

# ASX Announcement

## 22 August 2024

### FY24 Results 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 2024 and also provides commentary in respect of the business and financial outlook.

The presentation material is attached to this announcement.

Investors are invited to join Cogstate CEO, Brad O'Connor for a live webcast of this presentation today, Thursday 22 August 2024, at 8:30am Australian eastern standard time.

Investors can register via the following weblink to join the live event or receive the recording if unable to attend: <https://attendee.gotowebinar.com/register/1561058463047040604>

Additionally, a video recording of the presentation will be available later today at the Cogstate Investor Centre homepage: <https://www.cogstate.com/investors/>

This announcement was authorised for release by the Board of Directors of Cogstate Ltd.

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**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, Cogstate seeks to provide primary care physicians and consumers with brief, accurate and scientifically validated digital measures of cognition, with a focus on easy to use, self-administered tests that inform patients and save physician time. In this market, Cogstate has partnered with pharmaceutical company, Eisai, to distribute Cogstate assessments in the USA & Asia. For more information, please visit [www.cogstate.com](http://www.cogstate.com).

**For further information contact:**

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**Important Notices***Past performance*

Past performance is given for illustrative purposes only and should not be relied upon as (and is not) an indication of Cogstate's views on its future financial performance or condition. Past performance of Cogstate cannot be relied upon as an indicator of (and provides no guidance as to) the future performance of Cogstate. Nothing contained in this announcement nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee, whether as to the past, present or future.

*Future performance and forward-looking statements*

This announcement contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "should", "could", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this announcement are based on assumptions and contingencies that are subject to change without notice and involve known and unknown risks and uncertainties and other factors that are beyond the control of Cogstate, its directors and management. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance.

Actual results, performance or achievements may differ materially from those expressed or implied in such statements and any projections and assumptions on which these statements are based. These statements may assume the success of Cogstate's business strategies, including the that the results of any of those strategies will be realised in the period for which the forward-looking statement may have been prepared or otherwise. For example, Cogstate's performance in any one financial period is sensitive to whether or not contracts are signed in that period, or a subsequent period, and the rate of enrolment in trials of its customers which are influenced by factors that are outside of Cogstate's control.

Readers are cautioned not to place undue reliance on forward-looking statements and except as required by law or regulation, none of Cogstate, its representatives or advisers assumes any obligation to update these forward-looking statements. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in this announcement. The forward-looking statements are based on information available to Cogstate as at the date of this announcement. Except as required by law or regulation (including the ASX Listing Rules), none of Cogstate, its representatives or advisers undertakes any obligation to provide any additional or updated information, whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements.

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# Investor Update

August 2024



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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## Key Considerations

1

Alzheimer's disease R&D is progressing & expanding in a predictable manner

2

Eisai renegotiation was commercially sound AND provides important options for growth

3

Revenue growth is impressive in the context of Clinical Trials sales

4

Technology investment over recent years has created efficiency & margin improvement



# Alzheimer's Disease

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## Market Expansion

- More pharma companies are investing in Alzheimer's R&D

## Customer Growth

- Four pharma companies started phase 2 programs with Cogstate in FY24, three of which were new customers
- Cogstate support of successful phase 3 program is important in winning new work

## Changed Environment

- Phase 3 trials have been slower as pharma execs wait to understand the market for newly approved treatments, including regulatory acceptance and barriers to adoption
- Lack of phase 3 Alzheimer's trials reduced Clinical Trials sales contracts executed in FY24

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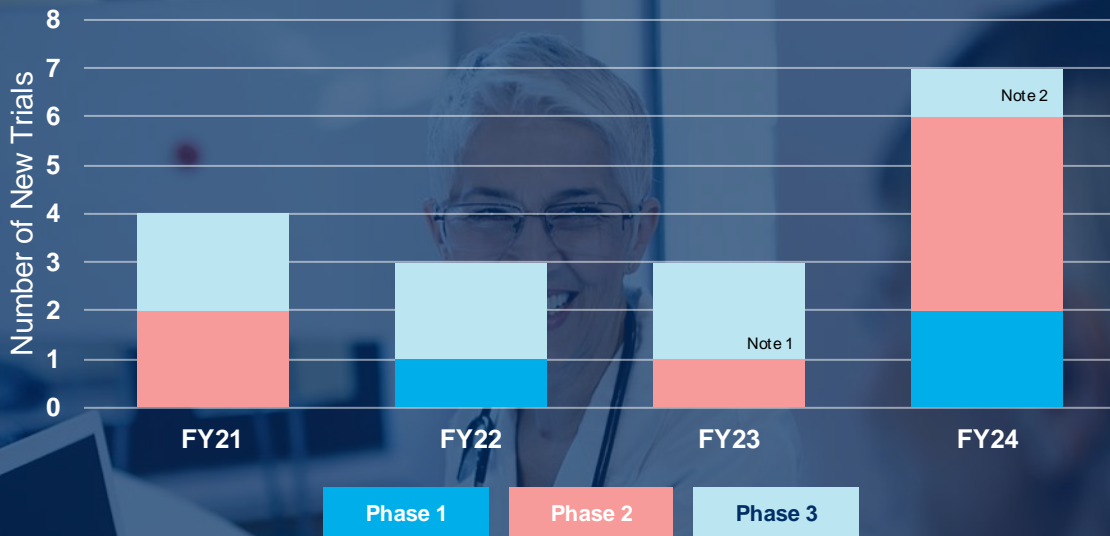
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## Cogstate Alzheimer's Trial Starts Large Pharma Customers



	FY21	FY22	FY23	FY24
Value of Alzheimer's contracts <sup>3</sup>	\$35.4m	\$74.5m	\$25.7m	\$12.9m
Alzheimer's as a % of total contracts	75%	90%	75%	48%
Large Pharma as a % of total Alzheimer's	87%	80%	83%	100%

## Growth in Alzheimer's Large Pharma Customers

Cogstate strategy is to engage sponsor teams at the earlier stages of development and follow a therapy through to later stages.

Total contract value to Cogstate of one disease-modifying Alzheimer's program can be up to \$80m across phases 1 to 3.

Due to the cost of these phase 3 programs, they are usually only run by large Pharma.

Growth comes from securing early-stage Alzheimer's trials from large Pharma, which then advance to phase 3

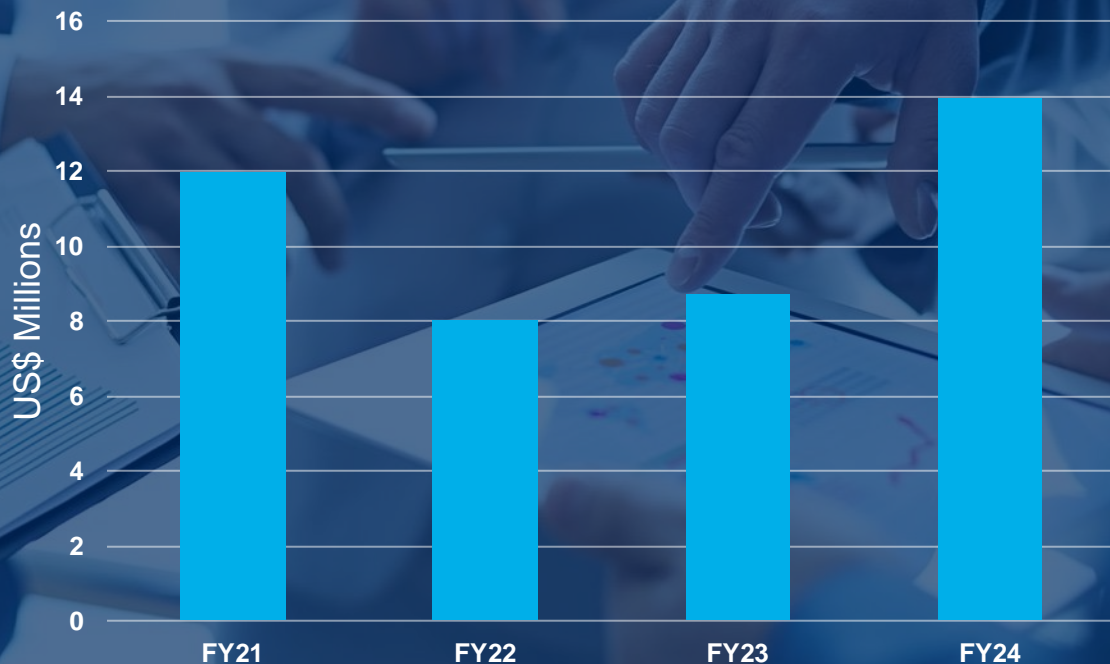
Note 1: Trials suspended before patients recruited, subsequently reorganised in early FY25. Limited revenue impact in either FY23 or FY24 from either contract.

Note 2: Start-up agreement only (low value, allowing Cogstate to begin work). Full agreement executed early FY25.

Note 3: Value of contracts executed in any period includes contracts for new trials as well as amendments to ongoing trials.

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## Value of Clinical Trials Sales Contracts - Excluding Alzheimer's Trials



## 60% Growth In Sales Outside Of Alzheimer's

Other significant indications include:

- Rare Diseases
- Major Depressive Disorder
- Migraine
- Narcolepsy
- Parkinson's disease
- Schizophrenia



# IP Ownership

## Financial Implications

- In FY20, licensed IP for \$45m plus royalties
- In FY24, bought-back for \$15m reduction in future payments to Cogstate, impacting cashflow from FY28-FY31 only

## Eisai Continued Relationship

- Eisai continue to market Cogstate technology to doctors in USA & community in Asia

## Commercial Implications

- Under non-exclusive license, Cogstate has regained IP ownership
- Roll-out of new Alzheimer's therapies has highlighted difficulties in US healthcare system - suggesting a need for better and earlier identification of impairment in the community
- Opportunity for Cogstate to identify patients for both treatment and trials – opportunities that were closed off to Cogstate without amendment

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# Revenue Growth

## Clinical Trials Sales

- \$27m of clinical trials sales
- Sales drive in-period revenue growth, especially growth in license fees

## License Fee Revenue

- Usually recognised in year contract executed
- Historical analysis suggests license fees usually 18%-20% of Clinical Trials revenue
- FY24 license fees 13% of Clinical Trials revenue

## Revenue Growth = Service Expansion

- 9% growth in FY24 Clinical Trials revenue, despite low level of license fees, reflects growing service offering by Cogstate
- Positioned well for improved revenue growth when sales growth returns with associated higher level of license fees

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# Technology Driving Margin Improvement

## Technology Investment

- Recent investment mainly focused on automation in Cogstate service delivery

## May-23 Staff Restructure

- As a result of efficiency gains, staff restructure undertaken in May-23
- Predominantly impacting Clinical Trials group

## Margin Improvement

- 6 points improvement in Clinical Trials gross margin reflecting lower staff costs
- That is, \$4.0m increase in gross margin from \$3.3m increase in revenue
- Bonus: Operating expenses also down 4% on prior year

1

Alzheimer's disease R&D is progressing & expanding in a predictable manner

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Eisai renegotiation was commercially sound AND provides important options for growth

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Buy-back of IP from Eisai was a good financial deal AND provides important options for growth

4

Technology investment over recent years has created efficiency & margin improvement



# Strong Start to FY25

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Net value of contracts executed FY25 year-to-date is \$9.3m. The Net value includes:

- Gross value of sales contracts executed since 01-Jul-24 (FY25 year-to-date) is \$29.6m
- Program of studies for a drug candidate was redesigned to consolidate multiple Phase 3 trials into a single larger trial
  - Same customer, same drug, new protocol with larger total contract value
  - The ongoing trials were suspended during FY24 and therefore did not meaningfully contribute revenue in FY24
  - Larger trial commenced in Jun-24 quarter under start-up agreement – therefore revenue now generating
- Reconciliation of completed phase 3 program where \$4.1m of budget was not used and therefore has been removed from contracted future revenue

Contracted future revenue has been adjusted to provide for both the new contracts as well as the reorganisation of older contracts.

As such, contracted future Clinical Trials revenue at 21-Aug-24 is \$95.0m, of which \$31.4m is expected to be recognised in FY25

	As at 21-Aug-24	As at 30-Jun-24	As at 30-Jun-23
Contracted Clinical Trials revenue expected to be recognised in coming financial year	US\$31.4m	US\$26.8m	US\$27.7m
Contracted Healthcare revenue expected to be recognised in coming financial year	US\$2.2m	US\$2.2m	US\$4.2m
<b>Total contracted revenue expected to be recognised in coming financial year</b>	<b>US\$33.6m</b>	<b>US\$29.0m</b>	<b>US\$31.9m</b>



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# FY24 Financial Results



# FY24 Financial Results

(All figures in US\$, unless stated)

## Clinical sales contracts executed

**\$27.0m**

Doesn't tell the full story.  
Alzheimer's growth profile for future periods.

-21%

## Contracted future revenue as at 21 August 2024

**\$110.9m**

Lower level of Clinical Trial sales contracts.  
Healthcare: Eisai amendment negative impact.

-16%

## Group Revenue

**\$43.4m**

Clinical Trials revenue growth  
Healthcare down due to Eisai contract amendment

+7%

## Profit before Tax

**\$7.1m**

Revenue growth.  
Cost control incl. restructure undertaken May-2023.

+135%

## Operating net cash flow

**\$5.8m**

Up from PCP of \$0.7m  
Growth in Clinical Trials.

+784%

## Net Cash Balance at 30 June

**\$29.4m**

Up from PCP of \$27.8m  
A\$5.5m spent on share buyback during FY24.

+6%

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# Cogstate Group

US\$ millions	FY24	FY23	YTY %
Revenue	43.4	40.5	7%
Gross Profit	24.6	20.8	18%
GP%	57%	52%	5% Pts
Operating Expense	(15.3)	(16.0)	(4%)
Depreciation & Amortization	(2.7)	(2.6)	6%
EBIT	6.5	2.2	196%
EBIT%	15%	5%	10% Pts
Other Income/(Expenses)	0.6	0.8	(29%)
<b>Net Profit before Tax</b>	<b>7.1</b>	<b>3.0</b>	<b>135%</b>

## Highlights

- Revenue growth resulting from Clinical Trials, offset by decline in Healthcare
- Strong improvement in gross profit margin resulting from May 2023 restructuring actions and cost management
- EBITDA and EBIT margins improving but not yet at target model
- Strong growth in Profit before Tax



# Segments

## Clinical Trials (including Research)

US\$ millions	FY24	FY23	YTY %
Revenue	39.4	36.1	9%
Direct Costs (excluding depreciation)	(13.5)	(14.0)	3%
SG&A	(4.2)	(4.3)	3%
Gross Contribution	21.7	17.7	23%
GP%	55%	49%	6% Pts

## Healthcare

Revenue	4.0	4.4	(9%)
Direct Costs	(1.1)	(1.3)	14%
Gross Contribution	2.9	3.1	(8%)
GP%	72%	71%	1% Pts

# Highlights

## Clinical Trials

- Growth in revenue despite low in-year revenue yield due to low new contract sales
- Strong improvement in gross profit margin with benefit from May 2023 restructuring actions, cost management, partially offset by lower than historical average SW license mix

## Healthcare

- Decline in revenue a result of renegotiated global licensing agreement.
- Improving margin resulting from cost benefits from May 2023 restructuring actions, offset by investment in go-to-market strategy development.



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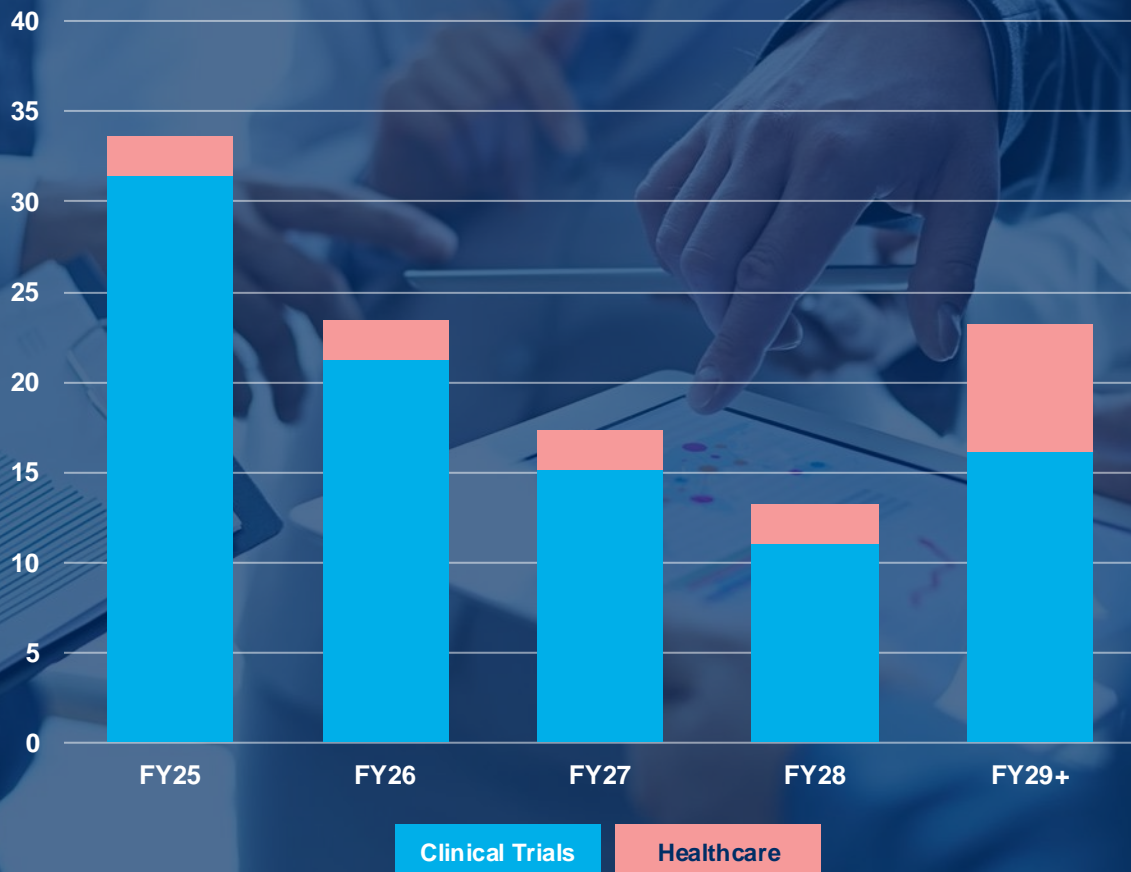
# Cash Flow

US\$ millions	FY24	FY23	YTY %
Net Profit after Tax	5.4	3.6	53%
Depreciation & Amortization	2.5	2.1	18%
Disposal of Assets	0.1	0.4	(118%)
Non-cash employee benefits	0.8	1.6	(53%)
Grant funding received	(0.3)	(0.3)	(12%)
Exchange Rate differences	(0.5)	(0.1)	461%
Change in working capital	(2.2)	(6.6)	(67%)
<b>Operating Cash Flow</b>	<b>5.8</b>	<b>0.7</b>	<b>784%</b>
<b>Cash Flow used in investing activities</b>	<b>(1.1)</b>	<b>(1.7)</b>	<b>(34%)</b>
<b>Cash flow used in Financing activities</b>	<b>(3.2)</b>	<b>(0.9)</b>	<b>260%</b>
<b>Total Cash Flow</b>	<b>1.5</b>	<b>(1.9)</b>	<b>175%</b>

## Highlights

- Increased receipts from customers from growth in Clinical Trials
- Reduced employee costs following May-23 restructure
- Lower cash flow used in Investment activities results from lower capitalisation of labour costs
- Higher cash flow used in Financing activities due to share buy-back program : US\$3.6m (A\$5.5m)
- US\$29.4 million net cash

# Future Contracted Revenue Run-Off



## Analysis

- FY25 revenue under contract, \$33.6m as at 21-Aug-24
  - Clinical Trials is \$31.4m, compared to \$27.7m at 30-Jun-23, up 13% YTY
  - Healthcare is \$2.2m, compared to \$4.2m at 30-Jun-23, reflecting to renegotiation to the Eisai global licensing agreement.
- Expected recognition of Clinical trials revenue reflects reorganisation of large trials, with more revenue in outer years

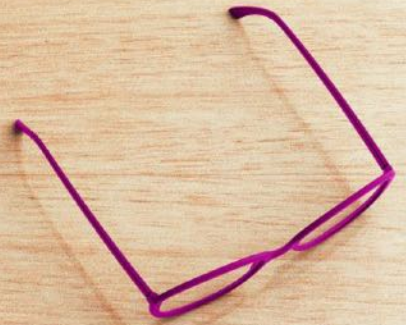
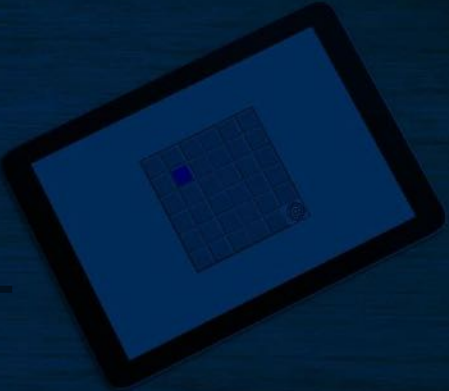
Clinical Trials revenue backlog \$95.0m at 21-Aug-24 vs \$98.0m at 30-Jun-23

	Clinical Trials Revenue At 21-Aug-24 US\$m	Clinical Trials Revenue At 30-Jun-23 US\$m
FY25	\$31.4	\$30.3
FY26	\$21.3	\$18.2
FY27	\$15.1	\$11.4
FY28	\$11.1	\$8.3
FY29+	\$16.1	\$2.0

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# Business Updates



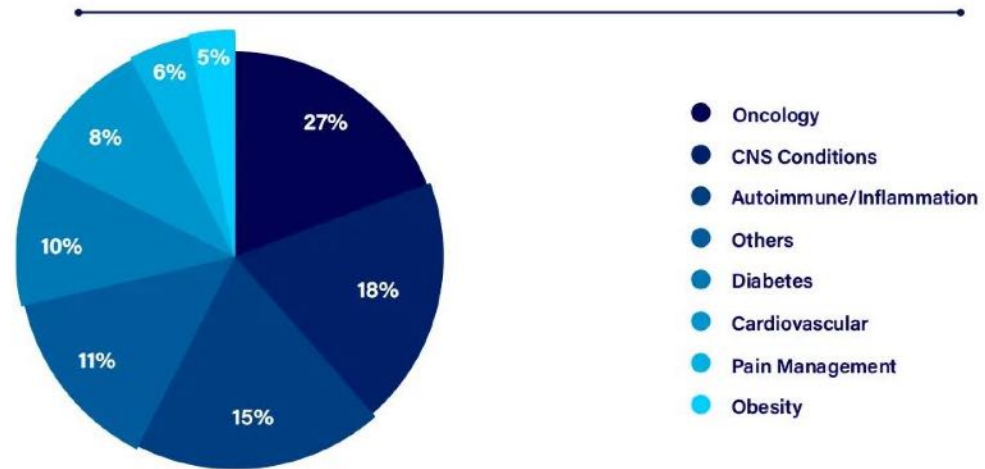
# Central Nervous System diseases is a large and growing area of drug development with few strong competitors

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CNS is the second largest segment of the \$25B clinical trials market, taking 18% second to oncology.

NOVA1ADVISOR

U.S. Clinical Trials Market Share, By Indication, 2023 (%)

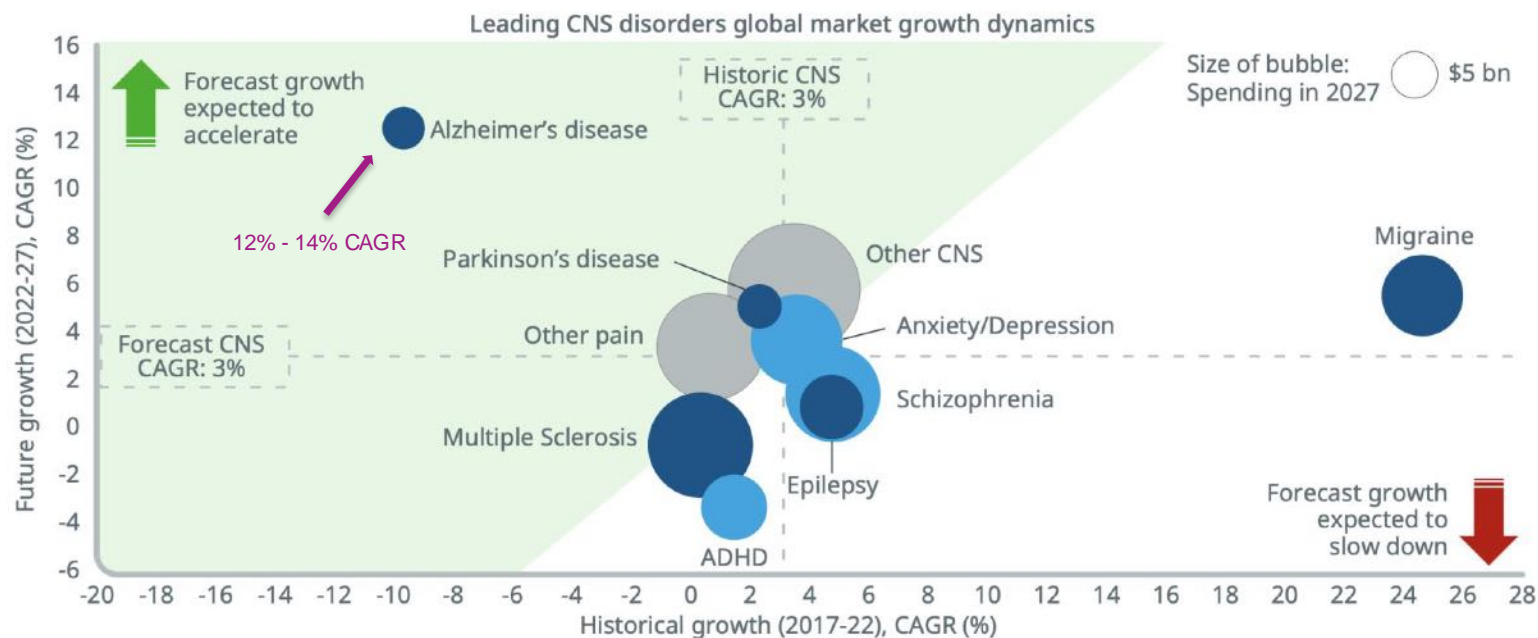


Source: [www.novaoneadvisor.com](http://www.novaoneadvisor.com)



# Alzheimer's disease is expected to be the fastest growing indication in CNS

Figure 11: Disease-modifying treatments are driving CNS growth dynamics



Source: IQVIA Forecast Link, IQVIA Institute - The Global Use of Medicines 2023.

# Alzheimer's disease is expected to be the fastest growing indication in CNS

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- First-gen early-stage AD drugs are on market – prescription rates are slower than expected but improving
  - Health system preparedness is happening and Cogstate has ambitions to play a role here
  - New dosage forms are coming
  - Label expansions for pre-symptomatic AD trials are well into phase 3 – where Cogstate has 100% market share
- This is fueling growth of Alzheimer's R&D investment, much like MS 30 years ago
- Alzheimer's trials are long to recruit and expensive to run; and we believe that, with technology, we can help improve speed and data quality at lower costs



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# Cogstate Focus Areas Next 12 Months



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# End-to-End Solution for Optimized CNS Endpoints

One the challenges with CNS trials is they depend on clinical outcome assessments that are prone to error and variance, which can diminish their sensitivity to drug effect. Cogstate brings a uniquely comprehensive set of technologies and solutions to address this challenge from every angle.





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# Cogstate Opportunity Outside Clinical Trials







## Re-Acquired IP

**Based on our assessment of the opportunity, Cogstate has re-negotiated its agreement with Eisai and re-acquired rights to Cogstate IP.**

Eisai now has non-exclusive license of:

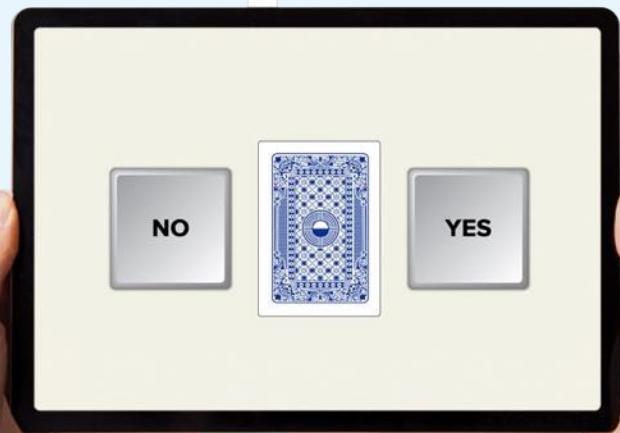
- Cognigram in USA; and
- CogMate in certain Asian countries.

Cognigram is FDA cleared medical device for physician use. Eisai will promote to USA based clinicians, with focus on Annual Wellness Visit available to all medicare recipients.

CogMate is a direct-to-consumer assessment, based on the Cogstate Brief Battery (same tests as Cognigram).

Cogstate will still receive a further \$11.5m of future guaranteed royalties under the amended agreement.





## FY25 Outlook

Encouraging start to FY25

- \$9.3m net sales contracts
- \$29.6m gross sales contracts

Significant market opportunity in CNS diseases

Opportunities for sales growth in Alzheimer's disease and other indications

Opportunities for exciting pilot programs outside of clinical trials with IP re-secured

Expect to grow revenue & profit in FY25

- No specific guidance provided, pending execution of sales contracts

Share buy-back has been suspended until further notice

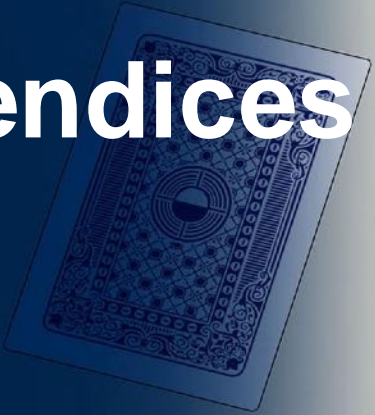
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# Appendices



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# Cogstate Offering In Clinical Trials





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Cogstate brings together **clinical science expertise, innovative technology, and operational excellence** to help clinical trial teams understand drug safety and efficacy.



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## Scientific Consulting

Strategic guidance on the selection, execution and analysis of cognitive measures.

- Access to thousands of cognitive data profiles generated in different study populations, interventions, mechanisms
- Endpoint selection, powering decisions, robust statistical analysis and interpretation of study results supportive of product efficacy, safety and differentiating claims





## Scale Management

Licensing and translating rating scale instruments for a study is a meticulous process that can dramatically impact trial start-up timelines and data quality.

- Licensing agreements, translations and linguistic validation, development of master source documents
- Migration to electronic formats (eCOA)
- Logistics management of printed source, hardware, manipulatives and instructions





## Remote Assessment

At-home data collection is increasing in Clinical Trials. Cogstate is expertly positioned to support remote administration of conventional clinical assessments as well as Cogstate proprietary digital assessments.

- Self-administered digital assessments
- Central rating via telehealth





## Rater Training

Clinical trial sponsors must ensure raters administer scales in the most accurate and standardized way possible.

- Prepare raters to administer scales to high standards in the timeliest way possible.
- Eliminate unnecessary training based on rater experience and leverage customized eLearning curriculum supportive of expedited study start-up.





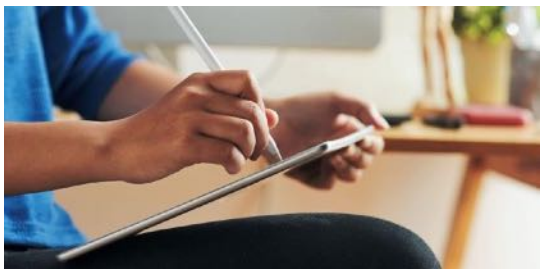
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## eCOA Solutions

Conventional paper and pencil assessments allow missing data and erroneous transcription. Electronic clinical outcome assessments (eCOA) allow for digital capture of study data with pre-set workflows, real-time edit checks and algorithmic flags to improve data quality.

- Patient-reported, clinician-reported, care partner-reported, performance-based
- Partner relationships





## Central Monitoring & Adjudication

Rater variability and error can be detrimental to a study, adding noise and diminishing signal detection.

- Develop and execute strategic, risk-based central monitoring programs to ensure the reliability and validity of clinical measures.
- 250+ highly trained clinical and scientific experts who provide in-language support in 40+ languages.





## Digital Cognitive Assessments

Increases the sensitivity and specificity of the measurement of human cognition.

- Designed and validated to assess memory, verbal learning, attention, psychomotor function, motor function, executive function, vigilance, and emotional recognition
- Batteries are customized for the unique aims of each study -- used in hundreds of global clinical trials for both pediatrics and adults.

