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 leading Australasian biotechnology company Living Cell Technologies (LCT)

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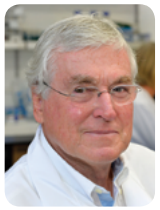

Message from the CEO

Welcome to the first issue of Living Insights for 2016.

I thank you all for your support over recent months as the company has focused on achieving two major milestones.

1. The commencement of the Phase IIb trial of NTCELL® for Parkinson's disease.
2. Ensuring the company has sufficient funds to complete all implants in the trial.

I'm pleased to report that we have met both those milestones.

The goal of becoming the first disease-modifying treatment for Parkinson's disease to reach the market is highly motivating both for the medical and commercial outcomes.

I look forward to keeping you regularly updated on our progress.

Ken Taylor
CEO

NTCELL trial

The initiation meeting of all those involved in the Phase IIb NTCELL clinical trial took place in March and patient recruitment is now under way.

The trial aims to confirm the most effective dose of NTCELL, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub group.

Because of the innovative nature of the product and because the study is launch-enabling, we have had to gain approvals and authorisations from the New Zealand Minister of Health, Medsafe, the Northern A Health and Disability Ethics Committee, the Auckland Hospital Research Review Committee and relevant consultation groups including Maori.

The comprehensive data proving the quality, safety and preclinical efficacy was critical to gaining these approvals.

We have had a very encouraging meeting with the Data Safety Monitoring Board (DSMB). This board is made up of three independent members with expertise in neurology and infectious diseases. The board supports our study design and will play a crucial role, as in the first trial, of monitoring patient safety and approving the study progression.

We meet regularly with the neurologists, neurosurgeons, statistician, study directors and nurses to co-ordinate the initiation and execution of the trial.

Funding

In order to initiate the trial we also had to confirm that we had sufficient funds to complete it. The recent private placement and subsequent share purchase plan raised A$3.3m total.

Combining this with existing cash reserves and the 20 percent eligible research and development rebate from Callaghan Innovation, I am now confident we will be able to complete the implants in the Phase IIb study without seeking further funding.

It is particularly pleasing that the group of high net worth individuals who took part in the previous private placement all re-invested in this latest placement, and new respected professional investors also contributed.

Funding drug trials the Japanese way...

According to a recent editorial in Nature...

Japan has introduced a system for patients to pay for clinical trials. And it appears patients are willing to pay for a treatment that is not yet known to be effective. One of the approved treatments, HeartSheet – a treatment for severe cardiac failure, costs nearly 15 million yen (US$122,000).

Companies are getting clinical trials subsidised before they know if the treatment works. This reflects the huge medical need to identify novel cell therapies to try to relieve the colossal health costs associated with diseases common to aging populations such as Parkinson's disease.

Market for NTCELL

There are 7-10 million people living with Parkinson's disease worldwide.

The incidence of Parkinson's disease increases with age, with only around 4 percent of people with Parkinson's disease diagnosed before the age of 50.

The global population aged over 60 is expected to increase from 12 percent in 2013 to 21 percent in 2050 so we can expect to see a corresponding growth in the number of people living with Parkinson's disease.

In 2014 Parkinson's disease drug sales totalled US$2.4 billion.

This is expected to increase to $2.9 billion by 2020.

Current treatments for Parkinson's disease do not reverse or slow the degeneration of neurons in the brain. Most existing pharmaceutical treatment options focus on restoring the balance of dopamine and other neurotransmitters to reduce the symptoms. But such treatments eventually cease to work. Cell-based therapies are the widely-accepted new frontier for Parkinson's and other neurodegenerative diseases.

A recent report by technology research company, Technavio, predicts that the regenerative medicine market in the US will grow at a compound annual growth rate of more than 33 percent by 2020. Regenerative medicine encompasses the process of using therapeutically induced or laboratory grown human tissue to treat diseased or damaged human cells, tissues or organs. The report identifies Living Cell Technologies as a prominent company in this field.

In contrast to other cell based therapies such as stem cells, NTCELL is not a reprogrammed cell involving manipulation of DNA or RNA. NTCELL is encapsulated choroid plexus cells that, when implanted, do exactly what nature developed them to do – release multiple nerve growth factors and protectants to prevent neurodegeneration and restore neuronal homeostasis. Moreover NTCELL does not require immuno-suppression when implanted and only one surgical procedure is envisaged.

While there are many potential treatments in early stage development, NTCELL is the most advanced disease modifying cell therapy currently in development.

Forthcoming meetings

BIO International Convention
The Global Event for Biotechnology

2016 BIO International Convention

The 2016 BIO International Convention is the largest pharmaceutical and bio conference in the world. It takes place in San Francisco from 7-10 June. Callaghan Innovation has invited Living Cell Technologies to participate as part of its presence. This meeting will be invaluable as we work to confirm our launch plan for NTCELL and look at ways technology can improve the manufacture of NTCELL such as automated cell sorting.

International Congress of Parkinson's Disease and Movement Disorders

The 20th International Congress of Parkinson's Disease and Movement Disorders will take place in Berlin from 19-23 June.

At the congress, our principal investigator Dr Barry Snow will present an update on the safety and efficacy of NTCELL from the Phase I/IIa study. By June all four patients will have reached 1.5 years, and the first patient will have reached 2.5 years post NTCELL implant.

For a summary of the initial trial...
▶ *Watch the video here*

or on the LCT website:
▶ *www.lctglobal.com*

Broker engagement

In the past month LCT has presented to Forsyth Barr, and met with Craigs Investment Partners. CEO Dr Ken Taylor also has meetings planned with a number of brokers in Australia in the coming months.

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