#### AUGUST 2015 • ISSUE 5

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) In this edition

- An update on NTCELL
- An update on DOL strategy

# Message from the CEO

Welcome to this issue of Living Insights. As you'll be aware, there have been a number of significant developments at Living Cell Technologies over the past few months.

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In June Dr Barry Snow and I attended the International Congress of Parkinson's Disease and Movement Disorders in

San Diego. At the congress Dr Snow presented the results of the Phase I/IIa clinical study of NTCELL® for Parkinson's disease. Colleagues in Parkinson's disease research from around the globe showed great interest in the research. It was most encouraging to see that NTCELL is the farthest advanced of the cell therapies currently in development anywhere in the world. The study has shown us that NTCELL has tremendous promise as the first potential treatment that targets the underlying disease rather than just mitigating the symptoms of Parkinson's disease.

The positive results of the Phase I/IIa study give us a strong foundation for the design of a follow-up Phase IIb study, which we anticipate will get underway in the fourth quarter of this year.

The board and leadership team have also been hard at work refining the strategic direction of the company, the structure of the business and our investment in DOL. We're planning to share the details with shareholders in an Investor Roadshow in Sydney and Melbourne in the third quarter of this year.

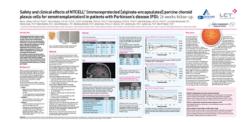
# **Update on NTCELL**

19TH INTERNATIONAL CONGRESS OF PARKINSON'S DISEASE AND MOVEMENT DISORDERS



At the 19th International Congress of Parkinson's Disease and Movement Disorders, Principal Investigator Dr Barry Snow presented the results of the Phase I/IIa clinical study of NTCELL in Parkinson's disease.

Visit Dr Snow's presentation poster on our website



## Treatment safe, patients improve

Most importantly, the study met its primary endpoint of safety, showing NTCELL implantation was well tolerated, with no adverse events considered to be related to NTCELL.

At 26 weeks post-implant, NTCELL also improved clinical features of Parkinson's disease in the four patients studied, as measured by validated neurological rating scales and questionnaires. The first patient implanted has passed 74 weeks post-implantation and her neurological scores continue to show improvement.

The positive response from the four patients, in combination with the safety data, is extremely encouraging. With input from regulators and scientific advisors we have designed the Phase IIb study and will submit it for approval in August. The larger study, which will also be led by Dr Snow, is designed to confirm the effects of NTCELL in patients with Parkinson's disease and to determine the most effective dosage.

# Update on NTCELL CONTINUED

### **Phase IIb study**

The patient in the Phase I/IIa study who appeared to respond best to NTCELL was the youngest patient who was diagnosed most recently. While the final design of the follow up study is still to be determined, the current intention is that it will involve up to 18 patients under the age of 65 who have had Parkinson's disease for at least 5 years. The primary endpoint of this Phase IIb study will address the efficacy of NTCELL as a treatment for Parkinson's disease.

Patients will be treated in groups. Each group will receive bilateral implants of NTCELL at a range of doses. In each group, one patient will receive a placebo dose. At the end of the study, the patients who received the placebo will receive an implant of NTCELL at the dose determined to be most effective.

The clinical study will initiate in 2015 and will be completed in 2017.

#### **Provisional consent**

After the study is completed in 2017 with a positive result, LCT intends to apply for provisional consent to treat patients in New Zealand with NTCELL for Parkinson's disease. People will then be able to pay to be treated with NTCELL for Parkinson's disease, thereby generating revenue for the company.

#### **FDA** approval

Once 100 people have been treated with NTCELL for Parkinson's disease we can begin discussions to get NTCELL approved for use with the Food and Drug Administration (FDA) in the United States and similarly with the relevant European authorities.



# Update on DOL strategy

In June Living Cell Technologies' 50% owned joint venture, Diatranz Otsuka Limited (DOL), announced plans to concentrate its research and development activities on supporting the development of DIABECELL® in the United States.

Operating under an exclusive licence for US development, DOL's other shareholder Otsuka Pharmaceutical Factory, Inc. (OPF), has now established a strong partnership framework to progress the US development program.

This alignment of DOL's expertise with the US program is part of DOL's previously announced commitment to focus on the development and FDA approval of DIABECELL.

As a consequence, research, development and manufacturing of DIABECELL in New Zealand will cease and there will be a reduction of staff at DOL's headquarters in Auckland.

LCT will continue research and manufacturing of NTCELL from DOL's Auckland facilities.

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

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