



ASX Announcement

Melbourne, 12 October 2012

CogState Awarded US\$3.7 million contract for Phase 3 Schizophrenia program

Highlights

- Sales contract awarded for a Phase III clinical trial program in schizophrenia that will generate US\$3.7m of revenue over the duration of the studies
 - Total value of clinical trials sales contracts since 1 July 2012 is US\$6.5m, up 58% compared to same period last year
 - CogState has already secured A\$8.5m of revenue that is expected to be recognised in the 2013 financial year
 - Revenue from the newly awarded studies will act to increase revenue in the second half of the financial year
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CogState Ltd (ASX:CGS) today announced that its Clinical Trials business has been awarded a contract with an international pharmaceutical company to utilise CogState's cognitive testing technology and associated services in a Phase 3 clinical trial program for the treatment of Negative Symptoms of Schizophrenia.

The contracts for three separate studies, collectively CogState's largest ever clinical trial program, will generate US\$3.7 million of revenue for CogState over the duration of the studies, which are expected to run until December 2015.

The contracts bring the total value of sales contracts signed by CogState's Clinical Trials business since 1 July 2012, to US\$6.5 million, a 58% increase on the US\$4.1 million sales achieved at the same time last financial year. For the full FY12 financial year, CogState secured sales contracts to the value of AU\$14 million, a 50% increase on the FY11 financial year.

"CogState Clinical Trials has built an impressive customer base of international pharmaceutical and biotechnology companies who use our testing tools as a way to accurately measure the cognitive effects of drugs on patients participating in clinical trials," said Brad O'Connor, Chief Executive of CogState.

"CogState tests have shown great sensitivity to cognitive change in schizophrenia. To our knowledge, CogState is the only cognitive test battery proven to show sensitivity to the effects of cognitive enhancing drugs in schizophrenia"



“Year on year, this business continues to grow. This contract – our largest clinical trial program ever - will see the CogState test rolled out across 24 countries, in 26 languages. It reinforces the growth potential of our clinical trials business”

The Phase 3 schizophrenia program consists of three clinical trials which will be conducted across 256 sites, in 24 countries. The CogState tests, which will be provided in 26 languages, will be used as a primary outcome measure in a long-term safety study and a secondary outcome measure in the remaining two efficacy studies.

A total of 1110 patients will be screened for the study in order to identify 638 randomised patients to participate in the study which is expected to run until December 2015.

The Phase 3 clinical trial program is for the treatment of Negative Symptoms of Schizophrenia. Negative symptoms involve a diminution or loss of normal functions and include features such as flat or blunted affect and emotion, poverty of speech, inability to experience pleasure, and lack of motivation.

In addition to these symptom domains, diminished cognitive abilities are recognized as distinct core features of schizophrenia.

While antipsychotic medications are highly effective in reducing positive symptoms, they may have only modest impact upon negative symptoms. Effective treatment of negative symptoms remains an unmet medical need with devastating impact on function and there are no currently approved medications for the treatment of NSS in the USA.

Contracted Future Revenue

All commentary in respect of contracted future revenue assumes a US\$/AUD\$ exchange rate of 1.05. Any increase in the relative value of the US\$ will improve CogState's revenue position, which is reported in AUD\$. Conversely, a decrease in the relative value of the US\$ will reduce the forecast AUD\$ revenue.

At this time last year, CogState Clinical Trials business had secured A\$6.4 million of revenue for the 2012 financial year. The Clinical Trials business went on to record A\$11.8 million of revenue.

For the current 2013 financial year, CogState Clinical Trials has at this time secured A\$8.5 of revenue, a 33% improvement on last year. Of the contracted revenue, A\$1.8million was recognised during the period 1 July – 30 September 2012 and a further A\$6.7 million is expected to be recognised in the period 1 October 2012 – 30 June 2013. CogState Clinical Trials currently has A\$11.7 million of contracted revenue that will be recognised in future periods, of which A\$5.0 million will be recognised in future periods beyond the 2013 financial year.



The nature of CogState's sales contracts makes revenue recognition uneven. The timing of recognition of contracted revenue is determined by various study milestones and contracting provisions. At this time, CogState expects to record relatively modest revenue for the first half of the financial year and a stronger performance in the second half of the financial year.

Notwithstanding the strong contractual position, compared to last financial year, a higher proportion of revenue will be recognised in the second half of the year. CogState anticipates that total revenue for the first half of the financial year will be approximately A\$5.0 million, a 27% reduction on the A\$6.9 million of revenue recognised in the first half of the 2012 financial year.

Business conditions for CogState's clinical trials segment are positive and CogState expects to sign additional sales contracts over the course of this financial year, which will further increase the final revenue from clinical trials for the 2013 financial year. At this stage, that impact cannot be accurately quantified.



About CogState

CogState Ltd (ASX: CGS) specialises in the development and commercialisation of rapid, computerised tests of cognition (brain function).

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, Merck, Johnson & Johnson, Novartis, Lundbeck, Dainippon Sumitomo, Targacept, Otsuka, and Servier.

Axon Sports is dedicated to protecting and training the Athletic Brain. Our goal is simple - to transform how athletes protect and train their brains for sport. Axon Sports launched in August of 2010 with the Axon CCAT, a baseline concussion management system that is currently used by major professional teams and leading medical providers to safeguard the cognitive health of athletes of all ages.

While athlete safety is of critical concern, Axon Sports was founded with a much broader goal: transforming the way athletes train for sport. We are currently developing products to train the athletic brain and accelerate the curve of skill acquisition. Today, athletes develop key cognitive skills through practice time and game experience. However, we believe there are ways to isolate and train high-speed decision skills off the field or court, through 'athletic brain training'. Axon is developing new training tools that will speed up this learning process and accelerate the acquisition of athletic expertise. Using Axon programs, athletes can get added 'mental reps' without taxing the body or risking injury.

In June 2012, CogState entered into an agreement with Merck Canada Inc. providing it with the exclusive right to market and promote the CogState Test to primary care physicians in Canada. The first commercial sale is expected to occur before the end of 2012. In the primary care or general practice setting, the CogState Test 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. The CogState Test can also be used to monitor changes in cognitive function following concussion or after treatment with drugs or other types of interventions.

For further information:

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