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ASX Announcement

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Cogstate Test to be used in large paediatric clinical trial

Medical technology company Cogstate Limited (ASX:CGS) has today announced its technology will be used in a large paediatric clinical trial in the United States.

Under the contract worth approximately US\$1.4 million over four years, the Cogstate Test will be used to measure any changes to cognition as an endpoint measure of safety.

This latest contract consolidates the Company's growing foothold in the paediatric clinical trials market. This is the second paediatric contract signed in the last seven months with a combined value of approximately US\$3 million. Four contracts have been signed over the last few years for the Cogstate Test to be used as an endpoint in paediatric safety studies.

"Our central involvement in paediatric safety studies is a new exciting growth area in our clinical trials business and suggests a growing awareness of, and appreciation for, Cogstate's pediatric tools for their sensitivity, reliability and comparatively low subject burden, a huge advantage in studies of ill children," said Mr Brad O'Connor, Cogstate Chief Executive Officer.

In recent years there has been a fundamental shift in the way children are treated in clinical trials, with an enhanced focus on safety and efficacy as it relates to their physical and cognitive development. In children, safety is a difficult concept, because risks to physical or cognitive development may not be seen for months or years afterwards.

Cogstate is uniquely placed to conduct high quality, cost-effective testing of drugs with the potential to affect children's cognition and neuropsychology. The ease of completing a test is a major advantage.

"Our brief, game-like tests are well accepted by even the sickest children - for example, in an earlier study we found more than 98% of children with acute lymphoblastic leukemia were able to complete them. Previous methods using onerous paper and pencil tests yielded far lower adherence rates in sick children, resulting in missed opportunities to compare the risks and benefits of various treatments."

"With normative data for over 40,000 children, many of whom have been tested annually, Cogstate offers a unique benchmark for tracking normal cognitive development," Mr O'Connor said.

The trial was initiated at the request of the clinical sponsor.

"Regulators were encouraging the sponsor to include an onerous battery of paper and pencil tests in the trial; understandably, they were concerned about the ability of sick children to complete these."

"When the sponsor learned of our work in this area, they engaged us to find a solution that the children could easily complete, but which would still deliver the highest quality data. Cogstate was able to provide robust scientific support for the validity of the tests, and this was accepted by both sponsor and the regulator," Mr O'Connor said.

Increased Clinical Trials Sales Activity

The contract follows the award of US\$1.2m in other contracts in the Clinical Trials business already signed since 1 January 2014, creating a total of US\$2.6m worth of new contracts so far in the 2014 calendar year. Mr O'Connor said today's announcement reflects the strong sales pipeline for the Company's Clinical Trials business.

"In the first six weeks of 2014, we've signed US\$2.6m of contracts. Furthermore, Cogstate has initiated contracting on three additional new studies which have been awarded and will proceed to contract execution over the coming 6-8 weeks. Further details of these studies will be released at the time of execution of those sales contracts."

"We are extremely pleased that, after a slowdown in clinical trial sales throughout calendar 2013, we have seen a substantial increase in sales activity in the first few weeks of 2014. The current level of activity indicates that we can expect a robust level of sales contracts signed in this current half year with revenues recognised across the duration of the contracts."

"With seven of the ten biggest global pharmaceutical companies already using our clinical trials technology, we are continuing to build on the reputation and relationships we've established in the sector to date," he said.

For further information contact:

Investors (Global ex US)

Rebecca Wilson (Buchan Consulting)

+61 417 382 391

rwilson@buchanwe.com.au

Company

Brad O'Connor, CEO

+61 3 9664 1300 or 0411 888 347

boconnor@cogstate.com

Investors (US)

Lauren Glaser (Trout Group)

+1 646 378 2972

lglaser@troutgroup.com

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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.