

COGSTATE CLEARED BY FDA TO COMMENCE MARKETING COGNIGRAM™ IN THE U.S.

COMPANY TO LAUNCH COGNIGRAM™ DIGITAL COGNITIVE TESTING TOOL FOR U.S. HEALTHCARE MARKET IN CY2017

Melbourne – July 27, 2017: The cognitive science company, Cogstate Ltd (ASX.CGS) today announced that its healthcare division has received notification from the U.S. Food and Drug Administration (FDA) that the Company's 510(k) submission (K171658) for the COGNIGRAM™ cognitive assessment system has been reviewed by the Center for Devices and Radiological Health and found to meet the requirements of regulations 21 CFR 882.1470; Class II Exempt Medical Device. This notification allows the company to market the medical device for commercial distribution in the U.S.

The COGNIGRAM™ system is a digital cognitive assessment tool with self-administered assessment that can be completed both in-clinic and at-home. It is for prescription use, and is intended to aid healthcare professionals with an objective measurement of cognition for use in individuals aged 6 - 99 years old. The COGNIGRAM™ system can be used to assess cognition on a single occasion or cognitive change over periodic assessments. Performance on the COGNIGRAM™ system is unaffected by language, education, cultural background, or practice.

"After more than fifteen years of intense efforts in supporting academic research and pharmaceutical clinical trials around the world, Cogstate is excited to enter the U.S. market for cognitive assessment on the front lines of clinical practice," commented Frank Cheng, President of Cogstate Healthcare. "We look forward to bringing the proven and widely-published COGNIGRAM technology into the healthcare ecosystem to benefit an exponentially larger pool of patients."

"Many primary care physicians (General Practitioners) lack the tools and training to conduct rapid, objective cognitive assessments. The launch of the COGNIGRAM system will provide doctors with a rapid, scalable, standardised tool for detection of cognitive impairment and decline. The fact that COGNIGRAM requires no special equipment and can be administered in-clinic or online, in the comfort of a patient's own home, makes COGNIGRAM an adaptable solution for the primary care market," said Brad O'Connor, Chief Executive Officer of Cogstate.

Factors that may affect an individual's cognition include the presence of mild cognitive impairment (MCI), Alzheimer's disease, concussion, head injury, major depressive disorder, HIV related dementia, schizophrenia, attention deficit hyperactivity disorder (ADHD), multiple sclerosis, Parkinson's disease, the effects of medication or surgery, as well as a variety of psychological states (e.g. stress, fatigue).

Cogstate expects to begin commercialisation of the COGNIGRAM system in the USA before 31 December 2017, with initial commercialisation efforts focused on U.S. health systems, hospitals, physician practices, elder care organizations, schools and sports teams.

The company will provide further details on its commercial launch plans for the COGNIGRAM system, including revenue and expenditure expectations for FY18, at the company's full year results presentations.

About Cogstate

Cogstate Ltd (ASX:CGS) is a leading science and technology solutions provider dedicated to optimizing the measurement of cognition in clinical trials, academic research and healthcare. Cogstate provides enabling technologies and professional services for higher quality neuropsychological assessments and is a pioneer in commercializing rapid, reliable and sensitive computerized cognitive tests. Cogstate customers include the world's leading biopharmaceutical companies; elite sporting organizations and military; physicians and patients; renowned academic institutions and public-private partnerships. For more information visit www.cogstate.com.

Investor contact:

Brad O'Connor
Cogstate Chief Executive Officer
+613 9664 1300 or 0411 888 347
boconnor@cogstate.com