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ASX Announcement

28 February 2023

Cogstate 1H23 Results Presentation and Investor Webinar

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 2022 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 a live webcast and Q&A hosted by CEO, Brad O'Connor, and CFO, Darren Watson, today (Tuesday 28 February 2023) at 11:00am Australian Eastern Summer Time.

Investors can register via the following weblink to join the live event or receive the recording if unable to attend: https://bit.ly/H2FY2023Cogstate

This announcement was authorised for release by a sub-committee of the Board of Directors of Cogstate Ltd.

Investor Update

Financial results for the half-year ended 31 December 2022
Presented February 2023

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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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.

A significant portion of Cogstate revenue are associated with Alzheimer's disease – where improved biomarkers and improved understanding of disease progression is leading increased R&D spend and improved treatment options.

*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, and Japan but most of our staff are based in the USA.

~ 390 team members comprised of
- 200 employees +
- global network of 190 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.

Financial Results

1H23 (Jul-Dec 2022) Financial Highlights
(All figures in US$)

Clinical Sales Contracts Executed

-50%

$27.3m

$27.9m before cancellations / reconciliations

Contracted Future Revenue

+10%

$146.7m

Strong contracted revenue pipeline

Group Revenue

-15%

$19.5m

Clinical Trials revenue of $17.1m, down 18%, impacted by enrolment delays

Clinical Trials Margin

-11 pts

46%

1H22: 62%, down 16pts
2H22: 57%, down 11pts

EBIT

-$6.3m

($0.2m)

PCP gain of $6.1m
1H23 EBIT margin (1.2%)

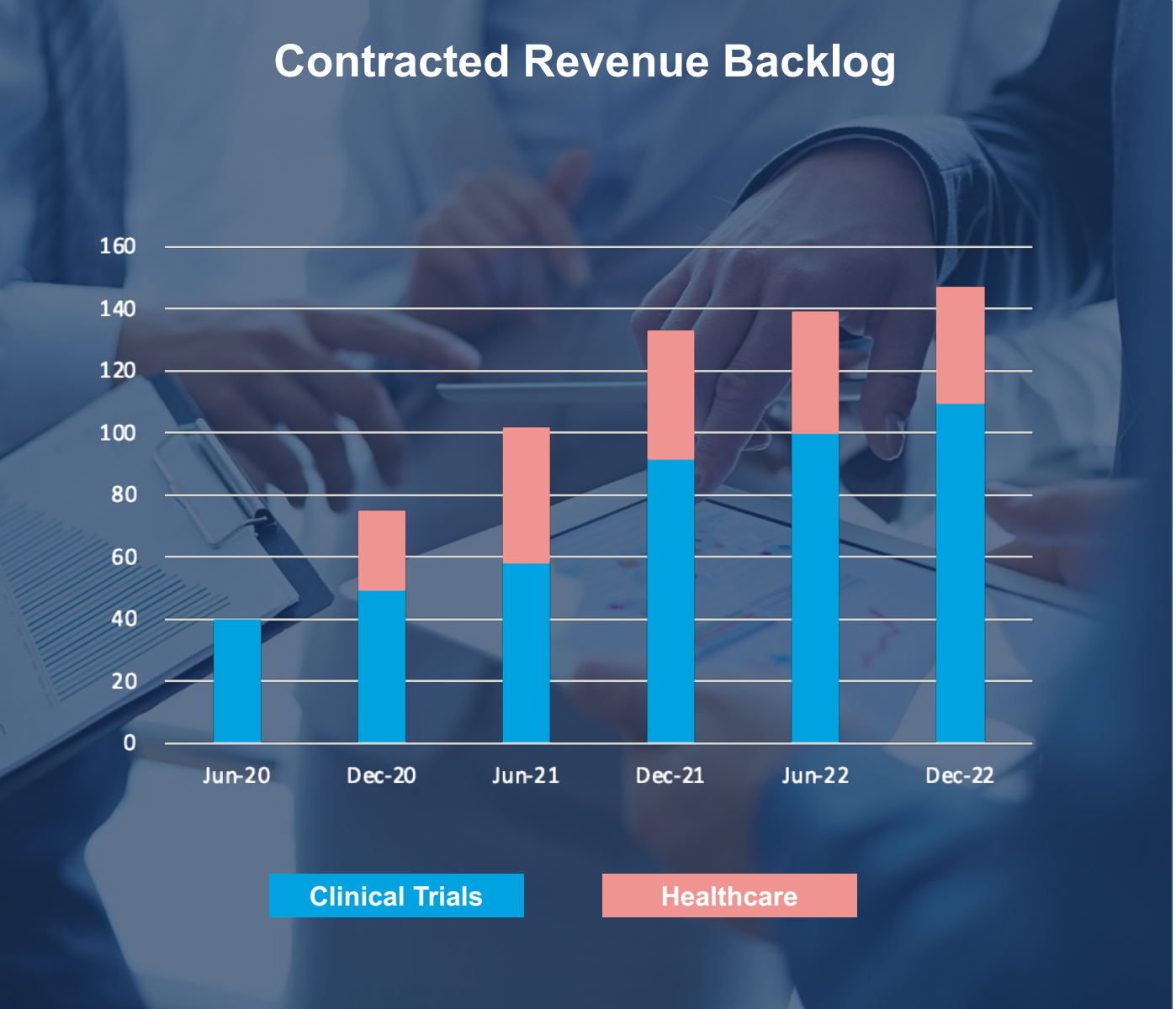
Net Cash Balance

+13%

$27.7m

An increase of $3.1m from a year ago

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



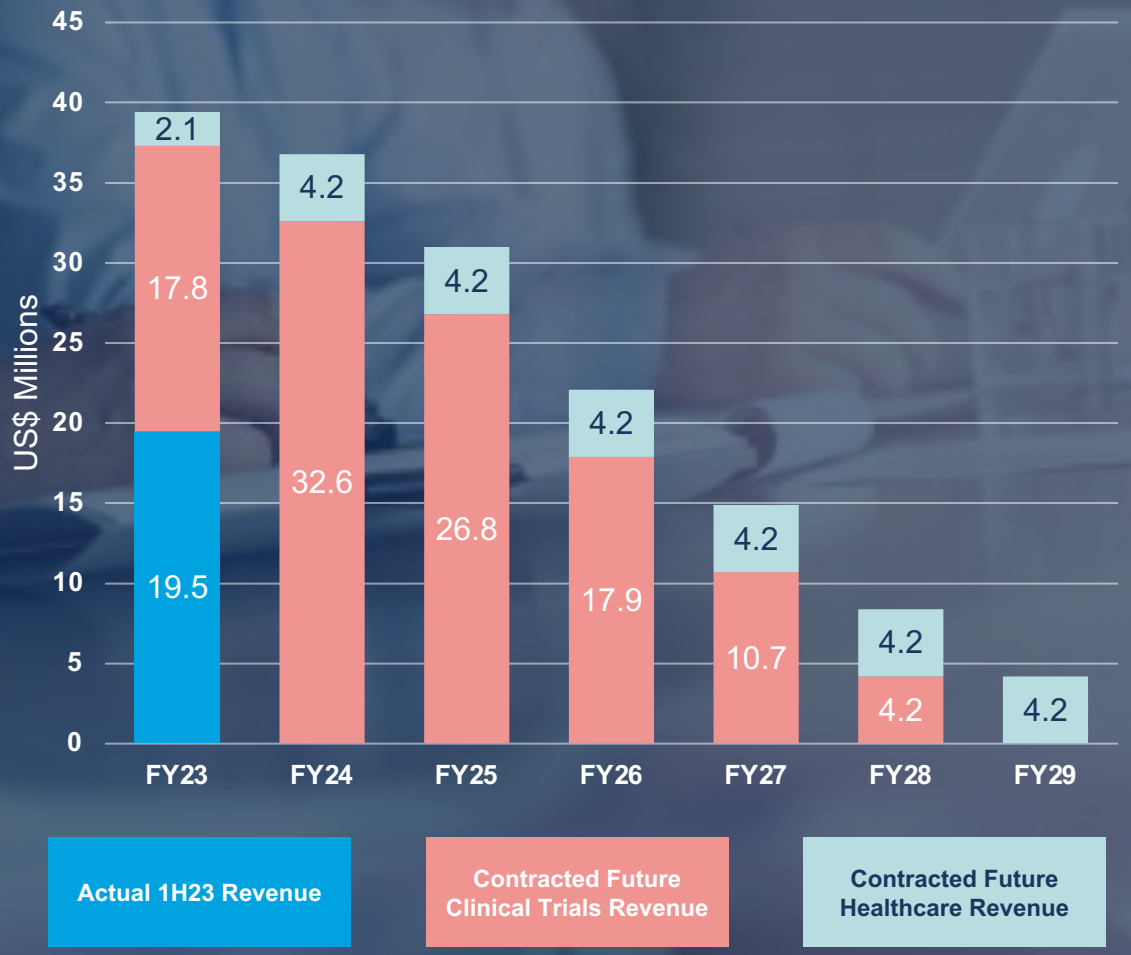
Year-On-Year Growth in Revenue Backlog

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

$146.7m Backlog at 31-Dec-22, up 10% year-on-year

- Clinical Trials Backlog $110.0m
  - Up 20% year on year
- Healthcare Backlog $36.7m
  - Amortisation of Eisai agreement
  - Decreases year on year as $4.2m revenue is recognised each year

Contracted Revenue Run-Off



Analysis of revenue to be Recognised in Future Periods

	Current As at Dec-22 US$	PCP As at Dec-21 US$	Growth US$	Annual Change %
Yr 1	39.4	41.0	(1.6)	(4%)
Yr 2	36.8	30.7	6.1	20%
Yr 3	31.0	24.5	6.5	27%
Yr 4	22.1	19.7	2.4	12%
Yr 5	14.9	14.0	0.9	6%

FY24 Clinical Trials Contracted Revenue $32.6m

- Up from $28.8m at 01-Jul-22 (up 13%)
- Compares to $26.5m pcp (up 23%)

	FY24 US$m
Balance at 01-Jul-22	28.8
FY24 revenue from contracts executed 1H23	3.9
FY24 revenue from delays to FY23 revenue	5.0
FY24 revenue delayed to subsequent periods	(4.0)
Reconciliations relating to completed study	(1.1)
Balance at 31-Dec-22	32.6

Contracted Revenue Historical Analysis

Extended timelines for large Alzheimer's studies have pushed close-out activities into FY27

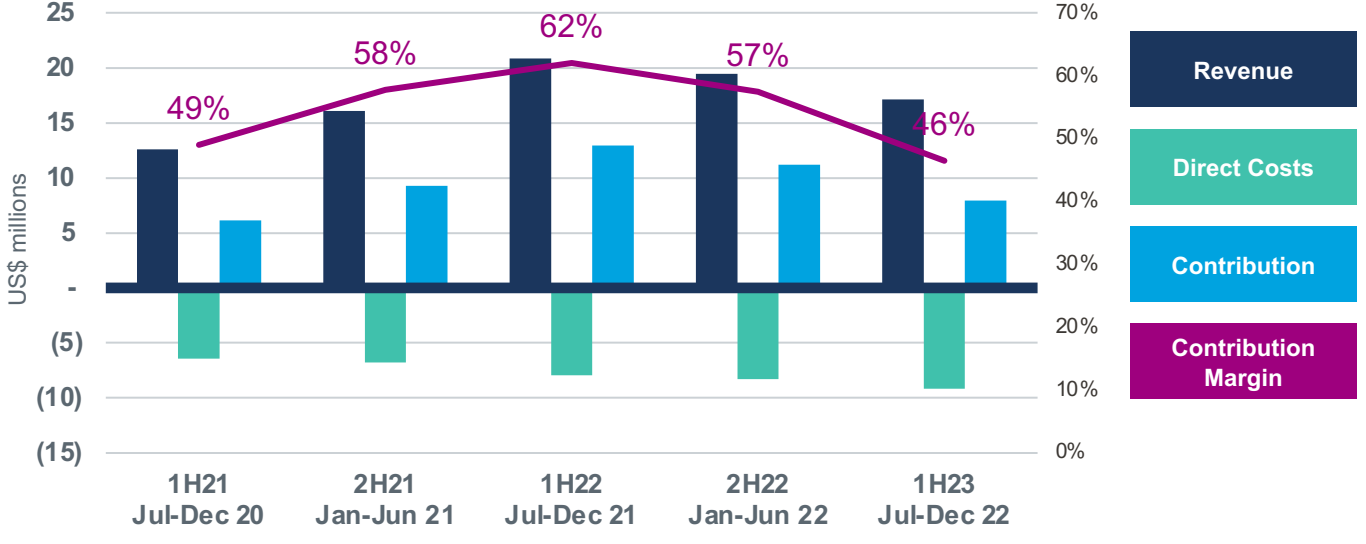
Contracted Future Revenue	At 30-Jun-22	At 30-09-22	At 31-Dec-22
FY23[1]	33.9	27.9	19.9
FY24	33.0	36.0	36.8
FY25	27.7	32.4	31.0
FY26	17.9	22.5	22.1
FY27	6.3	8.4	14.9
FY28	6.6	7.5	8.4
Later years	13.6	13.6	13.6
Total	139.0	148.3	146.7[2]

Notes:
1: FY23 contracted future revenue excludes revenue recognised in 1Q23 (30-Sep-22) and 2Q23 (31-Dec-22)
2: Contracted revenue balance is less at 31-Dec-22 than 30-Sep-22, reflecting the fact that revenue recognised in 2Q23 exceeded sales contracts executed during that quarter


Clinical Trials

Clinical Trials – Our Established Business

US$ millions	1H21	2H21	1H22	2H22	1H23
Revenue	12.58	16.09	20.85	19.48	17.13
Direct Costs	(4.92)	(4.97)	(6.36)	(6.70)	(7.13)
SG&A Costs	(1.50)	(1.83)	(1.56)	(1.59)	(2.04)
Contribution	6.16	9.29	12.93	11.19	7.96
Contribution Margin	49%	58%	62%	57%	46%

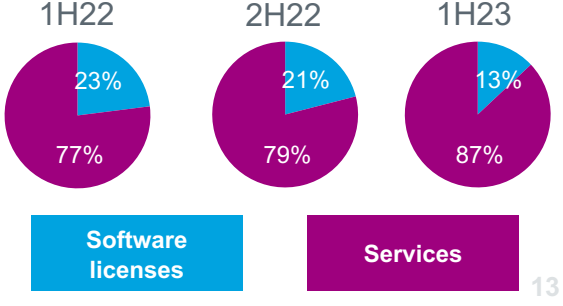


Revenue impacted by delays

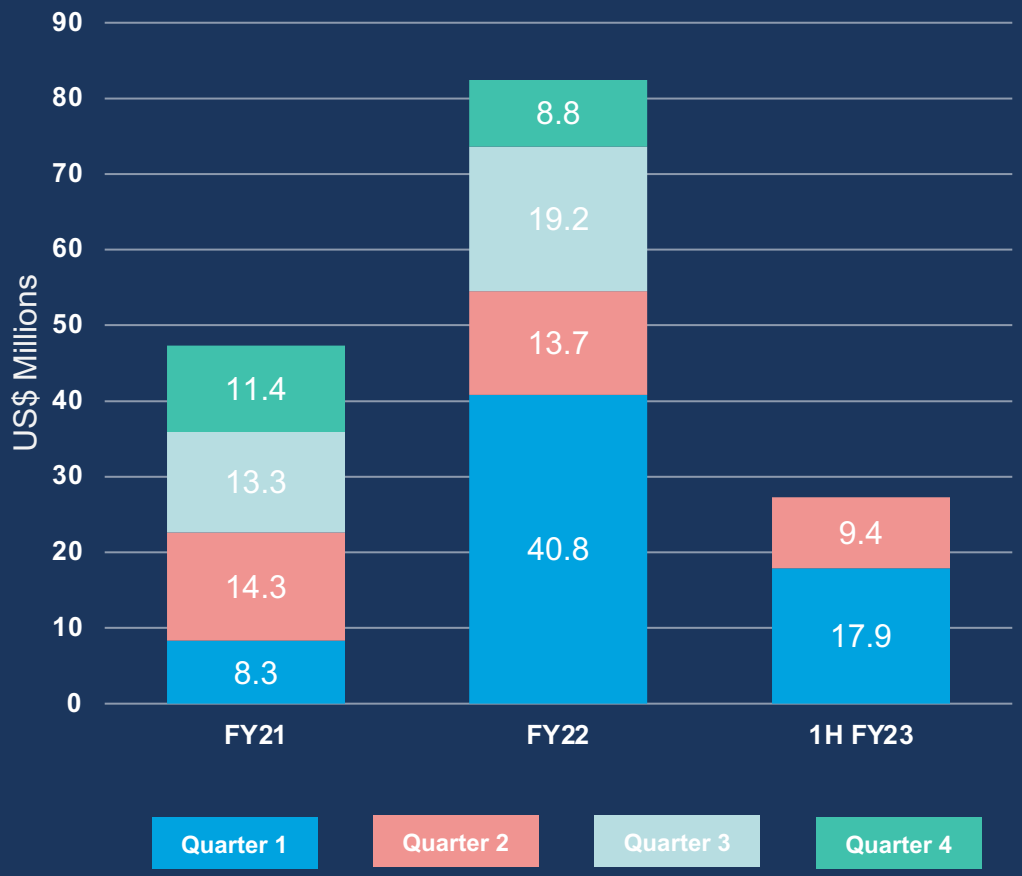
Delays in patient enrolment has impacted revenue with $3.3m of 1H23 revenue under contract deferred to future periods.

Contribution margin impacted by lower software license mix and the fixed nature of resource costs, with resource levels retained for expected ramp-up in revenue.

Software License mix:



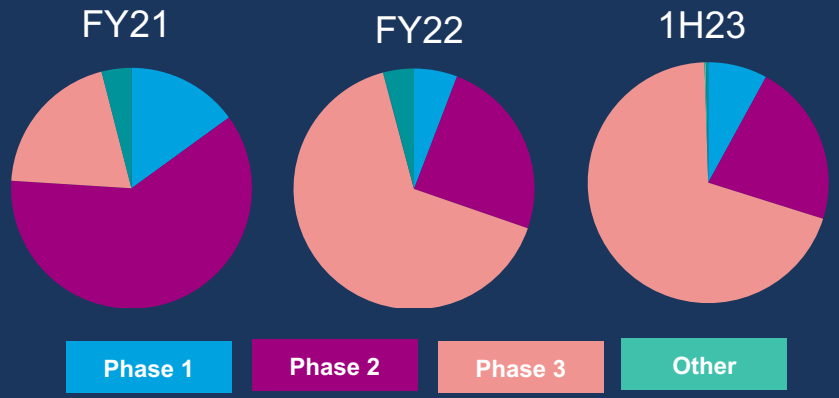
Clinical Trials Sales Contracts



1H23 sales contracts

- US$27.3 million CT sales contracts signed in 1H23
- 50% decrease from PCP primarily due to one particularly large study signed in 1H22
- 82% of the value of 1H23 sales contracts relate to Alzheimer's

Value of contracts signed, by study phase



Clinical Trials Business Update

Sales Efforts

Cogstate sales efforts in the Clinical Trials segment are focused on:

i. an increase in Alzheimer's R&D investment across the industry;
ii. the move to more decentralised trial design with Cogstate providing key technology and scientific services to support such design; and
iii. secure important sales contracts in indications outside of Alzheimer's disease (such as depression and other mood disorders).

Direct costs $7.1m

- Additional clinicians employed to deliver centralised rating activities as part of decentralised clinical trial offering;
- Additional geographic coverage (Japan) to support increased clinical trials in that country; and
- Increase in headcount in anticipation of coming workload.

SG&A costs $2.0m

- Increase in the size of business development team, specifically increased science support of sales activities; and
- Increased marketing cost.

1H23 sales contracts

- 82% were in Alzheimer's disease and 6% in Depression
- Approx. 13% was contracted through channel partners
- Approx. 5% were in respect of decentralised clinical trials but it worth noting that multiple pilots are underway where sponsors are validating decentralised approaches in anticipation of broader use

Contracted future revenue

$110.0m, up from $100.2m at 30 June 2022

- of which 87% relates to Alzheimer's disease trials.


Healthcare

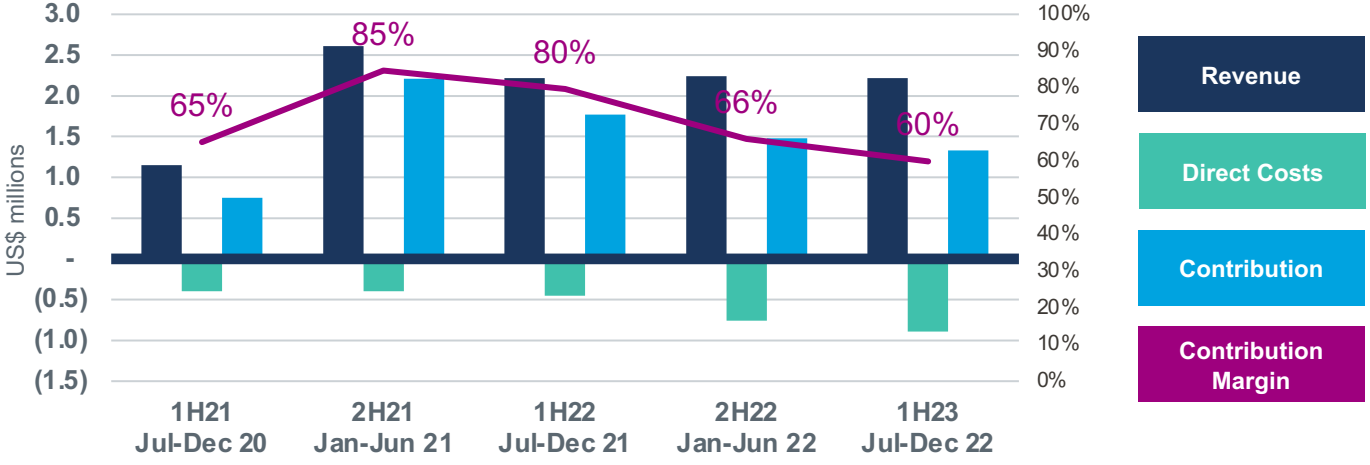
Global License

Eisai: Focusing on dementia as global pioneer since Aricept launch in 1997

- 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

Healthcare – Our Next Frontier

US$ millions	1H21	2H21	1H22	2H22	1H23
Revenue	1.15	2.61	2.22	2.24	2.22
Direct Costs	(0.40)	(0.40)	(0.45)	(0.76)	(0.89)
Contribution	0.75	2.21	1.77	1.48	1.33
Contribution Margin	65%	85%	80%	66%	60%



Eisai product launch stage begins

Revenue represents amortisation of contractual minimum payments from Eisai.

Lower margin a result of a program of work underway to assess go-to-market options.

Healthcare Business Update

Eisai global roll-out

- Eisai and Cogstate have previously announced the launch of Cogstate computerised assessments in Japan (branded as NouKNOW), Hong Kong and Taiwan (branded as CogMate).
- Since 01 July 2022, Eisai has launched Cogmate in Thailand and Korea.

Memory specific instance of Cognigram

- Cogstate is working with Eisai to produce an additional version of Cognigram that will be focused on identification of cognitive impairment most likely to be associated with early Alzheimer's disease, for launch in the USA.
- Cognigram, a class II medical device that has been cleared by the FDA in the USA, was designed as a general cognitive screener. The work on the new instance of Cognigram is currently underway and is being funded by Eisai.
- The new instance of Cognigram will:
    - be focused on the memory assessments that are the most relevant for identification of cognitive change associated with early Alzheimer’s disease; and
    - require less time to complete an assessment (less than 10 minutes).

Analysis of Alzheimer's Disease Market

Alzheimer's Disease R&D Drivers

Increasing probability of technical and commercial success for drug developers

1. Substantial unmet medical need given the modest efficacy of symptomatic therapies and inability to change disease course
2. Amyloid hypothesis and multiple other insights into biology raise the possibility for disease modifying therapies
3. Prevalence of AD and the prospect of earlier, predementia treatment identify huge addressable market
4. Successful conduct of clinical trial builds confidence in predementia trial designs and feasibility including patient identification and recruitment
5. Approval of aducanumab (Biogen) leads to increased confidence in regulatory pathway
6. Approval of lecanemab (Eisai) leads to a confirmed regulatory approval pathway
7. Eisai's approach to pricing lecanemab leads to increased confidence in reimbursement
8. Exploration of novel routes of administration (oral and subcutaneous) provide avenues that may present options for improved patient access to treatment
9. Multiple druggable biological targets currently under investigation with the prospect of future combination therapies to continuously improve efficacy

Current Status : Potential Therapies

External Catalysts:

Important phase 3 data from key Alzheimer's trials

LEQEMBI (LECANEMAB)

Positive phase 3 data released late September showing 27% slowing of cognitive decline.

Current status by geography:

- Received FDA accelerated approval
- Received priority review status in Japan
- Submitted marketing authorization application with EMA (Europe)

US pricing announced: $26,500 p.a.

Subcutaneous trial ongoing

DONANEMAB & REMTERNETUG

Donanemab: Topline data from phase 3 Trailblazer-Alz-2 study scheduled next quarter (Apr-Jun 2023)

Remternetug: an antibody protein, designed to target toxic amyloid plaques, linked to the onset of Alzheimer’s disease.

Lilly comment: “While the mechanism of action is similar between the two molecules, we are exploring alternative dosing regimens, including subcutaneous dosing”

Alzheimer's: Additional Thoughts

Different administration = additional trials

At present, leading Alzheimer's therapies require infusion, requiring substantial infrastructure.

Subcutaneous injection offers practical advantages, not the least of which is the removal of the need to attend an infusion center for administration of treatment.

Pharma will seek differentiation and reduce friction for adoption through developing improved administration, which will require additional clinical trials. There can also be patent extension benefits to developing new formulations permitting new administration.

Alzheimer's: Additional Thoughts

Larger trials and Real World Evidence trials requires better technology

As disease modifying treatments gain approval, post-marketing Real World Evidence studies will be important and more common to monitor long-term outcomes, provide insights into real-world patient populations, compare treatment options, and evaluate the cost-effectiveness of different interventions.

The need to conduct more and larger trials in new and more representative patient populations will create pressures for trial designs that leverage technology and new approaches (like those from Cogstate) to improve efficiency, scalability, and patient-centricity.

Cogstate's tools across both clinical trials and clinical practice in healthcare is expected to be a major competitive advantage.

Share Buyback

On-market Share Buyback for up to A$13 million of Cogstate ordinary shares

Reflects the belief in the business' future commercial prospects, the business' strong capital position, and supports the Board's ambition to improve returns for shareholders.

The timing and number of shares to be purchased under the Share Buyback will depend on the prevailing share price, market conditions and the capital position and requirements over the next 12 months.

Please refer to the Appendix 3C for further information in respect of the Share Buyback.

FY 2023 Outlook

Clinical Trials

Revenue:

- 2H23 revenue expected to increase over 1H23, but FY23 revenue expected to be approximately 6-9% below FY22

Contribution Margin:

- 2H23 in the range of 52% - 55%. Full year FY23 in the range of 48% - 52%.

Healthcare

- Expected to be consistent with 1H22

Group Earnings

- EBITDA is expected to be in the range of 12-15% of revenue
- EBIT is expected to be in the range of 6-8% of revenue
- Cash balance as at 31 December 2022 of $29m; expect positive operating cash flow for 2H23


Financial Charts

Financial Summary – Income Statement

	1H22 Jul-Dec 2021 US$ Million	2H22 Jan-Jun 2022 US$ Million	1H23 Jul-Dec 2022 US$ Million	Calendar Year 2022 US$ Million
Group Revenue	23.1	21.9	19.5	41.1
Clinical Trials Revenue	20.8	19.5	17.1	36.6
Clinical Trials Contribution	12.9	11.2	8.0	19.2
Clinical Trials Contribution Margin	62.0%	57.5%	46.5%	52.4%
Healthcare Revenue	2.2	2.2	2.2	4.4
Healthcare Contribution	1.8	1.5	1.3	2.8
Healthcare Contribution Margin	81.8%	65.8%	60.1%	63.6%
Research Contribution	(0.4)	(0.3)	(0.2)	(0.5)
Operating Expenses	(7.0)	(6.6)	(8.1)	(14.7)
EBITDA	7.3	5.8	1.0	6.8
EBITDA Margin	31.6%	26.3%	5.3%	16.5%
EBIT	6.1	4.6	(0.2)	4.4
EBIT Margin	26.4%	21.0%	(1.2%)	10.7%

Declining revenue resulting from delays in patient enrolment in key Clinical Trials with $3.3m of revenue under contract at 1 July 2022 delayed to future periods.

Lower contribution margin resulting from the revenue delays and the fixed nature of resource costs together with lower SW license mix. Cogstate has retained resource levels to ensure it is able to support growth in studies once enrolments scale up.

EBIT and EBIT margin decline a result of impact to Clinical Trials business with revenue delays and retention of resource levels.

Financial Summary – Balance Sheet

	31 Dec 2021 US$ Million	30 Jun 2022 US$ Million	31 Dec 2022 US$ Million
Cash	25.3	30.6	28.9
Trade Receivables	8.8	8.1	6.7
Property, Plant & Equip	1.1	0.9	0.6
Intangibles	8.6	10.8	11.3
Other Assets	8.4	8.0	7.4
TOTAL ASSETS	52.2	58.4	54.9
Trade payables	6.8	10.2	7.3
Deferred revenue	12.1	10.7	9.6
Employee provisions	2.3	2.6	2.5
Other liabilities	2.8	2.0	1.7
TOTAL LIABILITIES	24.0	25.5	21.1
NET ASSETS	28.2	32.9	33.8

Net cash balance of $27.7m, which is an increase of $3.1m 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 growth reflects the ongoing investment in product development to provide the platform for future growth.

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 reduction results from lower levels of billing due to the delay in trial enrolments.

Net Assets of $33.8m compared to $28.2m at the same time last year.

Financial Summary – Cash Flow

	1H22 31 Dec 2021 US$ Million	2H22 30 Jun 2022 US$ Million	1H23 31 Dec 2022 US$ Million
EBIT	6.1	4.6	(0.2)
Adjustments:			
Deferred Income	(3.9)	(1.4)	(1.1)
Working Capital	(2.5)	2.7	(1.0)
Depreciation & Amortisation	1.1	1.2	1.3
Non-cash employee benefits	0.9	1.3	0.8
Tax Paid	(0.5)	0.0	(0.1)
Other	0.1	0.0	0.1
Net Operating Cash Flow	1.3	8.4	(0.2)
Net Operating Cash Flow (excluding net customer related pass-through expenses)	1.8	7.3	0.4
Total Cash Flow	1.7	5.3	(1.7)
Net Cash Balance	24.6	28.7	27.7

Net operating cash outflow of ($0.2m) resulting from lower cash receipts arising from delays in invoicing to future periods attributable to the delay in patient enrolments

Working capital increased, reflects a lower receivables balance and lower trade and other payables.

Deferred revenue largely relates to amortisation of the Eisai upfront payment but includes license fees charges prior to release of access to customers.

Cogstate