

ASX Announcement

02 April 2024

Eisai and Cogstate Amend Global License Agreement

All figures are presented in US\$

Cogstate (ASX.CGS) announced today that it has amended its global license agreement with pharmaceutical company Eisai Co., Ltd (Eisai) to distribute Cogstate digital cognitive assessment technologies in healthcare markets effective 01 April 2024 (the “Amended Global License Agreement”).

The Amended Global License Agreement will allow Cogstate to continue to work in concert with Eisai, but also to explore an extended role that Cogstate can potentially play in building an integrated system to allow Alzheimer’s patients access to the right intervention at the right time.

Summary

- Cogstate has re-acquired global rights to its technology previously exclusively licensed to Eisai, (excluding for Japan) effective 01 April 2024
- Financial impact:
 - Cogstate retains initial Eisai upfront payment (\$15 million) and all royalty payments received to date (\$3.5 million)
 - Cogstate to receive future minimum royalties from April 2024 until the end of the term (August 2031) of \$11.5 million and agrees to forgo \$15 million of future minimum royalties
 - Reduction in future minimum royalties will have the greatest impact in financial years FY28 through FY31
- Under the Amended Global License Agreement, Eisai has been granted a **non-exclusive** license for Cognigram in the USA and CogMate in certain Asian countries until August 2031
- Cogstate has acquired sole rights to any jointly owned ancillary intellectual property that had been created since the commencement of the Global License Agreement
- The Amended Global License Agreement has **no impact on**:
 - Eisai’s planned launch of Cognigram to physicians in the USA, expected to occur this month (April 2024)
 - Eisai’s 6.8% Cogstate shareholding
 - the separate 10-year exclusive license granted to Eisai over Cogstate technology for Japan entered into in 2019

Chief Executive Officer of Cogstate, Brad O’Connor said “*Cogstate values its partnership with Eisai in both the Clinical Trials and Healthcare segments of our business. This month, we are looking forward to the USA launch of the new memory version of Cognigram that has been designed in conjunction with Eisai.*”

Mr O’Connor continued, “the Amended Global License Agreement provides Cogstate with clear rights in respect of all intellectual property and will allow Cogstate to explore additional opportunities for identification of the first signs of cognitive impairment in the community. We are also eager to explore whether there is an extended role for Cogstate in the identification of patients that may benefit from new Alzheimer’s treatments.”

Background

On 26 October 2020, Cogstate announced that it had entered into an agreement with pharmaceutical company, Eisai Co., Ltd., to exclusively distribute Cogstate digital cognitive assessment technologies in healthcare and other markets world-wide (excluding Japan) (the “Original Agreement”). The Original Agreement specifically excluded clinical trials, where Cogstate continued to market its offering independently.

Under the terms of the Original Agreement that was entered into in 2020, Eisai:

- Acquired exclusive rights for a 10-year term to Cogstate technology in the applicable markets (other than regarding clinical trials), even against Cogstate
- Paid an upfront payment of \$15 million to Cogstate
- Agreed to pay a royalty to Cogstate, which was based on a percentage of revenue generated, but which would not be less than \$30 million over the term of the license. To date, minimum royalties of \$3.5 million have been received by Cogstate (in addition to the upfront payment of \$15 million)
- Agreed to fund necessary product development activities to further tailor Cogstate solutions for each territory and use case. To date, product development reimbursement costs of \$0.7 million have been received by Cogstate, some of which will be repaid to Eisai in exchange for sole ownership of ancillary intellectual property that was previously jointly owned under the Global License Agreement
- Agreed to make commercially reasonable efforts to make the first commercial sale within the following timelines:
 - USA: within 1 year;
 - EU: within 3 years;
 - China: within 4 years;

Comparison of Key Commercial Terms

	Amended Agreement	Original Agreement
Products	USA – Cognigram Asia – CogMate	All Cogstate technology
Regions	USA & specified Asian countries	Worldwide (excl. Japan)
Exclusivity	Non-Exclusive	Exclusive
Minimum royalties from April-2024 to end of license (Aug-2031)	\$11.5 million	\$26.5 million

Additional details are noted as follows:

- Eisai will continue to pay Cogstate a royalty, determined by reference to a range of factors including retail market price (after allowance for customary rebates, discounts and/or sales taxes) of Cogstate technology, or calculated on a per user basis, and which will be no less than the minimum royalty detailed below:
 - Sep 2023 to Aug-2027: annual minimum of \$2 million (\$8m total)
 - Sep 2027 to Aug-2031: annual minimum of \$1 million (\$4m total)
- The term of the license will remain unchanged and will terminate in August 2031 unless extended by agreement of both parties; and
- Total payments made by Eisai to Cogstate under the Original Agreement, since the execution of the agreement in October 2020 (\$19.2 million) will be retained by Cogstate.

Under the Amended Global License Agreement, Eisai will hold a non-exclusive license to distribute specified Cogstate products in the following countries:

- Cognigram in the USA, including a shorter, memory only, version that has been developed in conjunction with Eisai; and
- CogMate in Taiwan, South Korea, Thailand, India, Malaysia, Philippines and Vietnam.

Both Cognigram and CogMate utilise the Cogstate Brief Battery, a collection of four cognitive tests that have been scientifically validated as sensitive to changes in cognition associated with early stages of Mild Cognitive Impairment (MCI) and early Alzheimer's disease.

Cognigram is a Class II exempt FDA listed digital medical device that can be marketed in the USA and is designed to be utilised by healthcare professionals.

CogMate is a direct-to-consumer product, with limited feedback provided to the individual patient. CogMate is not considered to be a "medical device" and therefore does not require regulatory approval.

Both the Original Agreement and Amended Global License Agreement specifically exclude the Clinical Trials market. As such, Eisai and Cogstate will continue to contract with each other as normal in respect of use of Cogstate technology and services in the context of clinical trials conducted by Eisai.

Accounting Treatment

- There will be no change to the accounting treatment of Eisai payments made under the Original Agreement in prior periods;
- In respect of FY24, the amortised amount of minimum royalties will reduce from \$4.1 million to \$3.6 million;
- During financial years FY25 through to FY31, the amortisation of minimum royalties will reduce from \$4.1 million per annum to \$2.1 million per annum.
- The amortisation of minimum royalties in FY32 will be minor, reflecting the period from 01 July 2031 to August 2031 only.

Discussion

Under the Amended Global License Agreement, in the critical USA market, Eisai plans to launch Cognigram to primary care physicians in April 2024. That is, the amendment has not altered Eisai's plans to launch Cognigram in the USA market and Cogstate is continuing to support Eisai efforts in that market.

Eisai will also continue to interact directly with consumers, via CogMate, in the Asian markets—an approach that Cogstate believes can show promise in other territories, including the USA, where the existing healthcare system may be slow to change.

Additionally, this amendment allows Cogstate to progress exploratory plans regarding alternative distribution approaches for our digital cognitive assessment technologies in the short- and mid-term. These approaches will be complimentary to the direct-to-primary care avenue Eisai will pursue in the USA, and include exploration of the following opportunities:

- Consumer health tracking behaviours and assessing how purpose-designed consumer cognitive measurement may fit into these existing habits;
- Assessing non-traditional healthcare delivery models and how related patient behaviours predict interest in cognitive health tracking;
- Community-based partnerships that bring cognitive measurement into the physical and online places where likely users come together; and
- Partnerships that can scale remote delivery of cognitive tests (including leveraging existing, proven capabilities and relationships in clinical trials area) to condense the timeline for medical diagnosis and treatment.

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

About Cogstate

Cogstate Ltd (ASX:CGS) is a leading 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. For more information, please visit 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.