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living insights

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)



Message from the CEO

Welcome to this issue of *Living Insights*.

In New Zealand we are fortunate to have had our COVID-19 restrictions eased, with most restrictions now lifted, except for the border. However the impact on business, the economy and the global movement of individuals will be much longer lasting.

Despite the global uncertainty, I can reassure you that LCT has a consistent business plan and a clear and well-defined strategy to bring revenue to the company.

While the shutdown, particularly of the university laboratories, has caused delay in the time to achieve milestones, the product targets are achievable and the revised timelines are feasible.

We were able to reduce expenditure significantly during the lockdown and have elected to prioritise projects to ensure we have cash to achieve a definitive project milestone, which is to initiate a clinical trial. We have sufficient reserves to meet our current obligations.

Ken Taylor
CEO

LC-002 for Treatment of Migraine - work resumes at University of Auckland

The team at the University of Auckland has resumed work on the migraine project. Migraines are usually treated with triptans. But for those who do not respond to the standard treatment new compounds are coming onto the market. These compounds are either antibodies or small molecules which directly block calcitonin gene related peptide (CGRP) or act directly on its receptor.

LC-002 is the first novel peptide designed to treat migraine that mimics the natural CGRP. Professor Debbie Hay and her team are completing pre-clinical characterisation of LC-002. In vivo activity is currently in progress.

Once these studies are complete we are planning a Phase I clinical trial, with input from our expert advisory board. We now anticipate initiating the Phase I study in 2021. In this trial we will be able to measure blood levels to support once daily dosing, giving us an almost instant measure of success. We are also able to measure the surrogate marker for migraine using laser doppler. Laser doppler measures blood flow in the forearm of subjects. By demonstrating prevention of vasodilation we can get a clear measurement of the surrogate marker for migraine.

Positive clinical efficacy data would be used to out license LC-002 to a global pharmaceutical company to fully commercialise it. We have already engaged with interested global parties and have discussed potential deal structures.

LP-003 for Treatment of Obesity

Obesity continues to be a growing global problem with few options other than bariatric surgery for effective treatment. LP-003 is a compound that promises once daily delivery to act on satiety centres in the brain to reduce the need for food intake and is an attractive initiator for the very dietary programmes that fail – people ultimately get hungry. We hope to prevent this.

We have made progress to identify our lead compound and, following input from our highly qualified advisory panel, we had intended to initiate a Phase I clinical study commencing in Q4 2020. Due to the COVID-19 lock down in New Zealand, this has been delayed.

We are prioritising the LC-002 migraine treatment project and, as funds allow, we will resume development of LP-003 for obesity.

We have already initiated discussions with ProSciento, a leading clinical research organisation based in San Diego which specialises in metabolic disorders including obesity.

We have also had productive discussions with formulation experts such as 3M which can design parenteral delivery technologies.

We continue to actively seek funding for both projects by out-license to a global pharmaceutical partner.

Professor Hay presents at Headache Congress

Professor Debbie Hay one of the principal investigators for our migraine project will present at the 14th European Headache Federation Congress which happens virtually from 29 June to 2 July. Debbie is recognised as a world expert on CGRP receptor biology. Her presentation should attract further interest in our anti-migraine lead compound LC-002.



BIO partnering

BIO Digital Week virtually convened over 7,000 participants from 64 countries across 28 time zones for a week of meaningful, thought-provoking conversations and BIO One-on-One Partnering. While it was unfortunate that we could not have face-to-face partnering and investment discussions we made contact with several pharmaceutical companies active in the migraine therapeutic area. Three have progressed to follow-up exchange of information. All companies confirmed that our target, blockade of CGRP receptors, is valid.





Congratulations Sir Bob

LCT founder and board member, Bob Elliott was made a Knight Companion of the New Zealand Order of Merit in June for services to medical research. He was previously made a Companion of the New Zealand Order of Merit in 1999.



Sir Robert, has been involved in medical research for six decades. Bob's discoveries include treatment for a fatal form of congenital heart disease in babies and a newborn screening test for cystic fibrosis. He co-founded the Child Health Research Foundation, now known as CureKids, which is the largest funder of child health research outside the government.

As well as his involvement with LCT, Bob is on the board of Cure Kids and patron of the NZ Cystic Fibrosis Foundation. He is a director and shareholder of Breathe Easy Limited, Kopu Limited, Visregen Technologies Limited, Fac8 Limited and NZeno Limited.

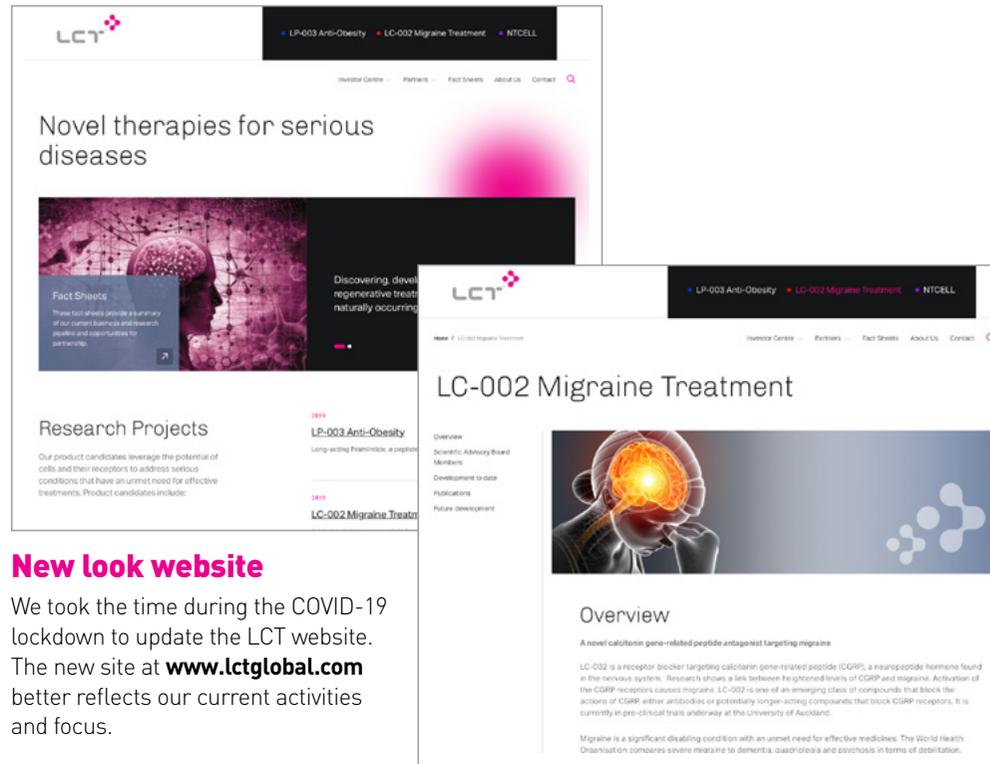
We congratulate Sir Bob, and his wife Lady Betsy, on this well-deserved recognition of his contribution to medical research.

NTCELL for Parkinson's disease

We continue to look for opportunities to fund a third clinical trial of NTCELL® in Parkinson's disease. The target patient group would be those in the early stages of the disease, whereas in the completed trials the patients had mid-stage Parkinson's disease.

However, much like our other xenotransplantation programme, DIABECCELL®, we do not have the necessary resources to complete the NTCELL programme of research here in New Zealand. To undertake a significantly larger clinical study outside of New Zealand will require a much larger company with more funds than LCT has. We have identified a suitable company with the view to negotiating a potential partnership.

As an alternative we are also investigating opportunities to out-licence NTCELL, similar to the arrangement achieved with Diatranz Otsuka Limited for DIABECCELL. We have made progress in talks with a potential out-licensing partner and hope to convert to a term sheet soon.



New look website

We took the time during the COVID-19 lockdown to update the LCT website. The new site at www.lctglobal.com better reflects our current activities and focus.

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

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