

Encapsulated porcine islets

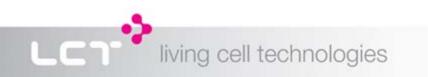
# ILCN living cell technologies

ASX: LCT - OTCQX: LVCLY

Diabetes – Neurodegenerative Diseases – Cell Encapsulation

World Leading Cell Implant Company

Australia - July 2010



## Safe Harbor Statement

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 as of the date of this presentation 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.

# LCT - World Leader in Cell Implants

#### **Products and Programs**

- "World first" lead product DIABECELL® 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

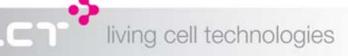
- Breakthrough encapsulation delivery eliminates need for immunosuppression
- Porcine cell implants
- Strong IP position

## **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:\$56
   M

## Market Cap as of 16 July, 2010 A\$ 58 M

283.8 M

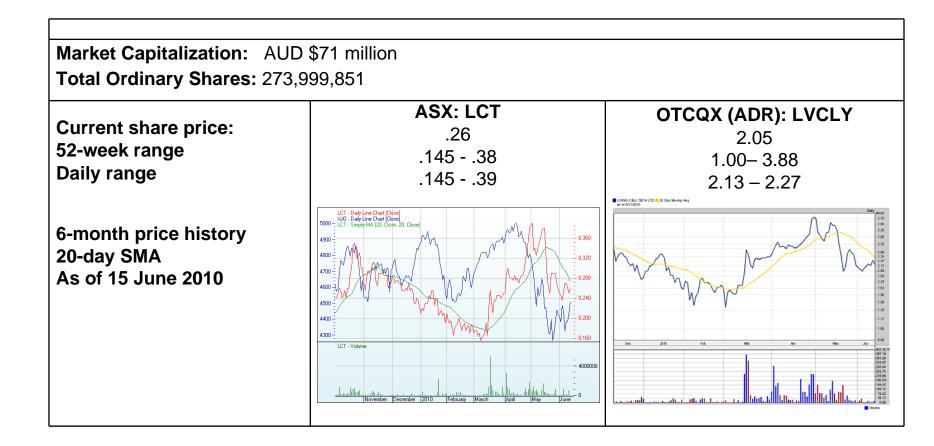
Outstanding Shares ASX: 84%, OTCQX (ADR):16%

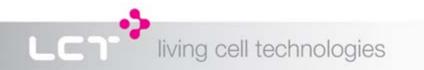
Trading Volume Q1 2010 ASX: 56%, OTCQX (ADR): 44%

Outstanding Options:7.8%



# LCT Trade Data Summary (15 June 2010)





# Type 1 Diabetes:

Significant Human Burden with Limited Options



#### 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
- Unstable diabetes with major swings in blood sugar levels, involves seizures and coma
- Shortened life expectancy and lifetime treatment per patient >\$1M

### **Limited Treatment Options**

•There is no cure for Type 1 diabetes

•Human islet transplants are severely limited by supply of human islet donors, and require patients to be on life long dangerous immunosuppression

- From 1990 2004, 740 patients with Type 1 diabetes received human islet transplants at 43 sites around the world
- •Stem cell research is still early, several years from the clinic

## Type 1 Diabetes: Market and Economic Burden

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

- •Total cost of diagnosed diabetes in US in 2007 was \$174 billion, 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
  - New cases every year: Australia 1,800 and US 30,000

•About 17% of Type 1 diabetics have unstable diabetes

•Cost of human islet transplant is about \$250K per patient, plus cost of immunosuppressant drugs, \$30-\$40K per patient per year

•Transplants receive reimbursement support around the world

## **DIABECELL®** Opportunity

NHMRC approves use of animal tissue – December 2009
 JDRF International and opinion leaders support LCT program
 Addresses management of life threatening medical condition safely, at reasonable cost, without relying on human donors or immunosuppression

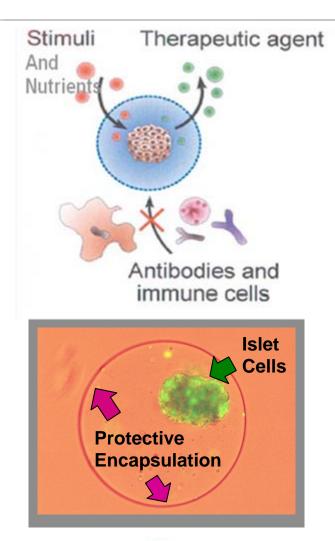
## The DIABECELL® Advantage DIABECELL® vs. Human Islet Implants

	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

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

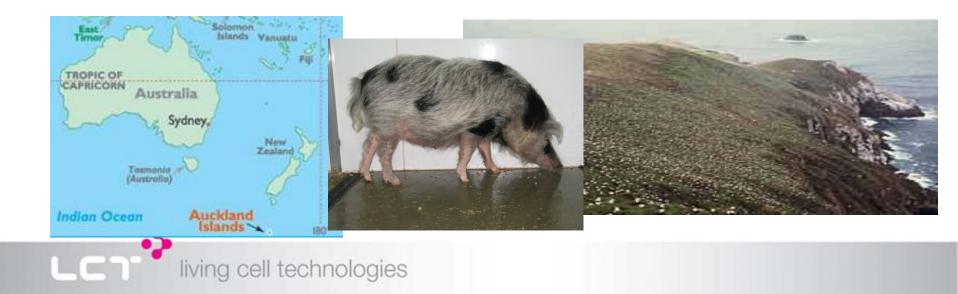
Islet Cell Implant Without Immunosuppression



- 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 injected into abdomen using a laparoscope
- Engineered structure of micro-capsules enables nutrients to reach cells but prevents immune rejection
- Immunosuppressants <u>not</u> required
- Cells function naturally in body

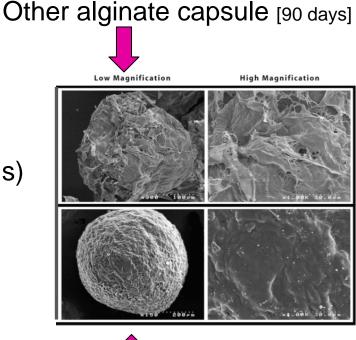
## LCT's Bio-certified Pig Supply A Unique High Value Asset

- Source herd from Auckland Islands isolated > 200 years no xeno-relevant viruses, parasites or bacteria, pigs do not secrete PERV
- Removed under quarantine by LCT; concession from NZ government for remaining pigs
- LCT owns and breeds its closed herds in two dpf facilities in NZ; 7 years of health and monitoring records, monitored regularly
- LCT pigs are biocertified according to US FDA guidelines 2003 for use in human therapeutics
- Study underway to assess value of medical grade porcine biomaterials from LCT pigs



## 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 Auckland, New Zealand

#### Subjects and Dose

8 adults with unstable Type 1 diabetes

- 4 received implants10,000 islet equivalents/kg (12 – 24 week follow up)
- 4 received 15,000 islet equivalents/kg (4<sup>th</sup> patient treated in July)

#### **Data Safety Monitoring Board in March 2010**

Approval to proceed to higher dose

#### Preliminary Report (July 2010):

#### Safety

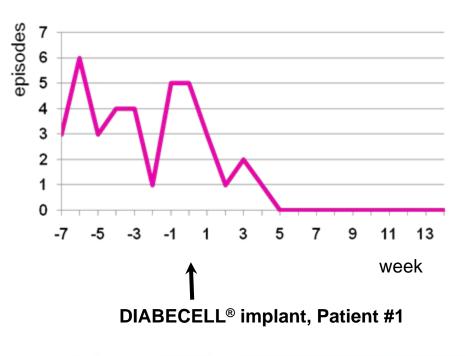
•Safety profile confirmed with no product-related significant adverse events

#### Efficacy (first 4 patients given 10,000 IEQ/kg)

•Improved blood glucose control by insulin dose reduction

•All 4 patients showed reduction or elimination of episodes of clinically significant hypoglycaemia

By 12 weeks, in three patients with hypoglycaemic unawareness, the number of hypoglycaemic unawareness episodes was reduced by 90% from 19 events down to just 2.



# Commercial Goals for DIABECELL®

DIABECELL® product to normalize lives of diabetes families

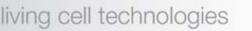
- Eliminate life threatening hypoglycemia
- Restore blood glucose control in unstable diabetes
- Insulin independence or reduced insulin dose

Commercial pathway and model

- Parallel pivotal clinical trials in multiple markets
- LCT as supplier of porcine tissue and encapsulated product
- Strategic licensing and alliances for international markets

High value product

- Treating 1000 patients will deliver an estimated EBITDA of > A\$150 million
- Significant revenue from small (1%) market penetration





DIABECELL® Cell Implant Product

# **DIABECELL®** Development Milestones

## 2010

- Higher dose Phase IIb trial NZ, dose seeking trials continue
- Q4 Report Phase II 8 patients from NZ trial
- Q4 Target product profile confirmed

## 2011

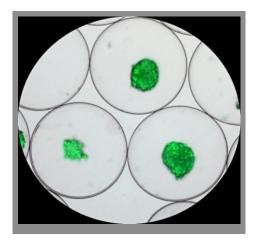
- Dose seeking trials continue (Australia, NZ)
- Approval for pivotal trial, NZ
- DIABECELL® approval Russia
- Strategic alliance DIABECELL® (12 mth data NZ)

## 2012

• S1 manufacturing facility scale up start

iving cell technologies

Completion and reporting of pivotal data



# **DIABECELL®** Commercialisation Milestones

## 2013

- Revenue from Russia
- S2 manufacturing facility scale up start
- LCT reaches profitability

## 2014

- DIABECELL<sup>®</sup> approval and revenue NZ, Australia, US, EU, tba
- Revenue from NZ, Australia, tba
- S1 complete, S2 interim capacity
- DIABECELL® annual revenue capacity \$57 million

## 2015

- S1 and S2 at capacity
- DIABECELL® annual revenue capacity \$81 million

# NOTE: These milestones exclude revenue opportunities from NTCELL collaborations, IMMUPEL out-licensing and other porcine biomaterials

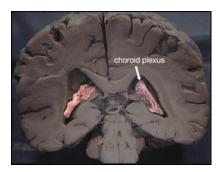


## LCT's Therapeutic Pipeline Added Value through Partnering

**RESEARCH**/ PHASE I / II **PIVOTAL** INDICATION PRECLINICAL PRODUCT DISCOVERY TRIALS TRIALS **DIABECELL®** Diabetes - 1 NZ, Russia, other jurisdictions NTCELL Parkinson's NTCELL Stroke NTCELL Hearing Loss Bionic Ear Institute, Melbourne Australia NTCELL Huntington's

LCT is accelerating the development of its programs by partnering

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



- Choroid plexus cells naturally produce brain hormones and growth factors that protect brain and nerve cells from degeneration or injury and enhance repair
- Encapsulated with IMMUPEL, high yield cells from LCT pigs
- NTCELL has been implanted in animal models of Parkinson's disease, Huntington's disease, Stroke and Hearing Loss



Untreated Treated Rat stroke model; white areas indicate damaged brain tissue

## Multiple Out-licensing Opportunities IMMUPEL Microsphere Capsules

- Proprietary encapsulation technology delivers living cell therapies without immunosuppression
- Broad applications; Several Cell Types Encapsulated

   Islet, Choroid plexus, Schwann cells, Stem cells and stem cell
   derived clusters, Liver cells, can be applied to other cell types
- Amenable to Various Cell Sizes

Currently deliver about mean 70 kDa but can do from 20-200 kDa
 Cells generally about 10 µm, prefer clusters of 50-100 µm

Processed by LCT in cGMP facility for licencees
 J&J collaboration; specific cell type, specific field of use

# 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

# LCT Value Proposition

- Consistent positive Phase II trial data
   Technical risk mitigated
- Significant revenue potential on horizon Estimated registration of DIABECELL<sup>®</sup> within 3 years
- Attractive investment returns \$1 billion business potential
- Global product reach

Strategic alliances with global pharma and biotech leaders Scalable product manufacture and supply

# Exclusive protected high value assets Unique bio-certified pigs Fully integrated proprietary manufacturing process Delivery technology eliminates need for immunosuppression

• Broad technology platform delivers multiple opportunities NTCELL applicable to multiple neurodegenerative diseases DIABECELL® potential beyond specific indications for type 1 diabetes IMMUPEL encapsulation technology can deliver other cell-based therapies Biocertified porcine biomaterials for medical products





## 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