



COGSTATE
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ASX Announcement

23 December 2013

Cogstate awarded tender for Phase 2/3 Clinical Trial in Alzheimer's disease

Medical technology company Cogstate (ASX:CGS) has been advised that it has been successful in its bid to provide Rater Training services to a Phase II / III study in Alzheimer's disease.

Following a competitive tender process, Cogstate received notification on Saturday 21st December 2013 (Australian time) that it had been chosen as a vendor to the study. Notification of acceptance of the Cogstate bid will be followed by negotiation of the contractual terms. It is expected that the contract for Cogstate's services will be concluded by March 2014. Whilst it is expected that the successful tender will lead to a binding contract, no assurance can be given at this time.

Details of the total contracted amount and revenue impact of the successful tender will be disclosed once contracting has been completed. Whilst it is expected that the total revenue under the contract could be material, the quantum cannot be ascertained at this time and in any event the majority of the revenue under the contract will be recognised after the end of the 2014 financial year. Assuming that contracting is completed by March 2014, the contract is estimated to generate less than \$0.5 million revenue in the year ending 30 June 2014.

This announcement is being made pursuant to section 708AA(12) of the *Corporations Act 2001* (Cth) (as modified by ASIC Class Order CO 08/35) the effect of which is that Cogstate is currently required to disclose "excluded information" (as defined in section 708AA(8) of the *Corporations Act*), notwithstanding that an exception in ASX Listing Rule 3.1A may otherwise apply.

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What is “Rater Training”

Rater training is a term used in the pharmaceutical industry when raters, or those who administer neuropsychological tests at study sites, are trained to rate properly. By training the raters to administer and score tests properly, the pharmaceutical company sponsor of the study is seeking to ensure that the best possible quality and uniformity of data is collected from the study.

At Cogstate, Rater Training describes a broad collection of services that Cogstate offers to pharmaceutical company customers, including scientific consultation, scales management, rater selection/training/certification/recalibration and quality control. These services are provided for all scales and tests, including traditional paper and pencil tests that are used in clinical trials to measure cognition.

Cogstate’s legacy of cognitive science and technology, the size and depth of its science team of neuropsychologists and its systematic integration of science, operations and technology make it unique as a vendor of these services.

During the 2012 financial year, Cogstate began to invest in creating a Rater Training division within its Clinical Trials business unit. The investment was prompted initially by existing customers, who were utilising Cogstate’s computerised tests of cognition but who were additionally seeking from Cogstate the provision of expertise in respect of the conduct of other non-computerised measures of cognition that were also being used in their clinical trials. Cogstate saw an opportunity to further leverage the expertise of its science group by adding additional services to its growing clinical trials business unit. Further, in many indications, such as Alzheimer’s disease, Phase III studies continue to utilise paper and pencil tests of cognition as the primary endpoint, therefore, by offering Rater Training services, Cogstate expanded the number of potential studies in which it could offer services and the size of those Phase III studies meant that significant revenue opportunities existed.

In order to begin structuring a Rater Training offering, Cogstate recruited Dr Amy Veroff to the Cogstate science team. Prior to joining Cogstate, Dr Veroff created and led a global company division that provided specialized scales services for more than 25 years and led rater training programs for more than 200 clinical trials, training more than 20,000 raters worldwide. In Asia, Dr Veroff led rater training programs for Alzheimer’s clinical trials. For a Pacific Asia validation study for Alzheimer’s scales, she trained raters from China, Taiwan, Singapore and South Korea, and she trained raters in Tokyo for clinical trials in Japan. Dr Veroff served on the Alzheimer’s Disease Cooperative Study (ADCS) Workgroup tasked with updating the Alzheimer’s Disease Assessment Scale (ADAS-Cog).

In the 2 years since Dr Veroff joined the Cogstate team, Cogstate has added experienced staff and capabilities to round out an exceptional Rater Training offering for pharmaceutical company sponsored clinical trials. During this time, Cogstate has been able to add Rater Training services to a number of clinical trials that were also utilising Cogstate’s computerised tests of cognition, thereby increasing total contract value.

In April 2013, Cogstate signed a US\$1.5 million study to provide Rater Training services for a Phase IIA study in Autism – the first time that Cogstate had been contracted to provide Rater Training services in a study which did not utilise Cogstate’s computerised tests of cognition.

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About Cogstate

Cogstate Ltd (ASX: CGS) is a multi-faceted cognitive assessment and training company, focused on the development and commercialisation of rapid, computerised tests of cognition (brain function). It has three distinct business units:

Clinical Trials: In the clinical drug trial market, Cogstate technology and associated services are used by pharmaceutical and biotechnology companies to quantify the effect of drugs or other interventions on human subjects participating in clinical trials. Since sales into the clinical trials market began in 2004, Cogstate has secured agreements with top pharmaceutical companies including Pfizer, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Novartis, Lundbeck, Daiippon Sumitomo, Targacept, Otsuka, and Servier.

Axon Sports: The mission of Axon Sports is to “protect and train the athletic brain”. Axon’s focus is to research, develop and deliver cutting edge tools to assess, monitor and improve the athletic brain.

Axon has been developing sport specific training products, initially focussed on American football and baseball, and the resulting technologies have now been launched within a small number of elite US college programs. In addition, the first of Axon’s consumer iPad apps was launched in 2012.

In the area of sports related concussion, Cogstate’s technology has been used by a number of highly regarded institutions and sporting organisations around the world for almost 10 years. That technology is now marketed to consumers as Axon Sports. Current users of Cogstate/Axon Sports in Australia include the AFL and NRL, whilst in the USA elite programs such as the NBA, WNBA, NHL as well as college programs such as University of Notre Dame, University of Michigan and University of Connecticut all use the Axon Sports system.

Healthcare: In the primary care or general practice setting, the Cogstate’s COGNIGRAM™ assesses cognition in patients and the reports generated on the basis of this assessment can allow physicians to identify subtle changes that could be indicative of the early stage of a neurodegenerative disease, such as Alzheimer’s disease. Cogstate intends to develop COGNIGRAM™ to monitor changes in cognitive function following concussion or after treatment with drugs or other types of interventions. In June 2012, Cogstate entered into an agreement with Merck Canada Inc. providing it with the exclusive right to market and promote COGNIGRAM™ in Canada.