

#### Living Cell Technologies Limited

#### Living Cell Technologies Corporate Presentation

**20 May 2010: Sydney, Australia, Auckland, New Zealand** – Cell implant company **Living Cell Technologies Limited (ASX: LCT; OTCQX: LVCLY)** advises that Chairman David Brookes is presenting at the Australian Securities Exchange Spotlight investor forum in Sydney on 20 May 2010.

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#### About Living Cell Technologies - <u>www.lctglobal.com</u>

Living Cell Technologies (LCT) is developing cell-based products to treat life threatening human diseases. LCT's technology enables healthy living cells to be implanted into patients to replace or repair damaged tissue without requiring the use of immunosuppressant drugs to prevent rejection. LCT also offers medical-grade porcine-derived products for the repair and replacement of damaged tissues, as well as for research and other purposes.

The Company owns a bio-certified pig herd that is a source of cells for treating diabetes and neurological disorders. For patients with type 1 diabetes, the Company implants microencapsulated islet cells so that near-normal blood glucose levels may be achieved without the need for administration of insulin or at significantly reduced levels. For the treatment of Parkinson's disease and other neurological disorders, the company implants microencapsulated choroid plexus cells that deliver beneficial proteins and neurotrophic factors to the brain.

#### LCT Disclaimer

This document contains certain forward-looking statements, relating to LCT's business, which can be identified by the use of forward-looking terminology such as "promising," "plans," "anticipated," "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to," "potential," "seeking to," "goal," "could provide," "intends," "is being developed," "could be," "on track," or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements



involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. LCT is providing this information and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.



ILCN living cell technologies

ASX: LCT - OTCQX: LVCLY

Diabetes – Neurodegenerative Diseases – Cell Encapsulation

## World Leading Cell Implant Company

Encapsulated porcine islets



## Safe Harbor Statement

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## LCT - World Leader in Cell Implants

### **Products and Programs**

- "World first" lead product DIABECELL<sup>®</sup> in Phase IIb clinical trials to treat Type 1 diabetes
- Pre-clinical programs in neurodegenerative diseases NTCELL for Parkinson's, Huntington's, stroke, hearing loss

### Platform

- Breakthrough encapsulation delivery eliminates need for immunosuppression
- Porcine cell implants
- Strong IP position

### **Process & Production**

- Owns unique biocertified pathogen free pig herds
- World's only internationally accredited laboratory to screen for porcine pathogens
- GMP facility for cell processing and encapsulation

### **Fast Growth Business Model**

- Commercialization of high value lead product within 3 years
- Global reach through partnering





## International Capital Structure and Trading

### **LCT History**

- Formed in 2003
- Acquired operations, IP and 20 years of R&D
- Listed ASX Sept. 2004
- Listed OTCQX June 2008
- Total funds raised to date:\$54M

### Market Cap as of May 17, 2010 A\$103 M

272.5 M

Outstanding Shares ASX: 88%, OTCQX (ADR):12%

Trading Volume Q1 2010 ASX: 56%, OTCQX (ADR): 44%

Outstanding Options:13%



## Type 1 Diabetes: Significant Burden and Market

### Occurs when the body's immune system destroys islets within the pancreas containing insulin- producing beta cells; lifelong need for replacement

### Human Burden of Type 1 Diabetes

- Requires multiple daily injections to stay alive and avoid coma
- Long term complications include kidney failure, blindness, limb amputation, heart attack, stroke
- Shortened life expectancy and lifetime treatment per patient >\$1M

### **Diabetes Market and the Economic Burden**

- Total cost of diagnosed diabetes in the United States in 2007 was \$174 billion, about half of global expenditure
- More than 220 million people world wide have diabetes
- About 10% of diabetics 22 million patients are Type 1
  - US: 3 million, Australia: 100,000, NZ:15,000

\*Sources: WHO (Nov 2009), JDRF, National Diabetes Fact Sheet 2007(NIH, CDC, ADA)

## DIABECELL<sup>®</sup>: LCT's Lead Product

Islet Cell Implant Without Immunosuppression



- LCT owns unique pathogen-free pigs derived from sub-Antarctica
- Porcine cells isolated and coated in patented alginate-based gel to form microcapsules
- Micro-capsules placed into abdomen using a laparoscope
- Engineered structure of micro-capsules enables nutrients to reach cells but prevents immune rejection
- Cells function naturally in body

# LCT's Enabling Delivery Technology

Protecting Living Cells in Microsphere Capsules

- Avoids immune rejection without immunosuppressive drugs
- Long term durability
- Applicable for other cells (e.g. stem cells)
- LCT manufactures ultrapure alginate
- Patent filed and potential for licensing
- Centocor R&D Inc (J&J) research collaboration with option to license LCT technology in a specified field





### DIABECELL<sup>®</sup> Clinical Data Safety and Proof of Principle for Efficacy in Humans

### Pilot study 1996 -2005 Auckland, New Zealand



10 yr cell survival and function Published in Xenotransplantation 2007 Phase I/IIa 2007 – 2010 Sklifasovsky Institute, Moscow, Russia

Subjects 8 adult Type 1 diabetes patients Insulin dependent > 5 years

#### Dose

5,000 – 10,000 islet equivalents/kg Up to 3 repeat implants

#### Safety

•No significant adverse events to date

#### **Preliminary Efficacy**

Improved blood glucose control with reduced HbA1c

- •Reduced daily dose of insulin injections
- •Two patients off insulin up to 32 weeks
- Intact capsules retrieved after 6 months
- •Pig insulin detected in patient blood

## DIABECELL<sup>®</sup> Phase IIb Trial in Progress Auckland, New Zealand

#### Subjects and Dose

8 adults with unstable Type 1 diabetes

- 4 received impants10,000 islet equivalents/kg
- 4 to receive 15,000 islet equivalents/kg

#### Data Safety Monitoring Board in March 2010

Approval to proceed to higher dose

#### Preliminary Report: Safety

• No product-related significant adverse events

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#### Efficacy

- Blood glucose control improved (HbA1c)
- Insulin dose reduction
- Hypoglycemic unawareness eliminated

Weekly episodes of life threatening hypoglycemic unawareness eliminated after DIABECELL<sup>®</sup> implant in first patient



## **DIABECELL®** Milestones

### 2010

- Q2 Higher dose Phase IIb trial
- Q3 Progress additional quality trial options
- Q4 Report Phase II 8 patients from NZ trial
- Q4 Target product profile confirmed

### 2011

- Trials in new jurisdictions
- Approval for Pivotal trial follows Phase II as final step for cell implant therapy

### 2012

- Manufacturing and pig breeding facilities to commercial scale
- Completion and reporting of pivotal data

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### 2013/2014

• Approval, registration and commercialization



## LCT Intellectual Property

## Patents - 32 granted, 49 pending; 15 patent families

- Use of cells from neonatal piglets for the treatment of diabetes
- Methods of preparing neonatal islets
- Use and method of preparing choroid plexus cells for the treatment of neurological diseases
- Method of selection of pigs suitable as source of tissue for human therapeutics
- Alginate encapsulation delivery technology

### Operational experience and know-how

- Breeding and screening of designated pathogen free pigs
- Expertise in alginate selection, composition and processing
- Manufacture of encapsulated live cells
- Fully integrated operations

## **Commercial Considerations**

**DIABECELL®** - a product to normalise the lives of those with Type 1 diabetes, in particular those with select considerations (unstable with hypoglycaemia; co-morbidities)

### Type 1 Diabetes: a huge un-abating market with unmet needs

- 20 million people world wide with Type 1 diabetes
   Example: 250 DIABECELL<sup>®</sup> implants would supply ~2% NZ market
- New cases every year: Australia 1,800 and US 30,000
- High value product: significant revenue from small market penetration of unstable diabetics – unaware hypoglycaemia afflicts up to 17% patients with Type 1 diabetes

#### Changing perception of relevance and opportunity

- NHMRC permits use of animal tissues Dec.2009
- Endorsement of Key Opinion Leaders JDRF support in 2010
- Competing technologies falling behind expectations (stem cells; human islets)

## The DIABECELL® Advantage DIABECELL® vs. Human Islet Implants

	DIABECELL®	Human Islets*
Donor availability	Unlimited	Limited
Donor cell infectious screening	Extensive and continuous	Must be done within days
Immunosuppression	Not required	Required
Surgical procedure	Simple laparoscopy	Extensive
Patient cost for islet replacement procedure	Less	More

\* Edmonton protocol

## Commercial goals for DIABECELL®

- Resolve unmet needs from conventional treatment for patients with Type 1 diabetes
- Achieve regulatory approval through parallel pivotal trials
- Flexible strategy for both delivery and supply of product for market
  - DIABECELL transportable for up to 4 weeks
  - Potential for strategic licensing and alliances internationally
- High value product 1,000 patients deliver an estimated EBITDA of >\$150 million; significant revenue from very small market penetration
- Address market opportunity of open and widening window



## Profitable Production of DIABECELL®

### DIABECELL® production easily scaled up

- Adult sows farrow every 4 to 5 months
- Capacity to harvest cells for up to 100 implants during scale up to 500 sow facility from 50 sows over 2 years
- Estimated 250 to 375 implants per annum from 500 sows
- Risk management and logistic considerations indicate 500 sow facilities as optimal
- Breakeven point at 80 patients
- Supply porcine cells for other LCT platform technologies and potential to be supplier for other uses of pure porcine tissues



## **LCT** Value Proposition

- Consistent positive Phase II trial data mitigates technical risk
- Significant revenue potential on horizon
  - Estimated registration of DIABECELL<sup>®</sup> within 3 years
- Attractive investment returns
  - \$1 billion business potential from DIABECELL<sup>®</sup> lead product
- Global product reach through strategic alliances and flexible supply
- Broad technology platform delivers added opportunities
  - NTCELL applicable to multiple neurodegenerative diseases
  - DIABECELL<sup>®</sup> potential beyond specific indications for Type 1 diabetes
  - Encapsulation technology can deliver other cell-based therapies

# **Appendices**



## LCT Board of Directors

- Dr David Brookes, Chairman, Adelaide, SA Australia Director of Atcor Medical Holdings Ltd; Chairman Innovance Ltd (NSX); medical practitioner
- Mr Simon O'Loughlin, Adelaide, SA, Australia Chairman of Bondi Mining Ltd; Director of Aura Energy Ltd, Petratherm Ltd, Chesser Resources Ltd, WCP Ltd and Probiomics Ltd
- **Mr Laurie Hunter,** San Francisco, CA, USA Director of Trident Resources, Madagascar Oil and Direct Petroleum Exploration Inc.
- Mr Robert Finder, Adelaide, SA, Australia Chairman of LBT Innovations; Director of National Pharmacies Australia; formerly MD & CEO Gropep
- **Mr David McAuliffe,** Perth, WA, Australia Established biotechnology companies in Europe and Australia; currently Director of NeuroDiscovery Ltd and Western Australian ChemCentre
- Dr Paul Tan, Auckland, NZ

Chief Executive Officer and COO of Living Cell Technologies Ltd, member NZBio National Advisory Council

Emeritus Professor Robert Elliott, Auckland, NZ
Co-founder and Medical Director of Living Cell Technologies Ltd; Director NZ Childhealth Foundation
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# LCT's Therapeutic Pipeline

### Added Value through Partnering



LCT is accelerating the development of its programs by partnering

## LCT's NTCELL: Neurodegenerative Disease Alginate encapsulated porcine choroid plexus cells



- Choroid plexus cells secrete brain reparative hormones, neurotrophins, growth support factors and antioxidants
- Neurotrophins protect brain and nerve cells from degeneration or injury
- Neurotrophins recruit natural progenitor cells (stem cell like) to the site of disease or injury and enhance repair
- NTCELL has been implanted in the brain of study animals and shown to be tolerated with cells surviving beyond 6 months



# NTCELL – Encapsulated Choroid Plexus Cells

Scientific Publications on *in vivo* Effects of NTCELL Implants

#### Neurodegenerative disease:

NTCELL has been implanted in animal models of Parkinson's disease, Huntington's disease, Stroke and Hearing Loss

#### Neuroprotection:

NTCELL treatment in animals led to reduction in the size of lesions or area of the brain affected by disease

#### Functional recovery:

Smaller lesions associated with recovery from paralysis of affected limbs, reduction in abnormal movements and function of auditory nerve



Rat brain sections from stroke model White areas indicate damaged brain tissue