

ASX Announcement

28 July 2022

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Cogstate Investor Briefing

Cogstate Ltd (ASX:CGS) has today released an Investor Briefing that provides a business update in respect of the June 2022 quarter as well as revenue and earnings guidance for the year ended 30 June 2022, based upon unaudited financial results.

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:

Brad O'Connor, Chief Executive Officer, boconnor@cogstate.com

Investor Update

June Quarter Business Update

Results for the 12 months ended 30 June 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. 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 in this field and is uniquely positioned to support this need for clinical evaluation and self-assessment at scale.



FY22 Guidance

Updated guidance based upon preliminary un-audited FY22 results:

FY22 Results	Previous Guidance US\$	Updated Guidance US\$	FY21 Comparison
Revenue	\$44m - \$47m	\$45m	\$32.7m
Operating Expenses	31% - 33% of Revenue	30% - 31% of Revenue	38% of Revenue
EBIT Margins	20% - 24% of Revenue	23% - 24% of Revenue	10.4% of Revenue
EBIT	\$8.8m - \$11.3m	\$10.3m - \$10.8m	\$3.4m
Operating Cashflow	>\$5m	\$9.7m	\$16.1m

Other important FY22 metrics:

- \$82.5m Clinical Trials sales contracts executed during the period
- \$139.1m contracted future revenue at 30-Jun-22
- \$30.6m cash at 30 June 2022 (net cash \$28.7m*)

* Net cash is calculated as gross cash less borrowings and less cash receipts received from customers in advance for future pass-through charges

Key Highlights

Revenue was negatively impacted through the March and June quarters by slower than expected enrolment into a key Alzheimer's study, but was within guidance and represents 38% growth from FY21.

Operating leverage demonstrated by:

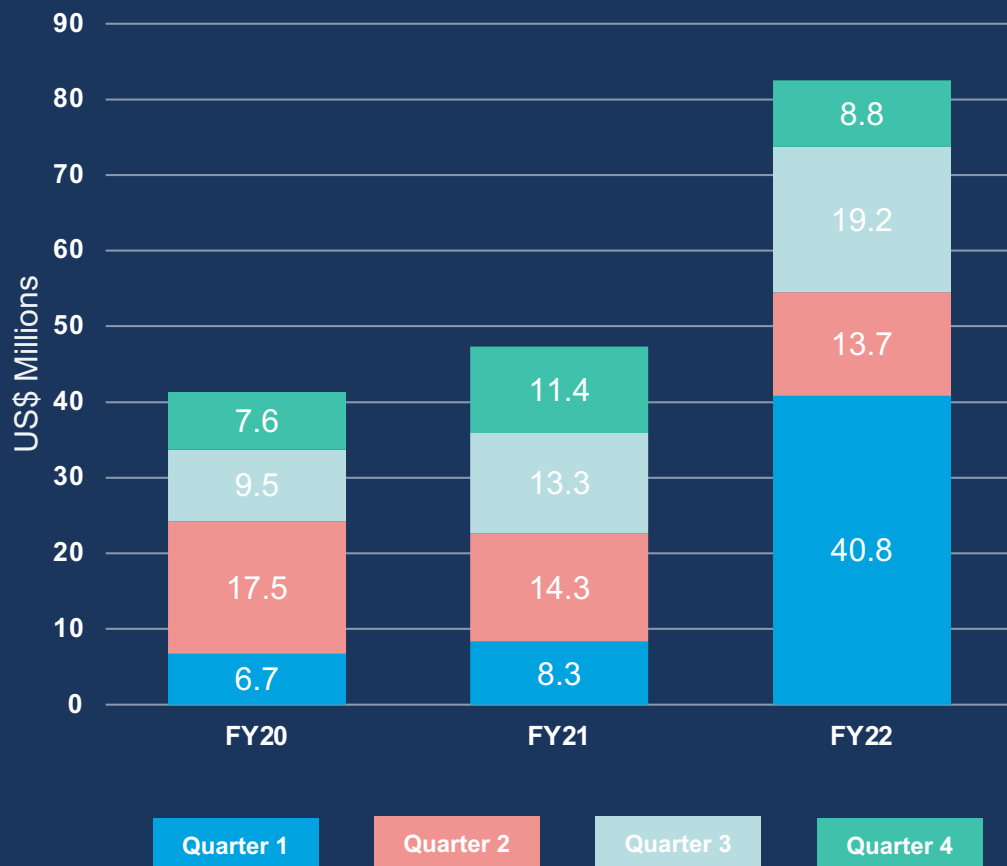
1. improvement in Operating expense-to-revenue ratio (down from 38% in FY21); and
2. improvement in EBIT margins (up from 10.4% in FY21).

EBIT growth from \$3.4m in FY21

Strong Operating Cashflow. Prior period included \$13.8m upfront license fee from Eisai.

Net Cash balance increased to \$28.7m at 30-Jun-22, up from \$22.4m at 30-Jun-21.

Clinical Trials Sales Contracts



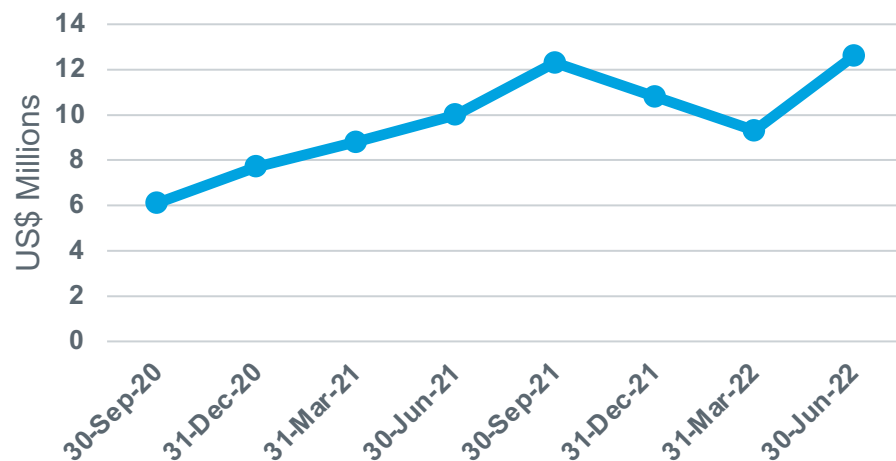
Record FY22 sales contracts

- \$82.5m executed in FY22, up 74% compared to PCP
- \$8.8m in 4Q22
- Alzheimer's disease clinical trials:
 - 84.2% of FY22 sales contracts
 - 65.3% of FY21 sales contracts

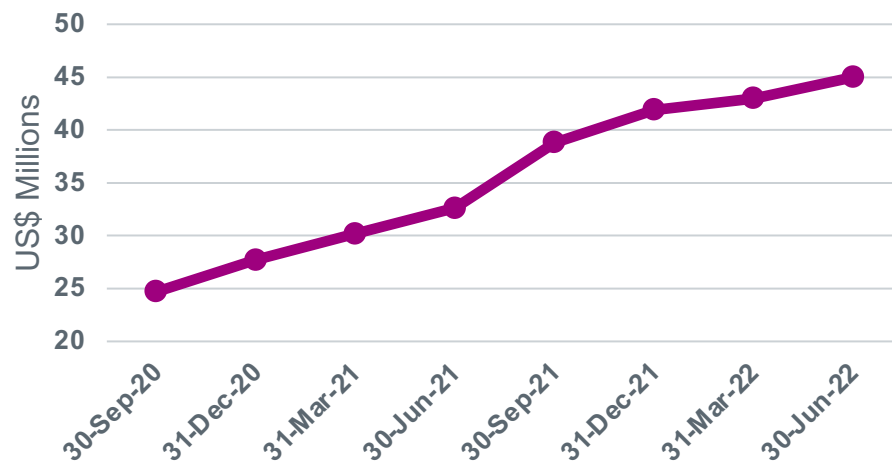


Group Revenue

- 4Q22 revenue of \$12.6m is a record quarterly result
 - This was despite slower than expected patient enrolment in a key Alzheimer's study that delayed recognition of revenue during both 3Q22 and 4Q22.
- Trailing 12-month revenue of \$45.0m, up 38% from 4Q21

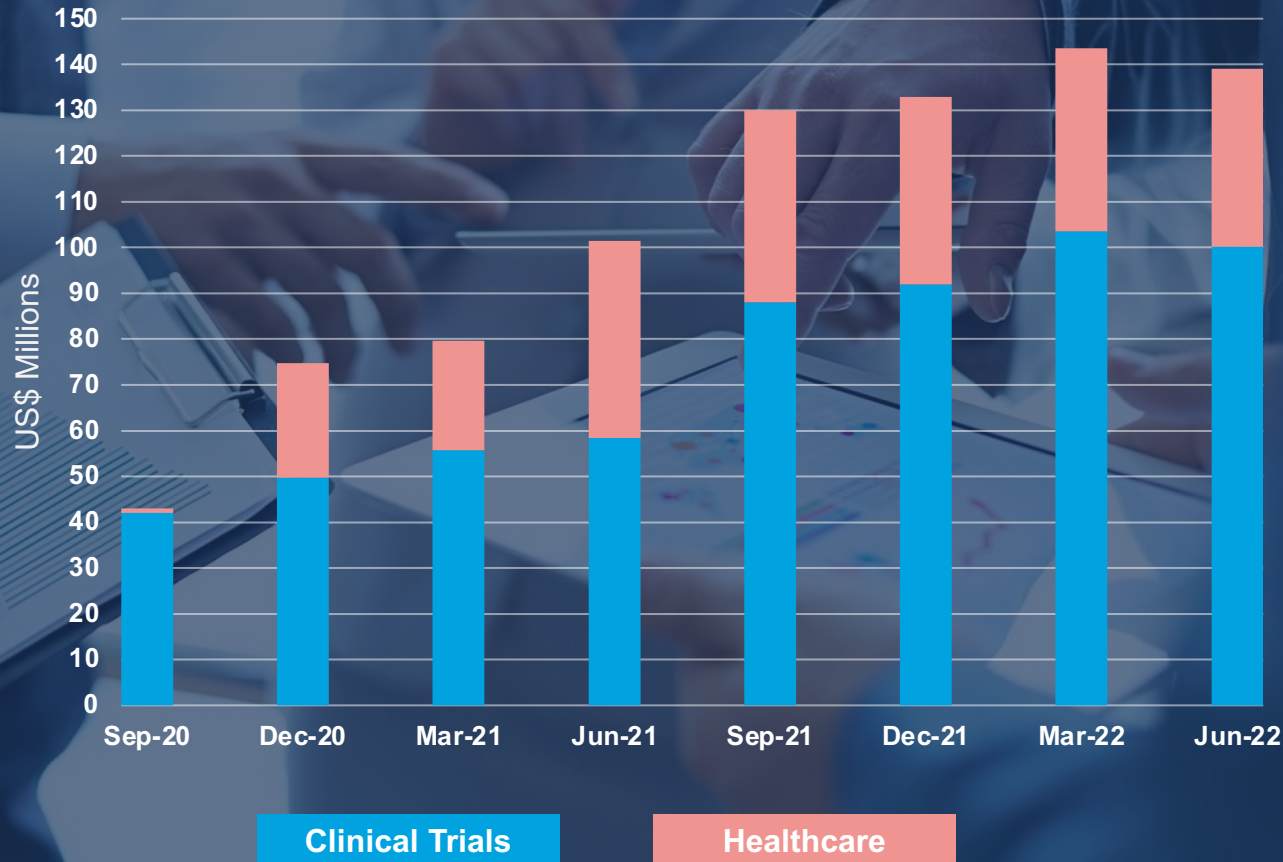


Quarterly Revenue



Trailing 12 Months Revenue

Contracted Revenue Backlog



Year-On-Year Growth in Revenue Backlog

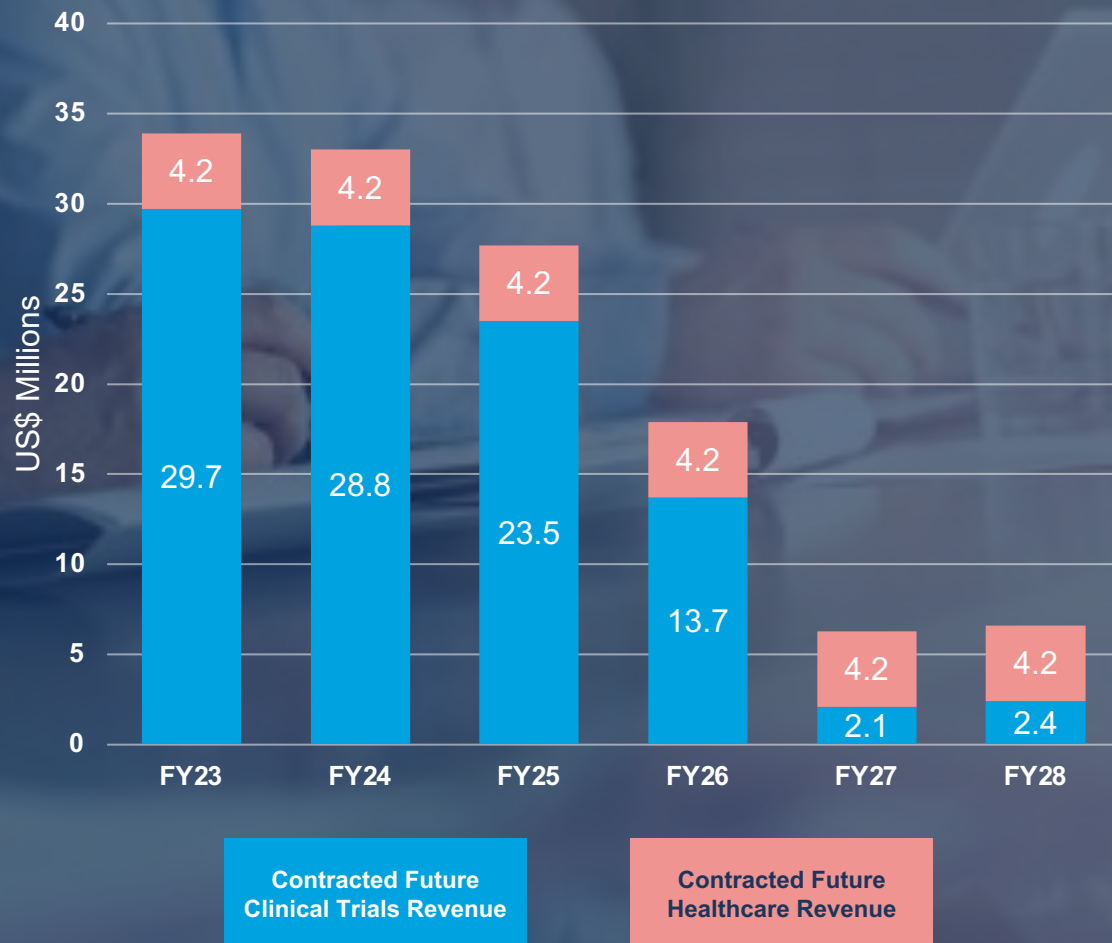
The long-dated contractual nature of Cogstate revenue provides revenue predictability and insight into future revenue performance.

\$139m Backlog at 30-Jun-22, up 37% year-on-year

- Clinical Trials Backlog \$100.2m
 - Up 72% year on year
- Healthcare Backlog \$38.8m
 - down 10% year on year

Revenue backlog decreased in 4Q22 from \$143.5m at 31 March, as Clinical Trials sales contracts executed (\$8.8m) was less than Clinical Trials revenue recognised (\$11.5m)

Contracted Revenue Run-Off



Study delays impacting revenue recognition

Notwithstanding \$8.8m of additional Clinical Trials sales contracts executed in 4Q22, contracted revenue for FY23 has not changed materially from that projected at 31 March 2022.

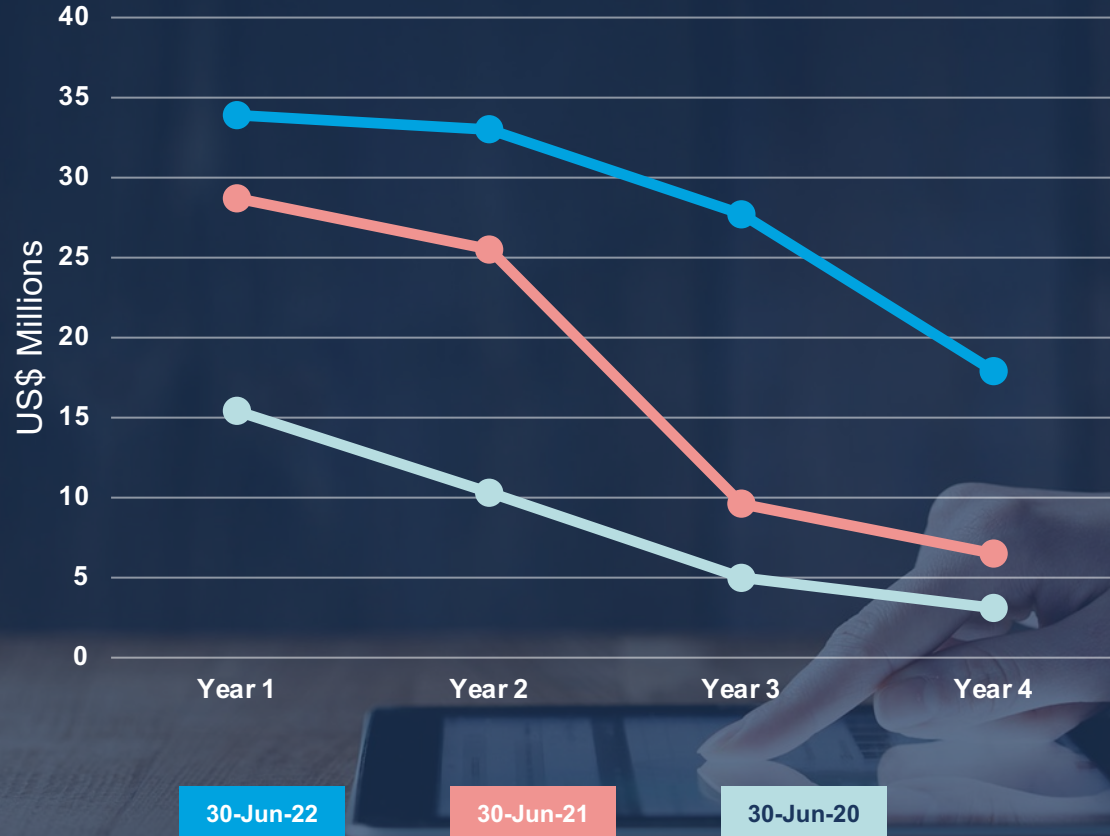
This is due to delays across a handful of unrelated trials that have impacted projected revenue recognition. The delays relate to:

- Problems with respect to manufacturing of drug; and
- Enrolment issues.

Additionally, two small trials in rare diseases have been terminated due to ongoing difficulty enrolling patients into the studies.



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.

A woman with long brown hair and glasses is looking down at a laptop. She is wearing a dark jacket over a turtleneck. The background is blurred.

Macro Trends Impacting Our Business

1

Breakthrough
Alzheimer's treatments

2

Global license
agreement with Eisai

3

Alzheimer's R&D has
increased

4

Increased adoption of
decentralised trial
designs



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Current Status : Potential Therapies



ADUHELM

Troubled study.

Controversial approval.

The other potential treatments will be considered separately by FDA.

CMS considers all monoclonal antibodies for Alzheimer's to be in a single class.



LECANEMAB

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

Topline data from phase 3 Clarity-AD study scheduled Northern Hemisphere Fall 2022 (Sept – Nov 2022).



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.



Pharma company activities to ensure clinical and commercial success for a new therapy

1. Develop and implement a rigorous communication plan to inform the medical and scientific community about the data supporting efficacy and safety. Prior to launch this will normally include presentation at relevant medical meetings and publication of clinical trials.
2. Make sure that these data reach the clinicians most likely to prescribe the medicine.
3. Get input from clinicians concerning any difficulties in identifying the appropriate patients and any questions they have that are not answered by the available clinical data.
4. Develop a plan to provide clinicians with diagnostic and assessment tools that they will need to prescribe the medicine appropriately and monitor safety and efficacy.
5. Post-launch: conduct additional clinical studies to provide data on outstanding questions such as duration of treatment, efficacy in patients with various co-morbidities, efficacy in special populations such as autosomal dominant cases or those older than included in phase 3, etc.
6. Line extensions for other diagnoses, such as Down's syndrome, could also be investigated.



Potential approval of a disease modifying therapy could positively impact Cogstate Clinical Trials business

- Infusion is not ideal, therefore seek next generation treatment
 - Eisai investigating subcutaneous injection
 - Lilly developing N3pG4, which offers option of subcutaneous injection
- Consider long term use of antibodies
 - once amyloid is lowered, can treatment cease or could the patient then move to other treatment options?
- Further understanding of Alzheimer's disease and different treatment options.
 - Clinical trials of drugs targeting something other than A β /amyloid, e.g., tau, inflammation, are likely to accelerate to enable combination therapy
 - Other sponsors will develop molecules that are similar but not identical; it happens with every new clinically successful agent designed to treat a common disease



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Global License



- 2 x 10-year licenses (Japan & Rest-Of-World)
- Excludes Clinical Trials business
- Total upfront payment of US\$16m across 2 agreements
- Additionally, Cogstate receives a 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



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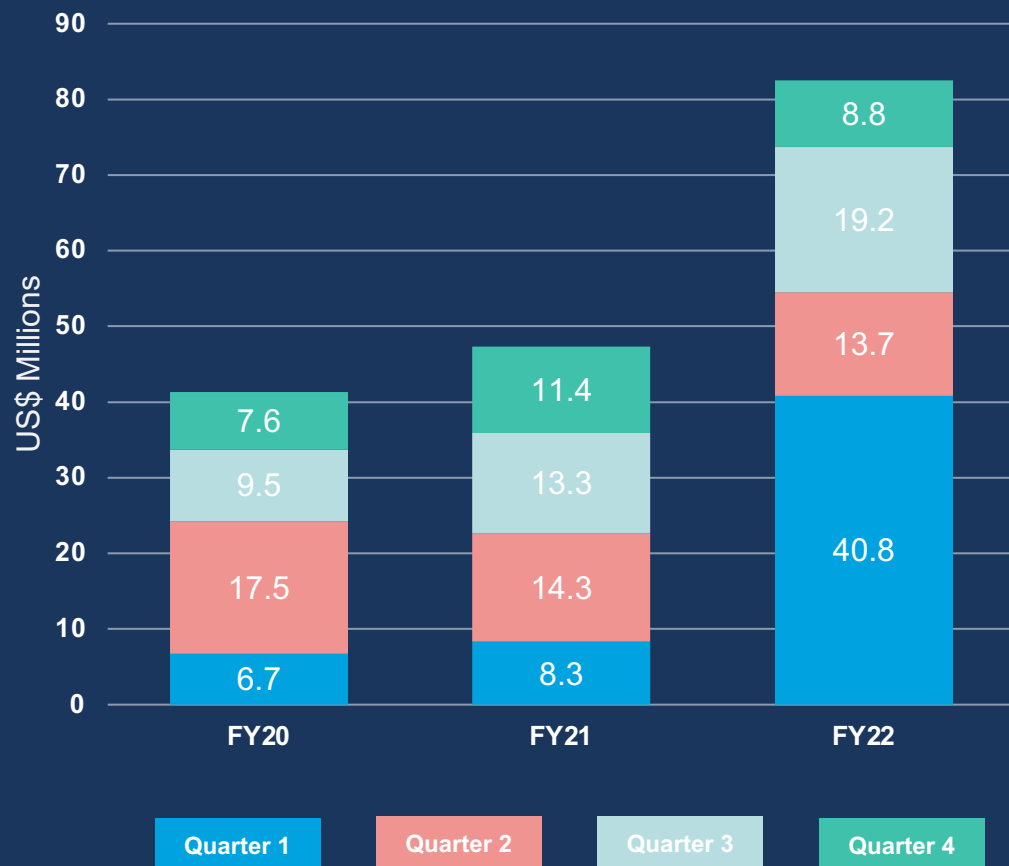
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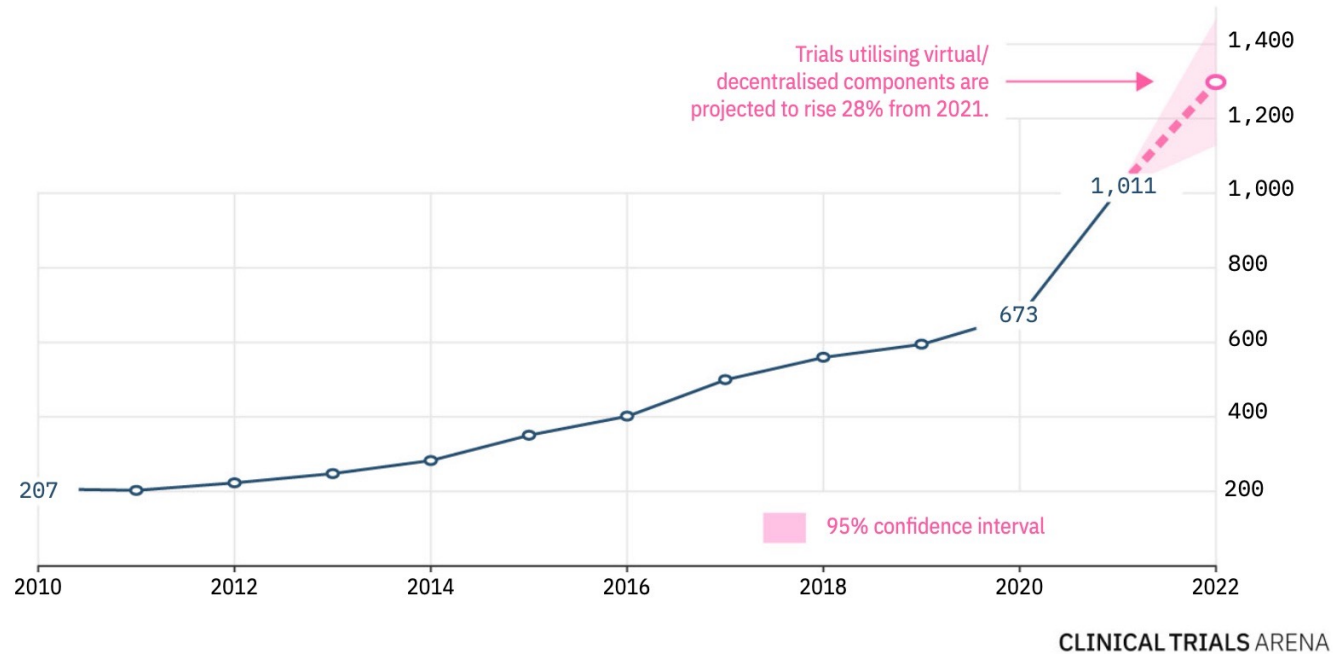
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A record number of drug trials are expected to utilise decentralised elements in 2022

Initiated worldwide drug trials identified as involving virtual/decentralised components



Trial categories by start date. Includes interventional drug trials which GlobalData identified as mentioning decentralised/virtual components in clinical registry protocols. 2021 figures include trials scheduled to begin before the end of the year.

Source: GlobalData

How is a decentralised trial different?

Traditional Trials:
Doctors in research hospitals
conducting in-person assessments

Decentralised Trials:
Home based assessment via
telehealth technologies



A man with grey hair and a beard, wearing a headset, is seated at a desk with a computer monitor. He is gesturing with his hands while looking at the screen. The background is a blurred office setting.

Outcomes

- Increased use of digital assessments
Cogstate technology is well validated for remote assessment
- Fewer professionals used
Lower training and monitoring cost and better use of scarce resources.
- More consistent administration
Less error, better data.
- Easier / faster to recruit
Larger geographic reach.
- More diverse patient population
Better trial, happier regulator.
- Greater share of trial budget for Cogstate
Transition of revenue from hospital sites to Cogstate.



Strategic value to Cogstate



Places Cogstate at the forefront of decentralised trial design and delivery in Alzheimer's studies



Positions Cogstate as a strategic partner for other tech providers.

We enable our partners to bid on trials in central nervous system diseases where specific solutions are required.



Positive Business Outlook

Clinical Trials Growing

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

High revenue backlog provides visibility of continued revenue growth.

FY22 has demonstrated sustainable segment profit margins.

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.

Data from phase 3 trials expected in the next year.

Improved Group Margins

Cost control has resulted in improvement in margins as revenue has increased through FY21 and FY22.

Growth in Earnings and Cash

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





Cogstate