



ASX Announcement

Melbourne, 21st October 2010

Address to the Annual General Meeting of Shareholders by
CogState Chairman, Mr Martyn Myer AO
CogState Chief Executive Officer, Mr Brad O'Connor

Martyn Myer

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Welcome.

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Broadly speaking, CogState provides technology solutions for the assessment of thinking in humans.

For over ten years, CogState has developed, and then scientifically validated, means by which we can reliably measure a person's thinking, that is their cognition. CogState has patented technology which has been shown to be sensitive to changes in cognition, even with repeated administration of the tests. It is a very powerful tool with multiple applications.

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Presently, CogState is applying this technology in three key areas – clinical drug trials, concussion management in sport and dementia screening.

In clinical drug trials, CogState works with pharmaceutical and biotechnology companies to quantify the effects that their drugs or devices have on the thinking of patients enrolled in the clinical trials. Clinical trials have been CogState's core business for the last 5 years.

In the sport market, CogState provides a tool to assist doctors and athletic trainers to help decide when an athlete should return to play after a concussive injury. CogState has been involved in the Sport market, albeit in a small way, for 8 years now.

CogState is also currently investing in R&D activity in the area of dementia screening, where CogState technology is used as a non-invasive means of identifying cognitive decline that may be indicative of early dementia. We are working towards the aim of mass market sales when drugs suitable or other therapies suitable for the treatment of dementia become available.

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CogState delivered its second consecutive profit result for the 2010 financial year. The Net Profit After Tax of \$1.6 million followed 2009's maiden profit of \$1.4 million.

Revenue from Principal Activities grew by 13% during the 2010 financial year, to \$9.7 million. However, the Net Profit from Principal Activities fell to \$0.5 million for the 2010 financial year, down from \$1.2 million for previous year largely due to investment in product development.

During the 2010 financial year, CogState made substantial investments of both cash and valuable management time in three major initiatives that we expect to deliver large returns over a sustained period.

Firstly, we successfully incorporated the Neuropsychological Test Battery (NTB) into our core clinical trial product. The NTB was developed by CogState Principal Scientist, Dr John Harrison when consulting to the large pharmaceutical companies Elan and Wyeth. Recently, the Food and Drug Administration in the USA has stated that it will accept the NTB as a primary endpoint in Alzheimer's disease studies – where previously the FDA's only public comment was in respect of another paper & pencil measure, the ADAS-Cog. CogState has now signed 10 contracts with pharmaceutical companies incorporating the NTB into CogState supported studies. We expect the NTB to be a major driver of CogState's growth in Alzheimer's disease studies in the coming years.

Secondly, we also devoted a significant amount of management time to analysis of opportunities in the Sports market, particularly in the USA. The result of that work was the Axon Sports joint venture that we first announced in June 2010. Brad will talk more about Axon Sports in his presentation.

Thirdly, we also invested substantial time, resources and cash in the development of a web-based training system for clinical trial sites around the world. The system, which uses subtitles for non-English speaking countries, will substantially reduce the workload of CogState operations staff, improving CogState gross margins in the 2011 financial year and beyond.

The NPAT result was boosted by the decision to bring to account the future benefit of accrued tax losses at 30 June 2010. The future benefit of those tax losses has not previously been recognised. The tax asset that has been brought to account reflects \$4.3 million of tax losses that CogState believes are more probable than not, to be offset against taxable income in future years.

CogState applied \$0.9 million of tax losses against its taxable income for the 2009 financial year and is expected to apply another \$0.6 million of tax losses against taxable income for the 2010 financial year.

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During the 2009 financial year, CogState benefited from the relatively weaker Australian dollar. Throughout the 2010 financial year, the Australian dollar appreciated considerably compared to the US dollar. The average exchange rate for conversion of CogState revenue during the 2009 financial year was 0.74, compared to 0.85 for the 2010 financial year.

Almost all of CogState's sales contracts and invoices are denominated in US dollars, and therefore, as a result of the higher Australian dollar, CogState's revenue did not grow by the same extent as base currency analysis would indicate.

The graph on this slide shows that sales revenue, when measured in US dollars, actually grew by 35% during the 2010 financial year, compared to the 13% growth when measured in Australian dollars.

Obviously, since May 2010, we've seen even further strengthening of the Australian dollar to current rates approximating parity with the US dollar. The Australian dollar strength will reduce CogState's revenue growth and impact on our profitability – at an average exchange rate of \$0.85, US\$8 million of sales revenue equates to A\$9.4 million whereas at an average rate of \$0.95 that same US\$8 million of revenue only equates to A\$8.4 million.

That said, CogState does have some natural hedge built into our business with operations in the US incurring an annual operating cost of approximately US\$2.3 million. Additionally, CogState did put in place a small hedging position in May 2010 when we took out a forward contract for US\$1.2 million at an exchange rate of \$0.842 which allows us to transfer US\$100,000 per month into Australian dollars at the \$0.842 rate.

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During the 2010 financial year, CogState signed 38 sales contracts, up from 32 in the 2009 financial year. The combined value of the sales contracts signed in the 2010 financial year was A\$10 million, up from A\$9.3 million in FY09. Measured in US dollars, we signed US\$8.8 million of sales contracts compared to US\$7.2 million in the 2009 financial year. Again, the relatively higher value of the Australian dollar impacted this result – growth in the value of sales contracts signed was 23% when measured in US dollars, compared to the 8% growth in the Australian dollar result.

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Over the last two years, CogState's core clinical trial business has delivered consecutive profit results. As discussed above, these results have been recorded whilst we have been investing in platforms for future growth, being our push into the Sport market with Axon Sports, our efficiency measures designed to deliver gross margin improvement and the R&D associated with dementia screening.

We know, and have the validation material to prove, that we have technology that is reliably sensitive to changes in a person's thinking.

The challenge and the opportunity for CogState is to use that same technology to answer questions about people's thinking in the broader community. In areas such as concussion in Sport and community Dementia Screening, CogState has the opportunity to market and deliver products that allow people to make decisions about their health.

Brad O'Connor

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In our core business of clinical trials, we added to our product offering during the 2010 financial year when we started to offer the NTB as part of our standard offering in Alzheimer's disease. In doing so, we needed to develop systems to support the use of the paper and pencil tests that make up the NTB. Those systems can be applied to a range of other tests that are used to assess the effectiveness of drugs in Alzheimer's disease studies as well as other indications.

Our customers routinely ask us for additional support in the training, administration and analysis of results from multiple tests other than CogState's. We believe that we can use our expertise developed for the NTB to support these other tests. This is a classic case of selling more products to existing customers.

We've also developed systems, such as the web-based site training system, that will improve our profit margins in future periods. Similarly we are now working on real time data integrity and data management systems that will identify errors that occur at site and seek to eliminate systematic errors from data. The automation of this work will substantially reduce the workload of CogState staff, further improving profit margins. Additionally, CogState's real time data integrity and data management systems will allow us to identify any errors that occur at site and ensure that systematic errors are eliminated, providing measurable benefits to our customers.

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The other opportunities for significant growth within CogState are in the areas of Sport and Dementia Screening. I will now spend some time discussing both of these opportunities.

Axon Sports, a joint venture between CogState and Quixote Investments, was launched in August 2010. Our partners in Axon Sports bring extensive experience in sports marketing; experience that was gained at companies such as Nike, SPARQ training and Footlocker.

The market for concussion testing, in the USA alone is estimated to be in the range of US\$150 to US\$175 million p.a.

At the time of launch, in conjunction with our partners at Axon Sports, we delivered a comprehensive analysis of the opportunity in the sports market including details of the Axon Sports business plan as well as the background for the key people behind Axon Sports. I don't intend to run through that presentation again at this time, but for those interested in viewing that presentation, a recording of it can be found by following this link on the CogState website.

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The important point to note in respect of the Sport market is that the issue continues to generate significant media and legislative interest in the USA.

At a national level there are two legislative initiatives. The first is the bill HR1347, the 'Concussion Treatment and Care Tools Act of 2010' or the 'ConTACT Act of 2010'. The second bill is HR 6172, the Protecting Student Athletes From Concussion Act. Both of those bills are currently moving their way through the Congressional committee process. At the same time as these laws are being mooted at a national level 11 states have passed legislation in some form dealing with management of concussions. Most other states have some form of legislation pending.

Our view is that concussion management is a significant issue that is not going to go away and that we have a proven product that has been well designed to provide valuable information to medical professionals as they seek to manage the risks posed by concussive injuries. Further, we think that we have partnered extremely well and that the marketing and distribution expertise of our partners will be a critical factor in the success of Axon Sports.

Axon Sports provides the potential for financial upside for CogState and its shareholders.

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Using the same technology and systems that we use in clinical trials, our R&D is now focusing on practical uses of the CogState technology in clinics and the community for wide scale screening and detection of cognitive impairment. We would like to present some specific examples of these promising target markets.

Community based screening, outside of the clinical trial system, for early stages of Alzheimer's disease in middle aged and older adults is one of our key research focuses. AD is characterized by gradual and progressive cognitive decline particularly in memory.

Early detection of AD when consequences are minimal is desirable. We have been studying community volunteers aged 50 years and above since 2007 with serial CogState testing, and have demonstrated and published that our tests are easy to use and acceptable to this population, and moreover cognitive decline on our memory measures predicts an increased risk for later AD, by showing a threefold increased risk of a positive amyloid-PET scan.

The graphic at the top of this slide, looking at the green line, shows the decline in memory over a 12 month period for an individual who presented as a healthy 50+ year old. The graphic immediately below, of the same person, shows the positive amyloid-PET scan.

These scans use a tracer to show the distribution of amyloid protein, which is one of the main pathological abnormalities of AD, and which accumulates excessively even decades before significant disability occurs in AD.

Our studies are therefore detecting patients at very high risk of developing AD at a time when the patient is otherwise healthy without other imaging or neuropsychological abnormalities. Hence, we are now developing this technology for wider application – to be used in conjunction with disease modifying drugs as they come to market, or diagnostic tests of AD which may be invasive, or both.

The technology is also being used in influential collaborative academic studies, such as those listed here.

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In addition, there are multiple other R&D areas we are exploring.

Large scale longitudinal studies typically enroll thousands of participants making cognitive surveillance a costly and resource-intensive process. Use of our computerized tasks including the new online version has the ability to make such research possible. It can allow the cognition of participants to be monitored with minimal cost and data handling. Significant decline can then lead to more detailed evaluation.

We have already deployed a fully working system in NSW in collaboration with the Brain Mind Research Institute (BMRI) and both the ANU and Sydney University, in a study of approximately 500 eligible participants screened from nearly 8000 using a web-based research system. In the USA, we are collaborating with the University of Minnesota to set up a similar cognitive monitoring system for one of the longest running longitudinal studies ever undertaken called "The Nun Study". The use of our technology by such well-respected studies will lead to further uptake and adoption and endorse the use of our technology in this area.

Similarly, the ability to cost-effectively monitor the cognitive performance of patients with HIV dementia or multiple sclerosis are active areas of research.

HIV patients on combination retroviral therapy (CRT) can be monitored to detect cognitive decline in order to adjust their treatment and monitor return to baseline.

In multiple sclerosis, our sensitive cognitive measures are being evaluated as cost-effective early warning indicators for patients on powerful immune therapies for improvement in cognitive outcome or detection of serious viral infections.

These are just a few of the areas in which CogState is active in pioneering R&D to expand the use of our technology into novel mass consumer markets.

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So, to summarise, we continue to see significant upside in our core clinical trial business.

We are working on significant technological advancements that will automate a number of time consuming tasks that are currently undertaken by CogState staff. This will allow us to deliver gross margin improvement in financial year 2011 and beyond.

We will seek to further expand our products in the clinical trial area – focussing on selling more products to existing customers. Our focus initially will be Alzheimer's disease studies where our customers are already requesting us to provide additional services.

The data integrity and data management tools that we have developed for the NTB will be utilised as we support other tests in Alzheimer's disease studies. We expect that the same tools will assist us to expand our product range in indications other than Alzheimer's disease, such as schizophrenia and depression.

We believe that we have partnered well in the Sport market. We continue to be impressed with the team behind Axon Sports, and believe that their collective experience in marketing and distributing sports products gives us a distinctive advantage.

To that end, we are currently negotiating a third party distribution agreement that, if successful, could increase the profile of Axon Sports significantly.

We believe that the market for concussion management tools will expand rapidly, driven by legislative changes and continued media attention. Sporting bodies, schools and parents are all increasingly aware of the risks of concussion and looking for an appropriate management system.

Finally, we are actively pursuing R&D activities that will allow CogState to take our existing technology and seek a broader mass market applications.

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As we did at this time last year, we will provide guidance in respect of the first half of this 2011 financial year.

In terms of sales contracts signed, after a slow start to the year we have seen a recent upturn in activity and we now expect the value of sales contracts signed in this December half to be approximately equal to the value of contracts signed in the first half of the 2010 financial year – in the order of US\$5.5 million.

However, first half sales revenue is expected to be significantly less than the first half of the 2010 financial year. At this time, we are anticipating total sales revenue to be in the range of A\$3.5 to A\$4 million. Down from A\$5.1 million for the same period last year.

The decline in sales revenue is being driven by two factors; firstly the high Australian dollar has reduced our A\$ earning significantly, accounting for approximately half of the revenue decrease. Secondly, the timing of contract sales, with the majority expected in the second quarter, means that a large percentage of the revenue from contracts signed in the first half will be recognised post 1 January 2011.

As a result of lower than expected sales, we are forecasting a loss from operations of approximately \$1 million for the first half of the year. In addition we are expecting below the line costs such as the loss from the Axon Sports JV and contract termination fees will produce additional costs of approximately \$0.6 million.

At this stage we are forecasting a first half net loss of approximately \$1.6 million, of which \$0.8 million can be attributed to the recent strength of the Australian dollar.

That said, our clinical trial prospects are now very strong, after a slow start to the year. With a large number of contracts expected to be signed between now and 31 December, we expect that revenue for the second half of the financial year will increase significantly from the first half.

We are confident in our strategy. We believe we do need to increase the size and scope of our clinical trial business to eliminate the current lumpiness in our revenues. We believe that we need to continue to push to exploit opportunities for use of CogState technology in the broader community. We think that Axon Sports will be the first such example of our capability in the broader community. Finally, our research is showing that our technology can be used effectively as a screening tool for cognitive decline in the community, a market with enormous potential well beyond our existing clinical trial business.