The Living Cell

A quarterly newsletter from Living Cell Technologies

February issue 2007

Chairman's message

I am delighted to announce that LCT has received confirmation that it will undertake a human clinical trial of its DiabeCell® product in 2007. Ethical and regulatory approval has been obtained in Russia for a two stage clinical trial in six Type 1 (insulin-dependent) diabetics. This is a significant milestone for the company and firmly positions LCT at the forefront of the xeno cell therapy field. The directors are pleased to also be able to offer shareholders the opportunity to purchase additional shares in the company through the share purchase plan. These shares are available at a discount to the current market price and at a time when the company is at a pivotal stage in terms of its development and ability to return value.

We have maintained a clear strategic goal of ensuring our lead product enters human clinical trials in 2007. As a global company, we are preparing our products for the global market. We will ensure all clinical trials are conducted according to FDA guidelines, regardless of the jurisdiction in which they are undertaken. A separate contract has also been signed with the Boston-based Contact Research Organisation GenyResearch to ensure all aspects of the protocols, data analysis and management are conducted according to these standards.

Our application to the regulator MedSafe to conduct a clinical trial for our type 1 diabetes product (DiabeCell®) in New Zealand is still on track. The December announcement of the licence from the New Zealand Government to manufacture a novel animal cell product for humans under Good Manufacturing Practice (GMP) was the first and most fundamental part in a three step process to obtain approval for a human clinical trial in New Zealand in 2007. LCT must now receive a 'Recommend for Approval' from MedSafe to conduct the clinical trial and final ethics approval.

The New Zealand DiabeCell® trial will cover slightly different protocols and endpoints and remains an important part of our regulatory strategy. A US FDA clinical trial is planned for halfway through this current clinical trial program.

I wish to thank all LCT shareholders for their support of the company. Obtaining approval for a human clinical trial for DiabeCell® is a significant milestone in the company's history. A final thanks must also go to David Collinson for his immense contribution as founder and CEO of the company. His hard work and dedication has driven LCT to this crucial stage of its development. We now await the various stages of the human clinical trial with great enthusiasm.

Simon O'Loughlin
Chairman

Investor highlights

30 January Diabetes clinical trial approved

LCT have announced its DiabeCell® Type 1 diabetes treatment has received approval to conduct a Phase I/IIA clinical trial in Russia designed according to FDA guidelines and supported by a Boston-based Contract Research Organisation.

The clinical trial in Russia would involve the transplantation of DiabeCell® into six Type 1 (insulin-dependent) diabetics in two stages. It is anticipated that the trial would start in Q2 2007.

> "The approval of the DiabeCell® human clinical trial is a significant milestone for this new treatment option for type 1 diabetes. This represents the only human clinical trial of this kind approved anywhere in the world and recognises LCT's thorough pre-clinical testing of the product in animal models showing no adverse safety effects and a significant reduction in insulin requirements."
>
> Dr John Court, scientific advisor to LCT and clinician in endocrinology.

The 12-month phase I/IIA trial will be conducted by Professor Nikolai Skaletsky at a research hospital in Moscow. Under the agreement, LCT will retain all IP and commercial rights to the product. Some rights for a licence to commercialise the product in Russia with LCT are provided for the Institute under the agreement. ▶

Breaking news

24 January

Dr Paul Tan Appointed LCT CEO

Dr Paul Tan was appointed Chief Executive Officer of Living Cell Technologies on 24 January, 2007.

Previously LCT Managing Director of NZ Operations, he has had wide experience on all aspects of assessment and selection of products for commercialisation, expansion of intellectual property, product development and managing critical paths, timelines and establishing and managing international partnerships. Dr Tan is a member of the Management Committee of the Auckland branch of NZBio, and sits on the Ministry of Health Interim Expert Committee for Xenotransplantation.

Investor highlights continued

19 December LCT granted approval to manufacture xeno products for human use

The New Zealand Government issued LCT with a licence to manufacture a novel animal cell product for humans under Good Manufacturing Practice (GMP).

The NZ regulator MedSafe issued a formal letter to LCT recommending a Licence to Manufacture Medicines be issued which will allow the use of its xenotransplant products in human patients.

This is the first and most fundamental part in a three step process to obtain approval for a human clinical trial in New Zealand in 2007.

14 December Possible prevention of type 1 diabetes

LCT released results of early stage research which suggests its NeurotrophinCell (NtCell) product may hold the potential to prevent or delay the onset of Type I diabetes. LCT injected choroid plexus cells from neo-natal pigs encapsulated in alginate into a non-obese diabetic (NOD) mouse model of Type 1 diabetes. The cell product was effective in protecting insulin secreting beta cells and preventing the onset of diabetes.

While the study is still at a very early stage, the initial indications are positive and will form part of LCT's future product development plans.

1 December Additional pig facility planned

LCT has held talks with businesses in New Zealand to build an additional disease free pig facility to help the company grow and extract cells and tissue for clinical trials and eventually the manufacture of other medical products. The site will also minimise LCT's risk by further diversifying the company's pig housing facilities.

▲ First islet cells manufactured in New Zealand under the newly awarded GMP accreditation.

Financial highlights – in brief

17 January Share Purchase Plan Offer Opens

LCT lodged the documentation for its share purchase plan with the Australian Stock Exchange (ASX) and announced the offer would remain open until 5 February 2007.

Australian and New Zealand eligible shareholders who hold shares in LCT at the record date of 10 January 2007 may purchase up to $5,000 worth of new shares (subject to a minimum application of $500) regardless of the number of LCT shares they currently hold.

The funds from the share purchase plan will assist in financing the clinical trial strategy for LCT's type 1 diabetes product DiabeCell®. ▶

Talking with a leader …

Dr Paul Tan,
CEO, Living Cell Technologies

We speak with Dr Paul Tan about the upcoming clinical trial in Russia.

Why will the trial be conducted in Russia?

LCT has always aimed to begin its clinical trial program in 2007. The Russia trial will be conducted in accordance with FDA guidelines and will be performed at the ANO – Institute of Biomedical Research – in Moscow. Prof Nikolai Skaletsky and the hospital have extensive experience in organ transplantation and also xenotransplantation, having performed over a thousand animal cell transplants in patients.

How will LCT ensure the trial follows FDA guidelines?

Both LCT and Prof Skaletsky wish to ensure that the quality of the study, data and reports are to a standard acceptable to other international regulatory jurisdictions, as are the studies in Russia conducted by international pharmaceutical companies.

Geny Research Group Inc, based in Boston, USA, has experience conducting clinical trials in Russia for Hoffmann La Roche and Sanofi-Aventis and is fully licensed by the Ministry of Health of Russian Federation. It will be the Contract Research Organization (CRO) supervising, monitoring and reporting on the study in Russia and will act as the project manager to ensure all elements of the trial adhere to approved FDA standards. They will oversee the protocols used and be

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Talking with a leader…

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responsible for all data analysis and management, and provide a trial report that may be submitted along with data from international studies, for regulatory approval in any jurisdiction.

Dr Olga Garkavenko, a senior scientist at LCT and expert on pig viruses, is of Ukraine origins and will be able to serve as an excellent in-house Russian interpreter.

What is the likely starting date?

Two patients have already been identified as suitable for the study and are able to be recruited. They will have to follow a strict clinical protocol to document the control of their diabetes for at least two months and they are expected to receive the first transplants in Q2 2007.

What will the trial design be?

LCT will conduct a 12 month trial – beginning with an initial transplant of a half dose and then a second transplant six months later with the second half dose. There is some data to suggest that two small doses may be more effective than transplanting one single larger dose. In Russia, Prof Skaletsky has given three rabbit islet transplants to his patients to obtain clinical benefit.

The trial will assess the occurrence of hypoglycaemic episodes and the occurrence of perioperative reactions. The primary endpoint will be to see a reduction in HbA1c levels over a 12 month post-transplant period.

There will be 6 adult patients treated – females will be over 35 years old and males all over 25 years of age. The candidates must have had type 1 diabetes for at least 10 years with no other complications, given their consent to participate and agree to all the follow-up monitoring for a period of up to 12 months.

Are there any other clinical trials planned for 2007?

As a company at the forefront of the xeno-cell therapy industry – and clearly 12 months ahead of the competition – LCT's intention is to conduct more than one Phase I/IIA Clinical Trial. It is still LCT's plan to test a different dose and protocol for administering DiabeCell® in a separate New Zealand trial. The different study designs would expedite the selection of a safe and optimal clinical protocol for using DiabeCell® in the clinic.

Financial highlights – in brief continued…

27 December Capital Raising Update

LCT announced further funding arrangements to boost share capital, in order for the company to take advantage of its accelerated clinical program. The Australian share broking firm Taylor Collison agreed to lead a placement of $800,000 at 17.5 cents per share with Australasian based sophisticated investors, as additional funding for the company.

These funds will be utilised for operations including further clinical trials, development and commercialisation efforts for the company's lead products.

24 November Annual General Meeting

LCT Chief Executive Officer Mr David Collinson and Medical Director Prof Bob Elliott presented at the company's Annual General Meeting in Sydney on Friday 24 November and outlined the company's plans for 2007.

Financial snapshot

Shares on issue	**123,416,800**
Market capitalisation	**$27,150,000**
Number of shareholders	**1,154**

Conferences & presentations

November 20–22 AusBiotech National Conference 2006

Ms Paris Brooke, General Manager (Australia), participated in the 'Business Partnering and Investment Forum' in Sydney and also met with the NZ Minister of Research, Science & Technology, Hon Steve Maharey.

Development portfolio

Disease	Discovery	Preclinical	Phase I/II	Pivotal	Market
Huntington's, Neurodegenerative diseases **NeurotrophinCell (NtCell)**					
Type 1 Diabetes **DiabeCell®**					
Haemophilia **Fac8Cell**					

Outlook for 2007

- Start human clinical trials for the DiabeCell® type 1 diabetes product
- Develop an additional disease free pig facility – to enable cell production to meet late clinical studies and market
- Progress pre-clinical studies of NtCell in Huntington's disease, stroke and hearing loss

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