

ASX Announcement

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All figures are provided in US\$

FY20 Half Year Results

Positive momentum across all areas of Cogstate's business

Cogstate (ASX.CGS) has today released its Appendix 4D – Half Year report for the six months ended 31 December 2019 (“1H20”).

Summary of 1H20 Results:

- **Significant improvement in sales contracts executed in the Clinical Trials segment:**
 - Record-high sales contracts executed, totalling \$26.9 million in its Clinical Trials segment (previous best: \$23.0m for the 1H17 period).
 - Record-high revenue backlog, as contracted revenue that will be recognised in future periods expanded to \$37.2 million at 31 December 2019 (previous best: \$35.0m at 31 Dec 2017), with \$10.1 million of this backlog expected to be recognised as Clinical Trials revenue in 2H20.
 - The increase in contracted future revenue at 31 December 2019 will result in an increase in Clinical Trials revenue in 2H20.
- **Establishment of licensing partnership model in the Healthcare segment:** Execution of an exclusive licensing agreement with pharmaceutical company Eisai Co. Ltd (“Eisai”) (including \$2.9 million upfront payment, comprising a \$1 million royalty payment and \$1.9 million equity investment) under which Eisai will market Cogstate digital cognitive assessment tools to physicians and consumers in Japan.
- **Fund raising:** The issue of new shares via private placements and an entitlement offer that raised \$7.5 million of new capital.
- **Financial summary:**
 - Revenue of \$9.7m, a decrease of 12.8% compared to 1H19.
 - Clinical Trials revenue decreased 24.8% to \$8.3 million as a result of the lower value of Clinical Trials sales contracts executed in the preceding 2019 financial year.
 - The decrease in Clinical Trials revenue was partially offset by an increase in Healthcare revenue, inclusive of the upfront royalty paid by Eisai in respect of licensing Cogstate technology for the Japanese market.
 - After tax loss of \$2.1 million (Loss before tax of \$2.9 million), consistent with the 1H19 result.
 - Strong cash position, with cash reserves of \$7.2 million at 31 December 2019 following capital raisings completed during the half year.

Commentary:

Commenting on the first half results, Cogstate CEO Brad O'Connor said, "Cogstate has made significant progress across all areas of our business over the last six months. While revenue declined, as expected, in the Clinical Trials segment and therefore the business has produced a loss for the half year, all forward looking indicators are positive and the business is well positioned for growth in the second half of the financial year, and beyond.

"In the Clinical Trials segment, growing awareness of Cogstate scientific and operational excellence supportive of data quality assurance services for Alzheimer's disease trials (particularly late stage drug development), combined with our proprietary digital assessments, has led to an increase in awarded contracts in this area. Furthermore, recent positive trial data and the potential upcoming release of the first disease modifying therapy for patients with Alzheimer's disease, has led to improved sentiment among Cogstate customers and increased R&D investment in dementia related diseases. At the same time, Cogstate has seen an increase in awarded contracts in other therapeutic areas, including diseases where cognition is measured as a safety endpoint. These factors have combined to deliver our best half year sales result ever for the Clinical Trials segment, which, in turn, will deliver revenue growth and earnings improvement in the second half of the financial year.

"Cogstate's excellent reputation in the pharmaceutical research industry was instrumental in attracting new talent into the business during the half year. Specifically, we were very pleased to welcome Ken Billard as Chief Commercial Officer, to oversee the global sales organisation and execute strategies focused on the continued increase in adoption of Cogstate solutions in pharmaceutical clinical trials. Ken has brought to Cogstate proven expertise in sales leadership and strategic partnering, acquired through a 30-year career leading high-performing commercial teams across eClinical, healthcare and technology businesses.

"Additionally, during the half year, Cogstate has established a licensing partnership model in the Healthcare segment. Commercialisation of Cogstate technology to physicians and consumers has long been seen as an opportunity for Cogstate. In Eisai, Cogstate has found a good partner for commercialising our technology in Japan, and we are looking forward to the first product launch in the coming months. The structure of the agreement with Eisai for the Japanese market works well for Cogstate, in that it provides Cogstate with profit-share potential over the medium term without imposing a large cost base, thereby allowing us to keep overhead as low as possible in the Healthcare segment.

"Since undertaking a restructure of operations a little over a year ago, Cogstate has maintained a lower cost base, which positions the Company to show earnings improvement as the current record level sales in Clinical Trials translates into revenue during the June 2020 half year.

"All of this, combined with ongoing support of our shareholders to recapitalise the company over recent months, position Cogstate for further growth and improved financial results in coming periods."

Outlook:

The high level of sales contracts executed during the half year ended 31 December 2019, the resulting record contracted revenue backlog, and the strong sales outlook for the second half of the 2020 financial year, all combine to provide confidence of a sustainable increase in Clinical Trials revenue over the coming periods.

Through its partnership with Eisai, Cogstate will launch digital cognitive assessment technology to physicians and consumers in Japan during 2H20. Under the terms of the agreement that provides for a share of profits to be received by Cogstate, the product launch in Japan is not expected to impact FY20 earnings.

Notwithstanding growth in clinical trials contracts and increase in Cognigram revenue, Cogstate is expected to record a loss for FY20. As a result of the forecast improvement in Clinical Trials revenue in 2H20, Cogstate is forecasting improved financial performance in the second half of FY20.

Based on expected continued strength in clinical trial sales contracts through 2H20 and into FY21, Cogstate is targeting EBIT profit for FY21.

Further Details:

Further details in respect of each of highlighted items are provided below:

Significant Improvement in Clinical Trials Sales

For 1H20, Cogstate executed \$26.9 million of Clinical Trials sales contracts – the highest half year result ever recorded by Cogstate. This represented 170% growth on 1H19 and 240% growth on 2H19.

During the half year, Cogstate was awarded new business in a range of therapeutic indications including, but not limited to, Alzheimer's disease, Parkinson's disease, epilepsy, haemophilia, schizophrenia, oncology, and a range of rare diseases.

The revenue from the sales contracts executed during 1H20 is expected to be predominantly recognised after 31 December 2019. At that date, Cogstate had a backlog of \$37.2 million of contracted Clinical Trials revenue to be recognised in future periods, with \$10.1 million of this backlog expected to be recognised as Clinical Trials revenue in 2H20.

Establishment of Licensing Partnership Model in the Healthcare Division

As announced in August 2019, Cogstate entered into an exclusive licensing agreement with pharmaceutical company Eisai, under which Eisai will market Cogstate technology as digital cognitive assessment tools to physicians and also directly to consumers in Japan.

Under the terms of the agreement, Eisai agreed to:

- Acquire Cogstate shares to the value of US\$1.9 million at market price under a private placement (see above);
- Pay an upfront royalty to Cogstate of US\$1million;
- Fund necessary product development activities to further tailor Cogstate solutions for the Japanese user base; and
- Fund a commercial team in Japan.

Cogstate and Eisai will share profits equally after taking into account the associated cost of sales for the product in Japan. The agreement has an initial term of ten years, with performance criteria to maintain exclusivity at year five and eight. Commercial launch of the Cogstate technology in Japan is expected to occur by 30 June 2020.

Fund Raising

The issue of new shares via private placements and an Entitlement Offer has raised additional funds totalling \$7.5 million during the half year ended 31 December 2019:

- Australian Ethical Investment private placement - As announced on 8 July 2019, Cogstate issued 22,857,143 shares to Australian-based fund manager, Australian Ethical Investment, at a price of A\$0.175 per share raising \$2.8m (A\$4m).
- Eisai private placement (tranche 1) - As announced on 2 September 2019, Cogstate issued 6,700,000 shares to Eisai, at a price of A\$0.20308 per share by way of a placement, raising \$0.9m (A\$1.36m).
- Eisai private placement (tranche 2) - Following receipt of shareholder approval at Cogstate's 2019 annual general meeting on 21 October 2019, Cogstate issued 4,497,751 shares to Eisai Co., Ltd at a price of \$0.3335 per share, raising \$1.0m (A\$1.5m).
- Retail entitlement offer - Under the terms of the Entitlement Offer to shareholders dated 28 October 2019, Cogstate issued 14,875,339 shares at a price of A\$0.27 per share raising \$2.8m (A\$4m).

Financial Results Explanation

Notwithstanding the growth in Clinical Trials sales contracts executed and the increase in Healthcare revenue during 1H20, Cogstate recorded an increase in the loss for the half year. Analysis of the overall divisional results shows an EBITDA improvement of \$0.7 million compared to 1H19, inclusive of the following factors:

1. The contribution from the Clinical Trials division decreased by \$2.9 million (*negative impact*) (1H20 \$2.2m vs 1H19 \$5.1m)
 - Clinical Trials revenue for 1H20 was \$8.3 million – the lowest half year Clinical Trials revenue figure recorded by Cogstate since June 2015.
 - Direct costs in the Clinical Trials division were consistent with prior half year periods – reflecting the need to maintain threshold levels of resources to meet current work level as well as enable future growth and begin execution of contracted work that will produce revenue in the 2H20 and subsequent periods.
 - The increase in contracted future revenue at 31 December 2019 will result in an increase in Clinical Trials revenue in 2H20.
2. The contribution from the Healthcare division increased by \$2.2 million (*positive impact*) (1H20 \$1.2m vs 1H19 a loss of \$0.9m)
 - Healthcare revenue increased to \$1.3 million for the half year, inclusive of the upfront royalty paid by pharmaceutical company Eisai in respect of licensing of Cogstate technology for the Japanese market.
 - In addition, following a restructure during 1H19, direct costs associated with the Healthcare division fell from \$1.0 million in 1H19 to less than \$0.1 million in 1H20.
3. Overhead costs decreased by \$1.5 million (*positive impact*) (1H20 \$5.1m vs 1H19 a loss of \$6.6m)

The reduction on overhead costs reflects:

- Business restructure undertaken in 1H19 period and strong cost management during the 1H20 period;
- An increase of \$0.26 million in capitalisation of software development costs (\$1.14m) compared to 1H19 (\$0.88m) related to additional development of the Cogstate technology platform; and
- Reallocation of occupancy expenses to depreciation due to changes in the accounting standards (see below).

Changes to Accounting Standards

Depreciation and amortisation expense incurred in 1H20 increased by \$0.7 million compared to 1H19, reflecting two changes:

- Amortisation of intangible assets (capitalised software development costs) of \$0.3m; and
- Depreciation of leased assets of \$0.4m.

Depreciation of leased assets reflects the introduction of a new accounting standard on 1 July 2019 (*AASB 16 Leases*). Under the prior accounting standard (*i.e. AASB 117 Leases*), the obligation to make future payments under an operating lease arrangement was not included on the balance sheet - despite a company being committed to those future expenditures.

From a reporting perspective, the application of AASB 16 has resulted in:

- Inclusion of a Lease Asset on the balance sheet, non-current, against which depreciation has been applied;
- Inclusion of a Lease Liability, current and non-current, against which interest expense has been applied; and
- Change of the expense profile - rather than being an operating lease (e.g. rental expense), the expense component of the lease is now treated as depreciation expense and interest expense.

Partial Funding of Future Technology Development – Post Balance Date Event

Cogstate has entered into an agreement with the Alzheimer's Drug Discovery Foundation (ADDF) to partly co-fund the development of a smartphone application to deliver an existing Cogstate test on iOS and Android devices, which is expected to have relevance in both Clinical Trials and Healthcare markets. Under the terms of the funding arrangement, ADDF will reimburse Cogstate for technical development costs, as well as costs of scientific validation studies, up to an amount of \$1.36 million. The funding will be made available in a number of tranches subject to Cogstate's compliance with periodic reporting and other requirements (including progress towards achieving the goals of the project). Cogstate will fund the balance of the costs required to deliver the project.

The funding has been awarded through ADDF's Diagnostics Accelerator, an initiative established in collaboration with Leonard A Lauder (Co-Chair and Founder of the ADDF), Bill Gates and other philanthropic partners to fast-track the development of diagnostic tools and biomarkers for Alzheimer's disease and related dementias. To learn more about the initiative, please visit AlzDiscovery.org/accelerator.

Following successful technology development and commercial release, Cogstate will pay ADDF a royalty of 4% on the first \$150 million of revenue generated by the smart-phone application and 2.5% on all revenue thereafter, up to a cap of \$11.6 million of total royalty payments.

Under the development plan, a prototype version of the application is expected to be completed prior to 31 December 2020 and will then be available for scientific and commercial validations studies.

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

Summary Financial Results

	Half-year ended 31 December 2019 US\$	Half-year ended 30 June 2019 US\$	Half-year ended 31 December 2018 US\$
Revenue from operations	9,687,302	10,726,474	11,107,900
Clinical Trials			
Revenue	8,252,878	10,376,672	10,976,669
Cost of sales (excluding direct depreciation)	(4,354,786)	(4,312,136)	(4,254,063)
Gross margin	3,898,092	6,064,536	6,722,606
Selling & other direct costs	(1,701,032)	(1,498,776)	(1,598,452)
Clinical Trials EBITDA contribution	2,197,060	4,565,760	5,124,154
	26.6%	44.0%	46.7%
Healthcare Solutions			
Revenue	1,298,315	232,865	63,519
Direct costs	(69,482)	(109,050)	(997,226)
Healthcare Solutions EBITDA contribution	1,228,833	123,815	(933,707)
Research Solutions			
Revenue	136,109	116,937	67,712
Direct costs	(466,193)	(466,553)	(356,307)
Research Solutions EBITDA contribution	(330,084)	(349,616)	(288,595)
Other operating costs	(5,079,021)	(4,930,087)	(6,605,713)
EBITDA excluding share based compensation	(1,983,212)	(590,128)	(2,703,861)
Share based payments (expense of employee options)	17,956	(183,996)	133,021
Depreciation and amortisation	(899,562)	(264,547)	(230,892)
Profit/(loss) before tax	(2,864,818)	(1,038,671)	(2,801,732)
Interest income	11,862	8,824	10,750
Interest expense	(49,498)	(18,791)	(11,099)
Net profit/(loss) before tax	(2,902,454)	(1,048,638)	(2,802,081)

Explanatory Notes:

1: Sales contracts: In the Clinical Trials division, Cogstate enters into contracts (“sales contracts”) with both pharmaceutical and biotechnology companies for the provision of Cogstate technology and services, for use in clinical research trials, to determine the extent to which their investigational compound is impacting the cognition of the patient population. The contract value will differ for each clinical trial, depending upon the scope of the technology and services provided by Cogstate as well as the complexity and length of the trial. An increase in the total value of sales contracts executed will increase the revenue backlog and will, over time, result in an increase to revenue recognised by Cogstate.

2: Calculation of revenue from Clinical Trials division: Revenue from sales contracts is recognised over the life of the contract. The length of a clinical trial can vary from several months for a phase 1 study and up to 4-5 years for a phase 3 study. Revenue is recognised based upon achievement of pre-determined milestones. During each period, revenue may be recognised from (i) contracts in the backlog at the beginning of the period, as well as (ii) sales contracts executed during the period. Usually there is a time lag between an increase or decrease in the level of sales contracts executed and a corresponding change to recognised revenue.

3: Contracted future revenue backlog: Executed sales contract values that have not yet been recognised as revenue at period end are referred to as “contracted future revenue”. The revenue from these contracts will be recognised upon achievement of pre-determined milestones throughout the clinical trials. The contracted future revenue figure provides insight into future revenue performance.

4: Healthcare revenue: Cogstate has developed tools specifically designed to aid healthcare professionals, in general and specialist practice medicine, with objective assessments of cognition in patients. Cogstate’s Healthcare offering includes the system branded as Cognigram™, a medical device which allows for regular and standardised testing to assist in the early detection of cognitive decline that could be related to a range of factors, including neurodegenerative diseases such as Alzheimer’s disease. In August 2019, Cogstate entered into an exclusive licensing agreement with pharmaceutical company Eisai, under which Eisai will market, to physicians and also directly to consumers, Cogstate technology as digital cognitive assessment tools in Japan. Launch of Cogstate technology in Japan is expected to occur within the half year ending 30 June 2020. With an increased focus on brain health in the community and with the potential upcoming release of disease modifying treatment in patients with early Alzheimer’s disease, Cogstate is focused on the growth opportunity that the Healthcare market provides.

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 supporting 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 has recently entered into an exclusive licensing agreement with pharmaceutical company, Eisai, under which Eisai will market Cogstate technologies as digital cognitive assessment tools in Japanese markets. For more information, please visit www.cogstate.com.

For further information contact:

Brad O’Connor
Cogstate Chief Executive Officer
boconnor@cogstate.com