

# The Living Cell



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## Message from the CEO



Paul LJ Tan  
CEO

Welcome to the Quarterly Investor Newsletter. This quarter we have achieved a number of significant milestones including exceptional results from our lead clinical trial program, DiabeCell®. On March 31 2008, LCT released updated information from the ongoing Phase I/IIa clinical trial of DiabeCell® in Russia which reported that the six month follow up results were positive and the response to implants of DiabeCell® has exceeded expectations. We intend to ensure that DiabeCell® reaches the market as soon as possible .

## Update on DiabeCell. Clinical Trial Programme

Living Cell Technologies' Phase I/IIa DiabeCell trial remains in line with its objectives, having now enrolled four patients with Type 1 diabetes. The four patients, based in Russia, have received one implant of DiabeCell at its lowest dose to demonstrate a measurable improvement in glucose control and the need for insulin. One of the patients has now received a second implant, six months following the first.

On March 31, 2008, Professor Bob Elliot and Dr Paul Tan announced six month interim results from the Phase I/IIa clinical trial at the International Diabetes Federation (IDF) Congress in Wellington, New Zealand and the NZBio Conference in Auckland, New Zealand.

Results showed that four Type 1 diabetes patients who had been implanted with DiabeCell, revealed either improved or stable control of their blood glucose levels. Additionally, no remarkable adverse events have been reported, which was a primary end point for the trial concerning safety.

Further observations that were obtained from the six months' data revealed that Living Cell Technologies' proprietary micro-encapsulation technology prevented antibodies from destroying the gel capsules and enabled oxygen and nutrients to pass in and insulin to diffuse out. This mimics the natural development of insulin production which occurs in a person without diabetes. The nanobiocapsules, that contain DiabeCell have been implanted in patients without the need for toxic immunosuppressive drugs, a first for this indication.

Two of the patients have now completed six months observation and maintained significant prolonged clinical benefit.

A New Zealand trial is expected to commence shortly involving eight patients who will receive either double or triple the dose of the Russian patients. The cells must remain productive for more than six months, but preferably more than 12 months, to make the procedure economically viable.

	Implant stage	Results
Patient 1	Received first low dose of DiabeCell  6 months later: Received second dose of DiabeCell	<ul style="list-style-type: none"><li>- Daily insulin requirement was reduced by 40% over a 6-month period</li><li>- implanted microencapsulated cells were retrieved and contained viable cells</li><li>- there was no evidence of attack by the immune system, even though no immunosuppressive drugs were administered</li></ul>
Patient 2	Received first low dose of DiabeCell	<ul style="list-style-type: none"><li>- Daily insulin was reduced 100 percent during a 5month period</li><li>- Resumed daily insulin based on medical advice to obtain better blood glucose control</li><li>- Insulin administration was reduced by 82% at a 6</li></ul>

The approvals from the New Zealand government to use the cells from our unique pig herd (Gene Technology Advisory Committee – GTAC approval), to manufacture DiabeCell® (Medsafe GMP approval) and to conduct safety tests (International Accreditation - IANZ) were helpful in obtaining Scientific Committee and Ethics approvals from the Sklifosovsky Institute, Moscow. We now have in place an international clinical trial strategy.

As announced on 27 February 2008, LCT commenced discussion with the Barbara Davis Center, Denver, Colorado, a world renowned diabetes center to work towards conducting a trial in Denver. LCT intends to use the New Zealand GTAC, Medsafe and IANZ approvals and early clinical data from the trial in Russia as supporting documentation.

LCT is committed to using investor funds and grants from the New Zealand government efficiently to advance DiabeCell® as a product for patients with insulin dependent diabetes worldwide. We are still hopeful a trial will be conducted in New Zealand in the near future as part of our strategy. We continue to develop our pig breeding and manufacturing operations in New Zealand to support the international clinical trials and commercialisation programme.

		month follow up
Patient 3	Received first low dose of DiabeCell	<ul style="list-style-type: none"> <li>- Required an increased daily dose of insulin immediately after the first implant to cope with a personal psychosocial problem unrelated to the implant procedure</li> <li>- Has not yet completed 6 months follow up</li> </ul>
Patient 4	Received first low dose of DiabeCell	<ul style="list-style-type: none"> <li>- Received first implant in February 2008</li> <li>- Daily insulin requirement was reduced by 10% at only 4 weeks post implant</li> </ul>

### Interview with Living Cell Technologies' Medical Director, Professor Bob Elliott

As Living Cell Technologies' Medical Director, Professor Bob Elliott carries the weighty responsibility of ensuring that the company's lead clinical trial program is running smoothly and remains in line with the trial's objectives. Here he answers questions about how he came to be in this position and the significance of the roles shared by him and his team at Living Cell Technologies.



- *Can you define your role as Medical Director at LCT?*

My role at Living Cell Technologies is to ensure that the research and production teams are moving in the right direction towards identifying a potential cure or treatment for debilitating human diseases. I am currently directing the DiabeCell clinical trial program to ensure it is meeting the trial objectives.

- *How did you become an expert in this field?*

In 1959 in Colorado, I underwent a long apprenticeship which specialised in diabetes. In the 1970's, I worked at the Barbara Davis Center for Childhood Diabetes (BDC) in the US and later for a centre for human transplant. Since then I have been working on cell transplantation to identify a possible treatment for Type 1 diabetes.

- *What is your role in the Phase I/IIa DiabeCell trial?*

I designed the trial's protocols and am currently the lead instigator, regularly directing the doctors in Moscow and ensuring that they are keeping in line with the trial's objectives.

Due to the large network of business and corporate contacts that I have built over the years, I actively communicate with leading industry bodies including organisations such as the Barbara Davis Center for Childhood Diabetes.

- *Have there been any challenges with the DiabeCell trial?*

Yes. The major challenge has been in receiving regulatory approval. This has been an ongoing battle since 1996. We received regulatory approval to conduct the trials in Moscow, but are now waiting to receive approval to commence the trial in New Zealand. We are eager to commence this trial so

we can get the product to market.

Having to start the trial from scratch was also demanding. We were required to set up the pig herds ensuring they were pathogen free, arrange strong manufacturing laboratories, receive the correct licensing to analyse the cells and most importantly, perfect the technology to ensure that it worked successfully.

- *Is DiabeCell a safe product?*

Yes it is absolutely safe. We have seen no viral infections in any of the patients that have been implanted with DiabeCell. So far we have tested pig islet implants in 22 patients, all of which showed no adverse effects whatsoever.

- *Are you able to give us a brief regarding why you believe DiabeCell may have salient advantages for Type 1 diabetes that perhaps make it a suitable treatment, where others have failed in this indication?*

The most promising feature of DiabeCell is that it can be implanted into patients without the use of immunosuppressant drugs which cause negative side-effects. The fact that it is extremely safe should make it widely available. Other companies have tried to employ a similar technique using encapsulation technology but have not been able to administer the product without immunosuppressant drugs, creating an unsafe environment for the patient.

In order to ensure that our product was successful and would produce the results we expected with no associated risk, required years of perfecting every element of the technology's design.

#### Snapshot - Living with Insulin Dependent Diabetes - Mikkal Sveum

At the age of eight when most young boys are playing outside with their friends and consuming sugary party treats without a care in the world, Mikkal was injecting insulin into his body to ensure that he was able to function normally.



On average, diabetics undergo four insulin injections and at least five glucose checks per day. Living with the above can be stressful enough- but to add to that there are also the symptoms. Low or high blood sugar levels can cause irritability, feeling tired, hunger/thirst, dizziness, nervousness, excessive sweating or, at its worst- seizures. Without correct management, people with insulin-dependent diabetes experience cardiovascular problems, eye disease, kidney disease and nerve damage. Poor control also leads to severe mood swings.

Today, thanks to improved medical knowledge and the delivery of more effective treatment options, methods for managing blood sugar levels have enabled those like Mikkal to live a happy, normal life.

Mikkal effectively manages his blood sugar levels using a glucose meter, engaging in daily exercise which can lower blood glucose levels, and undergoing multiple injections. Over time, he has discovered that consuming roughly the same number of carbohydrates each day enables his blood sugar levels to remain more consistent.

Photograph shows Mikkal riding in the LCT sponsorship cycling T-shirt at the fundraising "Ride to Cure Diabetes" for the Juvenile Diabetes Research Foundation.

Thanks to new treatments, Mikkal now considers his diabetes to be well controlled but something that will always impinge on his life. Before leaving home, Mikkal instinctively checks his wallet for money, ensures that he is carrying a meter, spare insulin and a candy bar. At work however, Mikkal often forgets about his sugar levels particularly when he is faced with demanding situations. Consequently, he is immediately required to correct his blood sugar levels by eating a candy bar or taking insulin.

Leisure activities also take extreme planning - especially sports like scuba diving or surfing. These activities require the body to be at a certain sugar level. Traveling in foreign countries also has an element of fear for Mikkal.

Mikkal holds high hopes for better treatment options to replace the insulin pumps and glucose monitoring machines that he uses today. He believes a cure for Type 1 diabetes lies in cell biotechnology and is closer than we think.

"A cure for Type 1 diabetes would mean that I could live a more normal life without the feeling that something could easily go wrong if I don't pay attention. To children, a cure would mean that they could grow up without the fear of 'living on the edge'."

#### NEWS IN BRIEF

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#### Living Cell Technologies Receives a total of \$14M in Capital Placements

The combined funds received during late 2007 and early 2008 totalling in excess of A\$14 million, have placed Living Cell Technologies in a strong financial position. This was attributed through the placement of A\$6 million by Taylor Collison in November 2007 and a major investment by NaviGroup Management of US\$2.2 million in November 2007 and exercise of an associated option which raised another US\$6million in March 2008.

The capital placements received, will assist in the continuation of the DiabeCell Phase I/IIa clinical trials currently taking place in Russia and soon to be commencing in New Zealand. The funds will also support the establishment of new trials as well as the upgrade and extension of the production and manufacturing pig facilities.

These capital placements validate the global support that the company has attracted.

[[http://www.lctglobal.com/news/LCTreceivesUS\\$6m.pdf](http://www.lctglobal.com/news/LCTreceivesUS$6m.pdf)]

#### The Children with Diabetes Foundation offers support

Further international support for the company's DiabeCell clinical trial program came through a US based foundation called, Children with Diabetes Foundation (CWDF) on February 12, 2008. The Children with Diabetes Foundation is a USbased not-for-profit organisation which was formed to assist people living with diabetes and support clinical research in the field. The Foundation offered its support to Living Cell Technologies through establishing a fund which would enable supporters to contribute tax deductible donations towards the DiabeCell trials.

[<http://www.lctglobal.com/news/081202.pdf>]

#### Barbara Davis Centre for Childhood Diabetes signs term sheet with LCT

Living Cell Technologies signed a term sheet agreement with the Barbara Davis Center for Childhood Diabetes (BDC) in late February of 2008. The agreement will allow the two companies to collaboratively pursue regulatory approval to conduct a US clinical trial with the company's DiabeCell program.

The proposed U.S. trial is due to commence in 2009 and will be based on the

clinical protocols and results/outcomes from Living Cell Technologies' trials in Russia and New Zealand.

[<http://www.lctglobal.com/news/082702.pdf>]

#### Fourth US patent granted

On March 17, 2008, a fourth US patent was granted to Living Cell Technologies for the company's lead product DiabeCell, currently in development for Type I diabetes. The patent covers the use of DiabeCell in the treatment of Type I diabetes, and includes the technique for preparing encapsulated neonatal porcine pancreatic islets.

Living Cell Technologies currently holds several families of patents which have been filed worldwide including those for Neurotrophin Cell, Living Cell Technologies' product in pre-clinical development for the treatment of neurodegenerative diseases, as well as those surrounding methods of encapsulating live cells for human therapeutics.

[[http://www.lctglobal.com/news/LCTreceivesUS\\$6m.pdf](http://www.lctglobal.com/news/LCTreceivesUS$6m.pdf) ]

#### Preliminary clinical results presented at the 7th International Diabetes Federation and NZ BIO2008 Conference

Positive interim results regarding Living Cell Technologies' Phase I/IIa clinical trial of DiabeCell, were presented at the International Diabetes Federation (IDF) Congress in Wellington, New Zealand by Professor Bob Elliott and at the NZBio Conference in Auckland, by CEO, Dr Paul Tan on 31st March 2008.

Following the presentation of the six months interim results, Dr Paul Tan and Dr Anil K Anal, Living Cell Technologies' Material Scientist also presented clinical data on the company's proprietary nanobiocapsules on Wednesday 2nd April, 2008.

Living Cell Technologies' nanobiocapsules were shown to enable encapsulated pig insulin producing cells DiabeCell, to be implanted in patients without the use of toxic immune suppressive drugs. The technology also succeeded in enabling the gel capsules which allow oxygen and nutrients to pass inward and insulin to diffuse outward, to prevent antibodies from destroying the cells.

[<http://www.lctglobal.com/news/LCTannouncescompellingresults.pdf>

<http://www.lctglobal.com/news/LCTShowcasesProprietaryNanotechnology.pdf>]

### Financials

Ordinary shares	238.3million
Unlisted options	27million
Market cap.	\$59.5m
No. shareholders	1,805
Share price 7/4/08	25.0 cents

#### Product Portfolio

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

PO Box 3014  
Auburn, Victoria, Australia 3123  
Julia Hill, General Manager  
+61 3 9886 0247  
jhill@lctglobal.com

PO Box 23 566  
Papatoetoe, Auckland, New Zealand  
Richard Justice, Chief Financial Officer  
+64 9 276 2690 Extension 739  
rjustice@lctglobal.com

