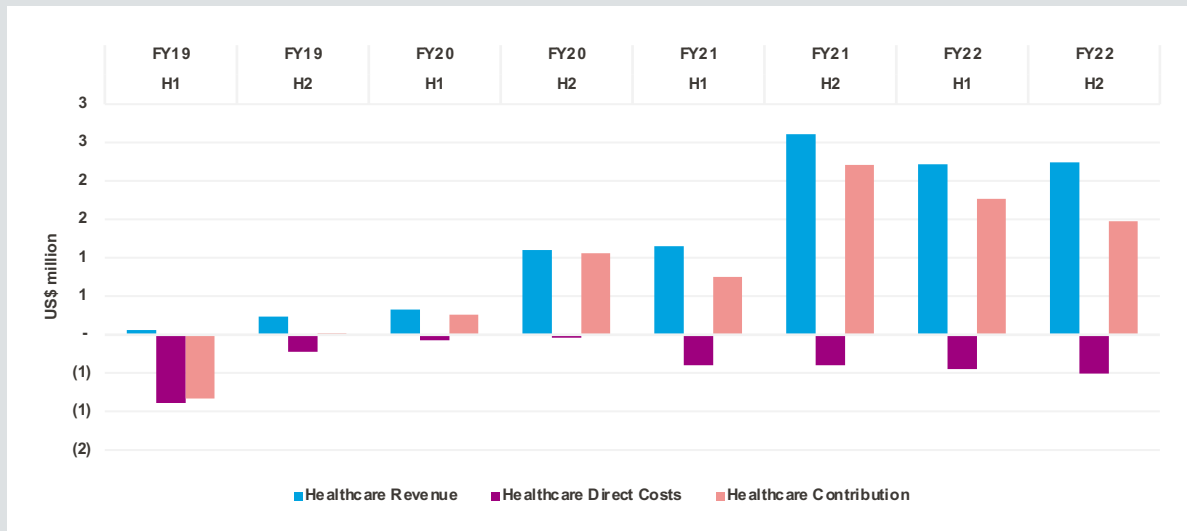
- Clinical Trials backlog \$100.2m (\$29.7m to be realised in FY23)
- Healthcare backlog \$38.8M (\$4.2m to be realized in FY23).
- Over the last 5 years, revenue backlog at the beginning of each year has ranged between 49% and 65% of final revenue for that year. As revenue and backlog both grow, contracts executed during the year are expected to have less impact on the revenue result in that same year.





Healthcare – our next frontier

US\$ millions	1H22	2H22	FY22	FY21	YTY%
Revenue	2.2	2.3	4.5	3.8	18.6%
Direct Costs	(0.4)	(0.8)	(1.2)	(0.8)	(51.8%)
Contribution	1.8	1.5	3.2	3.0	9.6%
Contribution margin	79.8%	65.8%	72.8%	78.7%	(5.9% pts)



Eisai Global & Japan License Agreement

- \$4.2m of revenue recognised in relation to Eisai royalty payments. This leaves \$38.8m to be recognised over the remaining period of the global licence.
- The earnings contribution from the segment increased 9.6% on PCP to \$3.2m, representing a contribution margin of 73%. The margin was lower than the 78% achieved in the PCP due to costs incurred to manage the Eisai relationship.
- Consistent with FY22, FY23 will see 12 months of royalty payments from Eisai Global and Japanese licences

*Refer to page 38 for details of the FY20 revenue restatement

Cash Flow

US\$ Million	FY22	FY21	YTY%
EBITDA	13.0	5.7	128%
Working capital movement	(4.0)	(2.5)	n/a
Upfront receipt from Eisai	0.0	13.8	n/a
Government Grants	0.0	0.1	n/a
Other	0.0	(0.3)	n/a
Net Operating Cash Flow pre pass-through charges	9.0	16.8	(46%)
Pass-through charges	0.7	(0.7)	199%
Net Operating Cash Flow	9.7	16.1	(40%)
Non Government Grants	0.00	0.6	n/a
Capital Expenditure	(0.4)	(0.6)	32%
Capitalised Software Development	(3.1)	(2.6)	(19%)
Other	0.0	0.0	n/a
Net Investing Cash Flow	(3.5)	(2.6)	(35%)
Financing Cash Flow	0.8	(0.2)	n/a
Net Increase in Cash	7.0	13.3	(48%)

Operating cash flow includes:

- Strong growth in EBITDA
- Working capital movement includes: \$4.2m of deferred revenue associated with the Eisai licencing agreement (FY21 \$2.9m), as well as an increase in Trade Receivables to reflect the higher revenue, offset by non cash Share Based Payments of \$2.2m (FY21: \$0.5m)
- FY21 includes an upfront royalty payment of \$13.8m (net of costs) from Eisai for the Global licence contract
- Cash Flow includes receipts of \$0.7m associated with pass-through charges to Clinical Trial Clients
- **Financing cashflow includes** \$1.4m of proceeds from the exercise of options, partly offset by lease payments (\$0.6m)
- **Cash balance** at 30 June 2022 is \$30.6m (\$28.7m excluding cash held for passthrough payments)



FY23 Outlook



External Factors Impacting Our Business



Alzheimer's R&D

Increased R&D spend positively impacting Cogstate Clinical Trials sales



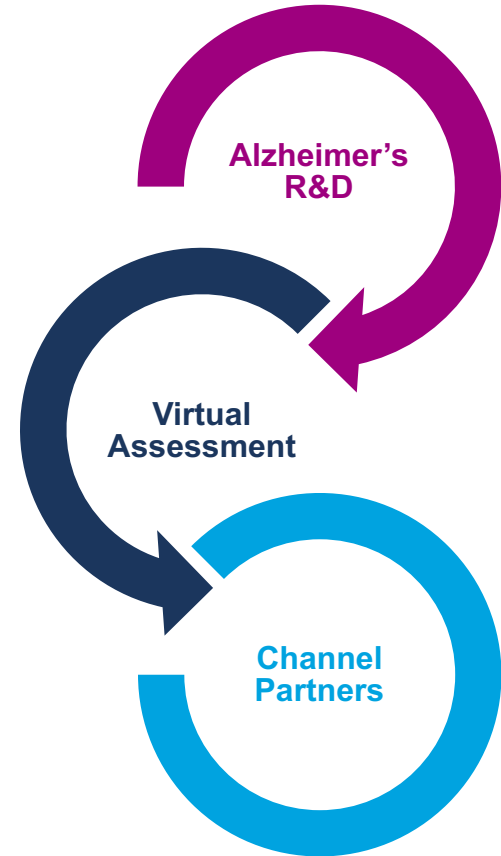
Virtual Assessment

Decentralised trial design, with at-home virtual assessment, has complimented our offering



Channel Partners

Success in growing sales through channel partnerships



Current Status : Potential Therapies

External Catalysts:

Important phase 3 data from key Alzheimer's trials



LECANEMAB

Completed rolling submission for accelerated approval based on Phase 2 data.

Topline data from phase 3 Clarity-AD study scheduled end of Sep-22



GANTENERUMAB

Topline data from phase 3 Graduate study scheduled Q4 2022.



DONANEMAB

Started rolling submission for accelerated approval based on Phase 2 data.

Topline data from phase 3 Trailblazer-Alz-2 study scheduled mid-2023.



FY23 Financial Outlook

- \$16.6m Clinical Trials sales contracts executed 1Q23 to date
 - up from \$8.8m in the most recent Jun-22 quarter
- Clinical Trials revenue expectations:
 - 1H23 revenue expected to be consistent with 2H22
 - 2H23 revenue will vary with the level of sales contracts executed throughout FY23 and therefore is unable to be accurately forecast at this time
- Healthcare revenue and segment contribution expected to be consistent with FY22
- Target EBITDA is 27% - 29% of revenue
- EBIT, based on current revenue forecast, expected to be at the bottom end of the target range of 20% - 24% of revenue
- Operating cashflow approx. 75% of EBITDA



Appendices

Financial Summary – Income Statement

Half Year Analysis	Jul-Dec 20	Jan-Jun 21	Jul-Dec 21	Jan-Jun 22
	US\$ Million	US\$ Million	US\$ Million	US\$ Million
Group Revenue	13.9	18.8	23.1	21.9
Clinical Trials Revenue	12.6	16.1	20.8	19.5
Clinical Trials Contribution	6.2	9.3	12.9	11.2
Clinical Trials Contribution Margin	49.2%	57.8%	62.0%	57.5%
Healthcare Revenue	1.1	2.6	2.2	2.2
Healthcare Contribution	0.8	2.2	1.8	1.5
Healthcare Contribution Margin	72.7%	84.6%	81.8%	65.8%
Research Contribution	(0.2)	(0.3)	(0.4)	(0.3)
Operating Expenses	(6.0)	(6.2)	(7.0)	(6.6)
EBITDA	0.7	5.0	7.3	5.8
EBITDA Margin	5.0%	26.6%	31.6%	26.3%
EBIT	(0.4)	3.8	6.1	4.6
EBIT Margin	(2.9%)	20.2%	26.4%	21.0%

Strong revenue growth over the last 18 months driven by the significant increase in new Clinical Trial contracts as well as Eisai agreement delivering Healthcare revenue.

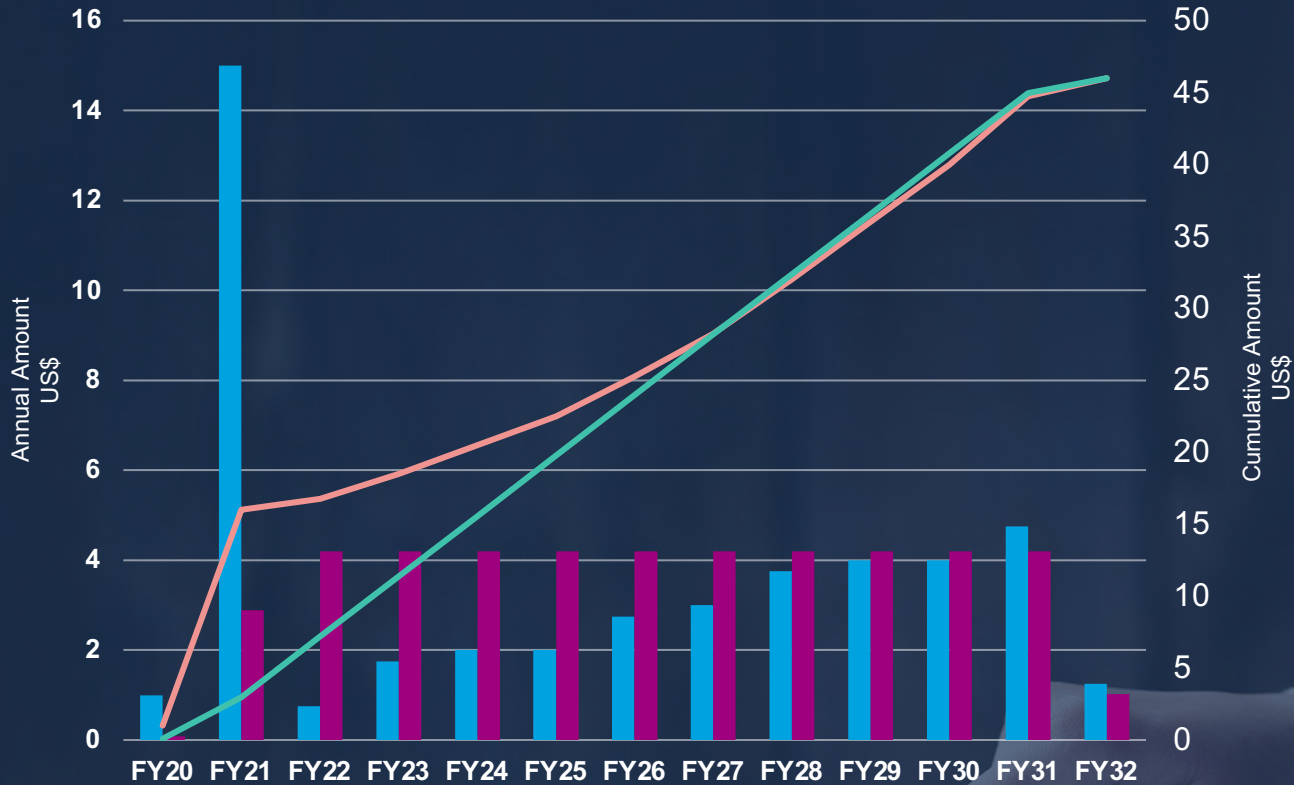
Study delays, completely outside Cogstate control, have resulted in lower Clinical Trials revenue and therefore lower gross margins in the most recent half year period (timing issue only).

EBIT margins in the Jun-22 half year period were negatively impacted by revenue delays (as referenced above), but remain within our model.

Global License



- 2 x 10-year licenses (Japan & Rest-Of-World)
- Excludes Clinical Trials business
- Total upfront payment of US\$16m across 2 agreements already received
- Additionally, Cogstate receives a low double-digit royalty on all revenue, which can not be less than US\$30m across 10 years
- Eisai fund additional development, regulatory and commercial activities
- All data jointly owned by Cogstate



Annual Cash Received
(Contracted Minimum)

Cumulative Cash Received
(Contracted Minimum)

Annual Revenue Recognised
(Contracted Minimum)

Cumulative Revenue Recognised
(Contracted Minimum)

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