

## Message from the CEO

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I am pleased to report steady progress with our clinical program. The New Zealand trial has advanced successfully to complete its second phase, with all eight insulin dependent patients having received DIABECCELL® implants. Four of these patients have received higher doses and shown no remarkable adverse events as a result of treatment. It is also very satisfying to see indications of benefit early in this trial as DIABECCELL® has previously not been given to diabetes patients, such as the volunteers in New Zealand, who have difficult to treat unstable diabetes.

This milestone for the New Zealand trial has been very enthusiastically received by the medical and financial communities. The **Juvenile Diabetes Research Foundation International** after due diligence assessment of LCT's diabetes program and clinical protocol has provided a generous financial grant to support the New Zealand trial. This

LCT again joined other leading New Zealand biotech companies at the annual Biotechnology Industry Organization (BIO) international convention held in Chicago, USA in early May. BIO is the world's largest biotechnology conference, hosting over 15,000 industry leaders from 49 US states and 65 countries. We had a successful week generating international interest and increasing LCT's presence on the world stage. During the week, I had about 40 meetings with potential collaborators as well as several media interviews, and LCT was selected to present a showcase presentation.

I recently returned from an investor road show with Susanne Clay in Australia where I met a number of current and prospective investors in LCT to update them on our progress. Their continued interest and support is very encouraging as we plan the next stages of our

## LCT's new Chief Business Officer -Susanne Clay



As LCT advances towards the commercialization of its product pipeline, the Company appointed Susanne Clay into the newly-created position of Chief Business Officer.

Susanne brings a wealth of commercial experience to LCT. She has spent more than 20 years in business and product development roles with a number of biotechnology companies in the United States and will be an important driver of the commercialization of LCT's product portfolio and in particular DIABECCELL® and NTCELL.

She brings with her a vital network of contacts within the biotechnology industry and in the financial markets. She started

most recent display of confidence from a key international sponsor of diabetes research, in addition to the recent support for our clinical development program from the New Zealand Government, demonstrate the widespread strong interest in our work.

While it is still too early to report the full outcomes from this trial, we can reveal that the first four patients with unstable diabetes treated with DIABECCELL® have all shown the benefit of reduction or elimination of episodes of low blood glucose levels that are often life-threatening. I look forward to sharing with you interim results that we expect to be reported in greater detail by October, and I am confident that the data will continue to support the further development and commercialisation of DIABECCELL® for Type 1 diabetes.

DIABECCELL® clinical trial program.

Our other programs are also producing considerable interest around world. In April a research paper written by LCT was selected as one of the best publications for 2009 by the prestigious **Journal of Neural Engineering**. This paper discusses the latest research we are conducting with our other living cell therapeutic product NTCELL and its promising potential for long term treatments of central nervous system diseases, including Parkinson's disease, Huntington's disease, stroke and hearing loss.



Dr Paul LJ Tan  
CEO

her career in the financial sector and will be a very important part of LCT's engagement with the US and Australian investment community.

Dr Paul Tan, LCT CEO said: "As our clinical program advances, LCT has received many queries from centres worldwide interested in conducting clinical trials with DIABECCELL®. To support this expansion, LCT needs an experienced business person like Susanne."

"LCT sees the engagement of potential new clinical trial partners as a key step towards commercialisation, with our partners likely to become treatment centres delivering our commercial DIABECCELL® product to the market in the near future.

With DIABECCELL® now implanted into humans, there is considerable interest in NTCELL for Parkinson's, Huntington's and Stroke. Susanne has the perfect background to advance new business initiatives and build shareholder value."

## DIABECCELL® Eliminates Hypoglycaemia in NZ Trials

Earlier this month LCT reported further positive results from the New Zealand Phase II clinical trial of DIABECCELL® being conducted at Middlemore Hospital in Auckland. All eight insulin dependent patients suffering from unstable diabetes have now received DIABECCELL® encapsulated porcine islet implants.

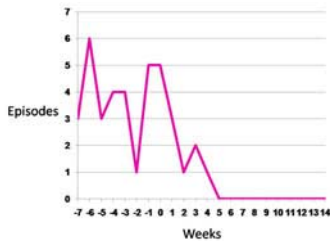
In the first group of patients, all have shown the benefit of reduction or elimination of episodes of low blood glucose levels that are often life-threatening. The dramatic results to date showing DIABECCELL®'s ability to ameliorate this serious complication of diabetes, known as hypoglycaemic unawareness, are a key indicator of benefit to patients.

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## Continued Support from New Zealand Government

LCT is very privileged to have the continued support of the New Zealand Government. Following on from its generous financial grant of \$4.04 million (NZ) in early 2010, the Government has

The first four New Zealand patients received one implant of DIABECCELL® at the dose of 10,000 islet equivalents per kilogram body weight (IEQ/kg) without remarkable adverse events attributable to the treatment. This continues to confirm DIABECCELL®'s safety profile. The results also supported the Data Safety and Monitoring Board's positive assessment and approval in March for LCT to progress to the second phase of its DIABECCELL® trial.



### **Elimination of life threatening unaware hypoglycemia episodes after DIABECCELL® implant (at week 0)**

Two patients have been followed up for 24 weeks and two patients for a minimum of 12 weeks. All patients have reduced the number or severity of hypoglycaemic events.

The second group of four patients in the New Zealand trial received a 50% higher dose of DIABECCELL®, by 15,000 IEQ/kg, with no significant adverse events attributable to the treatment.

The New Zealand patients are a new group of volunteers with insulin dependent Type 1 diabetes. DIABECCELL® has previously not been administered to people with unstable diabetes and who have life-threatening episodes of swinging blood glucose levels. Although we have not yet completed the detailed analysis of the first stage, we can report that early indications are positive. Control of blood glucose in the first group of patients has improved. Life-threatening episodes of hypoglycaemic unawareness have been eliminated or reduced. This is a complication of diabetes in which the patient is unaware of dangerous drops in blood sugar levels. This serious complication can lead to loss of consciousness, seizure and brain damage.

We have reported data from the two-year follow up of the initial Phase I/IIa DIABECCELL® clinical trial conducted in Russia with our international research partners. The data confirmed that the trial met all end points of safety and tolerability.

recently committed to work with LCT on a project for the development of new animal-derived therapeutics.

The project is supported by Investment New Zealand, a division of New Zealand Trade & Enterprise, the government's investment promotion agency. The joint study is to focus on identifying potential market opportunities for the unused tissue from LCT's bio-certified pathogen-free pig herd.

Given New Zealand's premier animal health status, Investment New Zealand aims to position New Zealand as the global location of choice for companies developing human therapeutics and biologics that require high quality animal-derived materials.

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## **LCT in the Spotlight**

### **ASX Spotlight Series**

On 20 May, LCT Chairman David Brookes made a presentation at an Australian Securities Exchange (ASX) investment forum on commercialization of innovation. Development of LCT's clinical program and plans to commercialize the DIABECCELL® product were presented to an audience of more than 60 professional fund managers, analysts and investors.

### **70th Scientific Session of the American Diabetes Association**

There were no significant adverse events attributable to the treatment.

For many years we have seen reports of effective treatments for diabetes in laboratory animals, but which do not necessarily translate to a benefit in humans with diabetes. The Phase I/IIa trial in Russia shows clearly that it is possible to get clinical benefit with pig cell implants in humans without using immunosuppression, thus confirming proof-of-principle of efficacy in humans with Type 1 diabetes. Patients in the trial showed a remarkable stabilisation of their blood sugar levels and fewer incidents of hypoglycaemic episodes. They were also able to reduce their required insulin dose on average by a third.

The significance of the findings is best summed up in the words of the Professor Boris Draznin, director of the Adult Diabetes Program at University of Colorado Denver, School of Medicine. He stated in April: "This is the first time that anyone with long-term insulin-dependent diabetes has come off insulin injections following islet cell implants without using immunosuppressant drugs."

Professor Draznin presented LCT's trial results in June to the international diabetes research community, which gathered together for the annual American Diabetes Association (ADA) meeting in Orlando, Florida USA. The ADA annual conference is the world's largest and most prestigious diabetes meeting, attended by over 20,000 members of the professional diabetes community including physicians, scientists, and other clinicians and health care professionals.

## Support from a world leading diabetes foundation - The JDRF

The Juvenile Diabetes Research Foundation is a world leader in setting the agenda for diabetes research and the largest charitable funder and advocate for research for type 1 diabetes.

The US \$0.5 million JDRF grant from JDRF is a collaboration with LCT for the Phase II trial of DIABECCELL® is part of JDRF's innovative Industry and Discovery and Development Partnership program. Through the program, JDRF partners with pharmaceutical, biotech, and medical device businesses that seek to develop drugs, treatments, technologies, and other therapeutics leading to a cure, reversal, or

On 27 June, the results of LCT's DIABECCELL® Phase I/IIa clinical were presented at the 70th Scientific Session of the American Diabetes Association in Orlando, Florida by Professor Boris Draznin, director of the Adult Diabetes Program at the University of Colorado, Denver, School of Medicine.



**The ADA annual conference is the world's largest diabetes meeting, attended by over 20,000 members of the professional diabetes community including physicians, scientists, and other clinicians and health care professionals.**

## Innovation

On June 29, LCT's CEO, Dr Paul Tan presented at the TechNZ Innovation Forum, aimed at connecting New Zealand's finest innovative people and ideas, held at the Auckland War Memorial Museum.



Tech NZ Innovation Forum, Paul Tan Marilyn Geaney, Peter Hosking

On 5 August, LCT will attend the Chiasma

prevention of type 1 diabetes and its complications. To date, JDRF has made 27 industry grant awards to support a variety of strategic type 1 diabetes research projects since the IDDP program was established in 2004.

## Cellular Xenotransplantation

### What does the Future Hold?

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By Professor Elliott, LCT Medical Director

The international medical research community recognized long ago the importance of being able to harness the potential of transplanting living cells for therapeutic use. It is also well known that the demand for viable human donor tissue for transplantation far exceeds the supply which has led researchers to examine the feasibility of animals as a source of cells for human therapeutics.

The potential drawbacks of such an approach were recognised from the outset. At the forefront lies the problem of tissue rejection by the recipient's immune system and the potential for inadvertent transfer of animal viruses. But consideration of the potential significant benefits of xenotransplantation (transplantation to humans from non-human species), outweighed the risks and were found to justify the search for effective therapeutic xeno-based approaches.

Many human diseases arise from the failure of specific cells, often for unknown reasons, to perform their normal function. Conditions such as Type 1 diabetes, and neurodegenerative diseases such as Parkinson's, Huntington's and stroke could all potentially benefit from effective xenotransplantation protocols.

The question arises, why use cellular xenotransplantation instead of drugs?

One reason is that healthy cells can respond to the body's control signals to recreate the normal situation, whereas delivery of drugs at different times

Synapse, focussed on fostering networks between New Zealand biotech sector and biotech student communities at the University of Auckland.

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## Recent

### Announcements

28 June – LCT Presentation at American Diabetes Association

10 June - LCT works with NZ government on animal derived biologics.

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## In the News

LCT continues to attract significant media attention, as part of the growing acknowledgment of the ground-breaking work the company is undertaking.



Bob Elliott, Medical Director

7 April – Business Spectator, 'Living Cell advances Diabecell trial'

throughout the day results in abnormal peaks and dips in the levels of the agent delivered to tissues.

To overcome the problem of immune rejection, one approach is the use of pharmaceutical immune suppression, in which the patient's immune system is dampened by drugs. This approach is itself high risk and patients are required to take these immunosuppressive drugs for the rest of their lives after their transplantation procedure. The side effects are often very unpleasant and the patient remains forever highly susceptible to infectious illnesses.

A more innovative approach, and that adopted by LCT from the beginning, is to try and 'hide' the transplanted animal cells from the body's immune system, so there is no problem with immune recognition and rejection. Some researchers have attempted to place the transplanted cells into sites that are naturally less visible to immune surveillance, but this approach has had limited success. LCT's novel encapsulation method effectively makes the cells invisible to the immune system and DIABECCELL® patients are not required to take immunosuppressive drugs.

LCT's breakthrough technology enables us to coat healthy pig cells with a gel-like material derived from seaweed. The product is small and spherical; having a pore size that excludes immune cells and molecules, but allows the free exchange of small molecules and cellular products. Compared to other immune barrier devices, the LCT capsule best meets the other necessary criteria: it is compatible with the body, sized to contain enough cells to deliver the treatment and shaped to allow the passage of oxygen, nutrients and secreted products.

The question of inadvertently introducing latent animal viruses that could become active and cause human disease has received much consideration over the past decades. Despite rigorous testing, there have been no reports of experimental infection of other species, including humans from pig viruses. Even so, LCT manages any potential risk by the use of its unique bio-certified pig herd, which has been accredited as free from such viruses due to its pristine source and care.

Most countries have developed guidelines for xenotransplantation that concentrate on safety of the procedures and the pathogen-free status of the animals (and explicitly exclude the use of primates or wild animals for which

8 April – Sydney Morning Herald Online,  
'Pig cells 'safe' to treat human diabetes'

28 April – Australian Financial Review,  
'Biotech gets grant'

1 May – The Weekend Australian, 'His  
little piggies may save lives'

9 May – Network Seven TV, Australia –  
Feature on LCT's work and progress

2 June - SKY Business TV – Interview  
with CEO Paul Tan

19 June – Weekend Press, 'Cell scientist  
determined'

19 June – Dominion Post Weekend,  
'Determination keeps scientist looking for  
new treatment'

the health status cannot be known). Such guidelines have allowed the cautious progression of clinical trials, with LCT being the leading the way.

An alternative cell-based therapeutic approach is potentially provided by the use of stem cells, however a number of problems have yet to be resolved before this technology is ready for human trials. For example, a small portion of the derived stem cells might be unstable and become cancerous and the ability to detect such cells prior to transplantation is still being researched.

Overall, given DIABECCELL®'s advanced stage of clinical development for Type 1 diabetes and LCT's promising research pipeline of therapies for neurological diseases, the outlook for LCT is bright. 1'

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