



LCT

living insights

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Published on an occasional basis, *Living Insights* is a source of up-to-date information for followers of the Australasian biotechnology company Living Cell Technologies (LCT)

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Message from the CEO

Welcome to the first issue of Living Insights for 2017.

LCT's goal is to be a profitable company earning revenue from the sale of NTCELL® as the first disease-modifying treatment for Parkinson's disease. A successful NTCELL implantation program beginning in New Zealand will achieve this goal.

Currently LCT has the product, technology, finance plan and necessary contacts to launch NTCELL in 2018.

LCT is dependent on completion and a successful outcome of its Phase IIb clinical trial of NTCELL in Parkinson's disease. The trial endpoints must answer the three questions raised by the NZ Ministry of Health, in particular definition of any placebo contribution to efficacy, to allow LCT to request marketing approval from the Ministry.

Therefore, our focus over the past few months has very much been on progressing the Phase IIb trial of NTCELL for Parkinson's disease.

This issue has updates on the trial as well as some financial news and outlines our plans for the next few months. Please read on.

Ken Taylor
CEO

NTCELL trial update

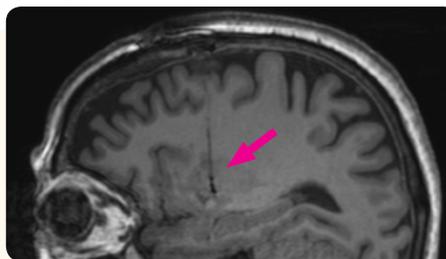
In December 2016 we completed treatment of the six patients in group 2 in the Phase IIb clinical trial of NTCELL for Parkinson's disease. Four patients had 80 NTCELL microcapsules implanted into the putamen on each side of their brain, and two patients had sham surgery with no NTCELL implanted. The final surgery took place on 21 December. There have been no safety issues in any of the six patients.

On 8 February 2017 we received permission from the Data Safety Monitoring Board to commence treating the patients in group 3. Four patients will have 120 NTCELL microcapsules implanted into the putamen on each side of their brain, and two patients will have sham surgery with no NTCELL implanted.

Treatment of the group 3 patients at Auckland City Hospital planned for February has been delayed by a month due to having to wait for Quality Assurance (QA) clearance of the batch of NTCELL prepared for group 3.

The third party we use, which had previously reliably met timelines for test results, had to resolve an in house assay procedure before it could provide a validated assay result. The issue was resolved but the QA clearance was confirmed only on 28 February.

We are now rescheduling surgeries beginning in March for this final group. This means it will now take approximately a month longer to complete the trial as the results are unblinded 26 weeks after the last patient in group 3 has been treated.



Sagittal MRI showing the cannula tract. Implanted NTCELL micro-capsules can be seen distributed through the putamen at the end of the tract.

Patent published

On 11 January 2017 we were pleased to receive written notification from the United States Patent and Trademark Office that our patent application "TREATMENT OF CNS DISEASE WITH INDUCIBLE CHOROID PLEXUS CELLS" No. 15/154,709 was published with a date of 15 December 2016.

The application was filed on 13 May 2016 and the provisional application No. 62/162,390 was filed on 15 May 2015.

The abstract of the application is:
"Compositions and methods are disclosed that relate to improved treatments for nervous system diseases and disorders using CNS-implanted semi-permeable biocompatible capsules containing encapsulated pathogen-free xenogeneic choroid plexus (CP) cells that are induced to produce altered (and in certain embodiments increased) levels of one or more cerebrospinal fluid (CSF) components. Capsules are selected as disclosed to be capable of induction of elevated CSF production levels by CP cells that are remarkably (>16 months post implant) long lived, without eliciting immunological rejection, inflammation or foreign body response reactions."

The published patent application recognises a significant number of claims relating to NTCELL.



Half year result

On 22 February we announced the half yearly report for the six months ended 31 December 2016.

The consolidated operating loss after income tax for the period 1 July to 31 December 2016 was \$2.1m (2015 loss \$1.4 m). The main reason for the increased loss is that during the period, groups 1 and 2 of the Phase IIb clinical trial of NTCELL for Parkinson's disease were treated at Auckland City Hospital and the cost of securing the supply and manufacture of NTCELL.

Research and development has increased significantly due to completion of groups 1 and 2 and the manufacture of NTCELL for the Phase IIb clinical trial. Callaghan Innovation Growth Grant income increased as a result of increased eligible R&D expenditure.

Services provided increased, reflecting the facilities provided to the 50 percent joint venture company Diatranz Otsuka Limited (DOL) now that the company leases the manufacturing premises. The company's share of joint venture losses exceeds its interest in the joint venture so the losses are no longer equity accounted.

As at 31 December 2016 net assets were \$9.8m compared to \$3.7m at 31 December 2015 and \$5.7m as at 30 June 2016. Cash and cash equivalents at 31 December 2016 increased to \$8.6m (30 June 2016 \$5.3m). This increase is primarily due to the capital raising of \$6.3m at the end of November, partially offset by increased R&D expenditure.

► [View the full report on the LCT website](#)



Living Cell Technologies has been named in the 2017 OTCQX® Best 50, a ranking of top-performing companies traded on the OTCQX Best Market last year.

LCT came in at number 36 in the annual ranking of the top 50 U.S. and international companies traded on the OTCQX market.

The ranking is calculated based on an equal weighting of one-year total return and average daily dollar volume growth in the previous calendar year. Companies in the 2017 OTCQX Best 50 were ranked based on their performance in 2016.

Tax loss rebate

As part of the New Zealand Government's focus on the importance of innovation to grow New Zealand, assistance is now available to tax loss-making research and development companies to enable them to "cash out" the tax losses caused by expenditure on R&D instead of carrying those losses forward to use at a later date.

This enables those businesses to have cash on hand when they need it most at the start-up stage of the business.

In exchange for forgoing \$500,000 of tax losses LCT received \$140,000 from Inland Revenue in January. The company has significant tax losses to carry forward so elected to access this cash assistance now.

Looking ahead

In August 2017 all four patients in the initial Phase I/IIa trial should have reached the next common point of measurement – being 130 weeks post treatment. We anticipate an update on their progress at this time.

Meanwhile all our efforts are focused on completing the final group of six patients in the Phase IIb trial and progressing our plans for commercialisation in 2018.

LCT is incorporated in Australia with its operations based in New Zealand.

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