living cell technologies

Cell-Based Therapy for Type I Diabetes

ASX: LCT - OTCQX: LVCLY

Investor Symposium: 27 October 2009

Prof Bob Elliott, Medical Director – Porcine Islets in Humans

Dr Paul Tan, Chief Executive – Commercializing DIABECELL®

Dr David Brookes, Chairman – LCT Company Assets & Value

Safe Harbor Statement

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Hallmark of Type 1 Diabetes
No Insulin Producing Cells Left

Replace lost cells

- Human cells

  limited source from cadavers
- Pig cells

  source not limiting

  similar protein structure

  used to treat diabetes for many years

  blood sugar range similar to humans

SUCCESSFULLY OVERCOME

- Immune rejection as an issue- without drugs!
- Any consideration of transmission of pig diseases
- ‘Yuck’ factor – irrational xenophobia as pig cells are safe and needed

Avoiding Rejection with DIABECELL®

Use of immune suppressant drugs

DANGER, DANGER,

Death and Destruction

DIABECELL designed to avoid chemotherapy

Cells placed in ‘immune privileged’ site
inside a semipermeable ‘capsule’.

Cells can do their job but rejection by the recipient human
is avoided (‘stealth coating’).

Avoiding Pig Diseases

- Source herd isolated
- Special certified bio-isolation facility
- Only world facility for monitoring pig viruses for xenotransplantation

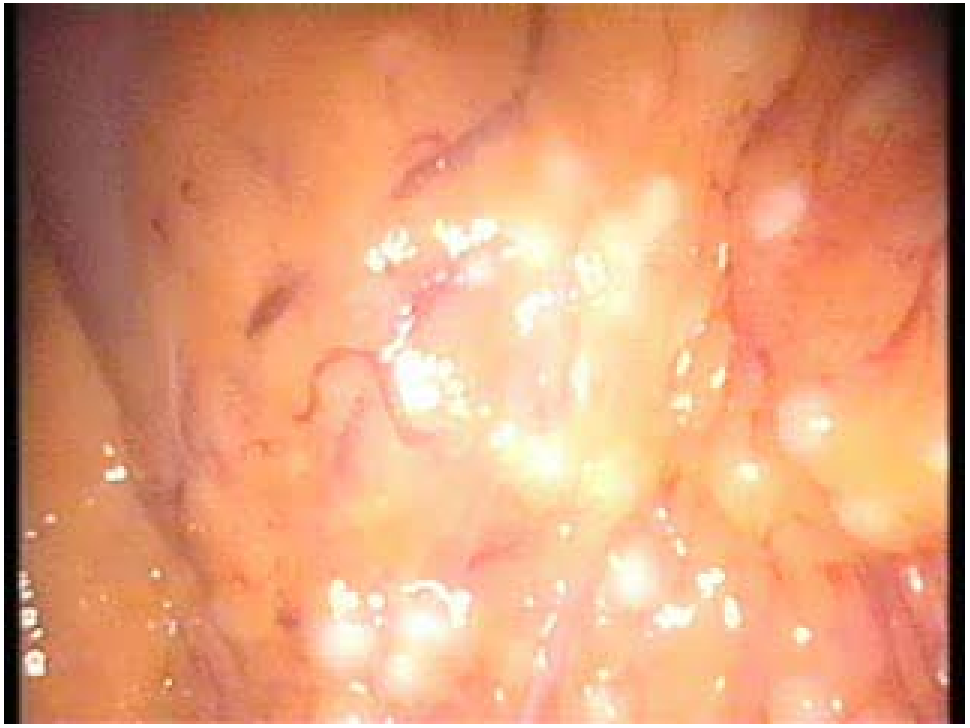
Clean Pigs

Clean Laboratory

LCT Manufacturing Unit

Transplantation 1996

9½ Years Later
Encapsulated cells within abdomen remain viable



Insertion of Cells (Russia)

DIABECELL®

Laparoscopic view of implant

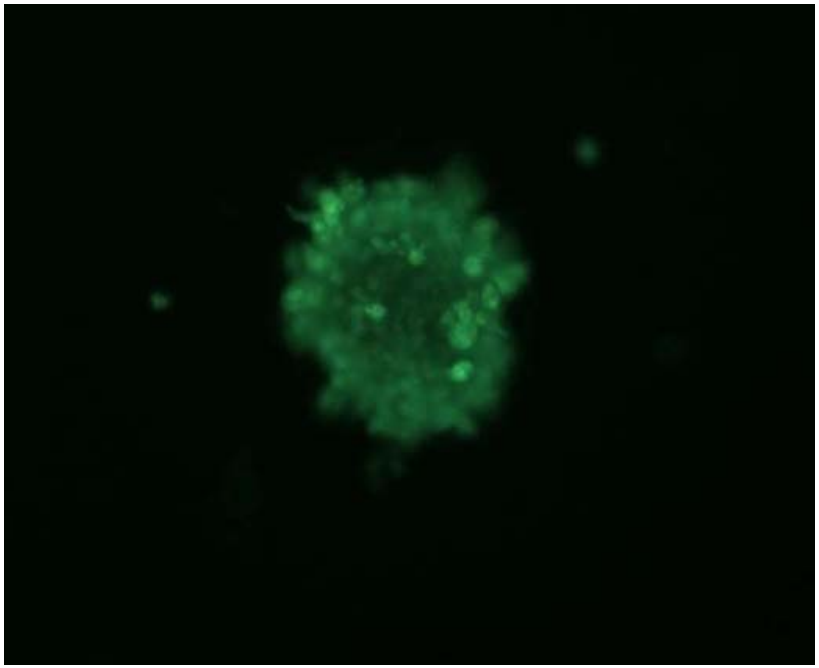
Results of Russian Study to September 2009

Patient No.	Number of Implants	Follow Up (wks)	Insulin		% Dose reduction	HbA1c		Glucose (mean last 3 months' follow up)
			Pre-Tx	Current	% of pre-Tx	Pre-Tx	Current	
1	3	120	113	96	15	7.1	6.9	6.7
2	3	100	22	0	100	8.2	8.1	7.3
3	3	88	60	53	12	10	7.6	7.1
4	3	82	30	27	10	7.6	6.8	7.1
5	2	54	68	50	26	9.8	7.3	7.7
6**	1	20	41	57*	-*	8.5	8.5*	9.4*
7	1	36	37	40	-8	8.3	5.4	6.1
8	1	12	83	83	0	11.3	8.2	9.2

**Declined further follow up

Note: HbA1c is a routine blood test that reflects control of blood glucose level. The American Diabetes Association recommends that HbA1c be less than 7%.

Pig Insulin Readily Measurable in Blood
Live Cells Recovered



World First Achievements

Information from Russian Trial

- Reduction in number and severity of low blood glucose episodes
- Reduction in number and severity of high blood glucose episodes
- Normalisation of average blood glucose levels
  - direct measurement
  - surrogate measurement: HbA1c
- Patient satisfaction high
- (Reduction in long term complications)

New Zealand Trial

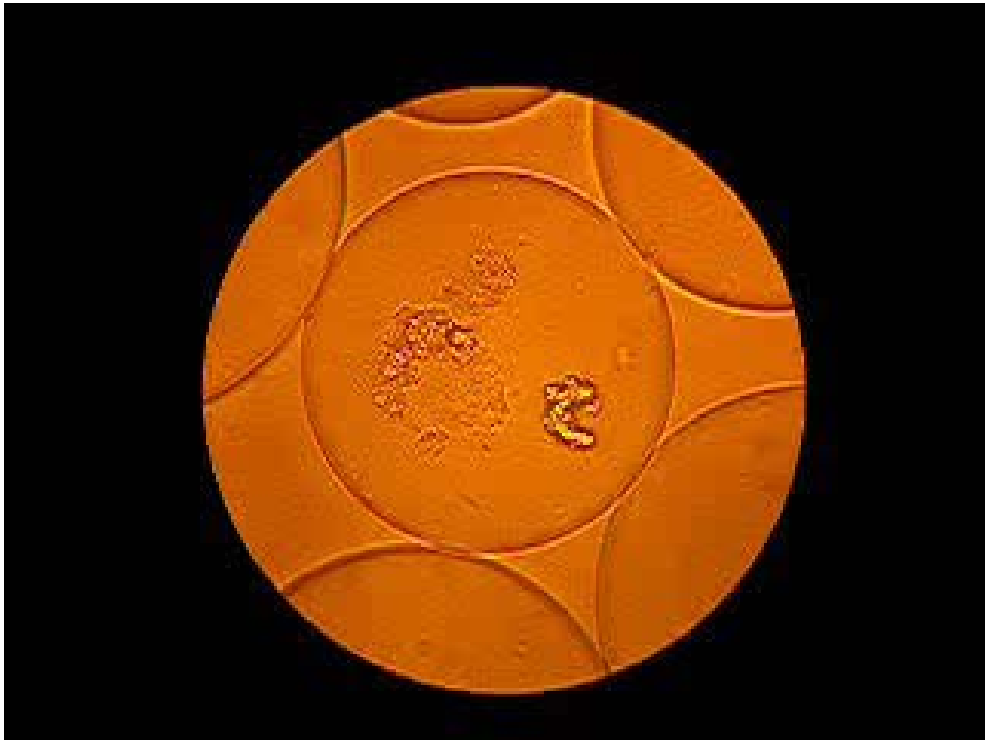
- Eight adult patients Type 1 diabetes

- Four: 10,000/Kg
- Four: 15,000/Kg

- Design difference to highlight ability of DIABECELL® to stabilise most brittle of insulin dependent diabetics

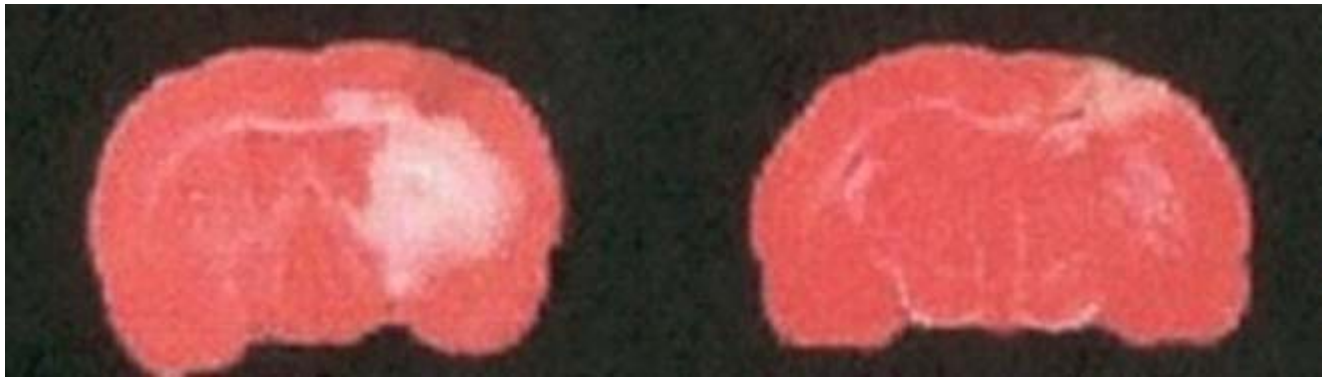
New Pig Facility, Invercargill

NTCELL



NTCELL

Preclinical studies
Stroke

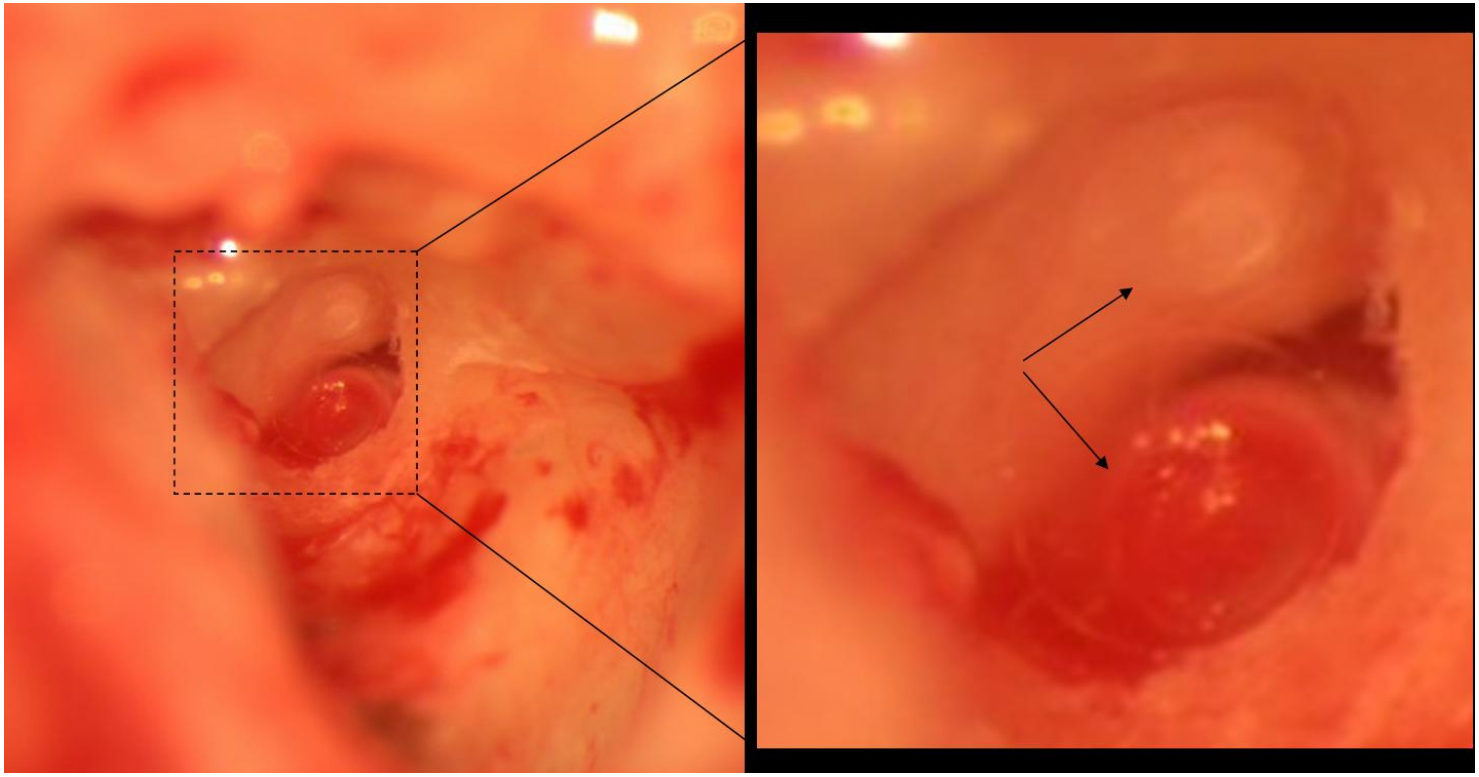


Untreated Treated

White areas indicate damaged brain tissue

Similar in **Parkinson's** and Huntington's

NTCELL – Hearing Loss



Liver and Other Cells

- Haemophilia
- (inborn errors of metabolism)
- (liver failure)
- (Other possibilities: Obesity, Cancer etc)

Other Islet Cell Transplant Technologies

- Human cadaveric donors - disappointing, dangerous, expensive, limited supply
- Stem cells-pancreatic cell lines are difficult to replicate and usual concerns relate to cell line differentiation and tumours
- Genetically modified human cells - ?futuristic
- Other xeno commercial competitors

  not in clinical trial

End Part -1

Commercialization of DIABECELL®

Encapsulated Porcine Pancreatic Islets

In development for normalization of blood glucose
In Insulin Dependent Diabetes
Implantable without immunesuppression

ASX : LCT and OTCQX : LVCLY

Auckland, New Zealand
Sydney, Australia

Paul LJ Tan

Contents: neonatal porcine pancreatic islets, ultrapure sodium alginate, polyornithine. Dose:150,000 islet equivalents in 150 ml for transfer into saline prior to laparoscopic administration into the abdomen.

LCT Investment Opportunity

- A cell-based treatment for type 1 diabetes
  - a major health problem with increasing frequency
  - potential application to insulin dependent type 2 diabetes

- Lead product DIABECELL® advantage
  - delivers cells releasing porcine insulin as needed in response to blood glucose
  - minimally invasive surgery into abdomen
  - proprietary micro-encapsulation technology permits implant without use of immunosuppressive drugs

- DIABECELL® positive preliminary data from clinical trial
  - eight patients in clinical trials treated with DIABECELL® YTD 2009
  - early data shows significant reduction in daily insulin requirements with no significant adverse events

- LCT in a phase for growth in value
  - larger trials with higher effective dose and
  - expansion of GMP manufacturing capability
  - significant revenue potential within 3 years of product registration

Porcine Based Pipeline Products

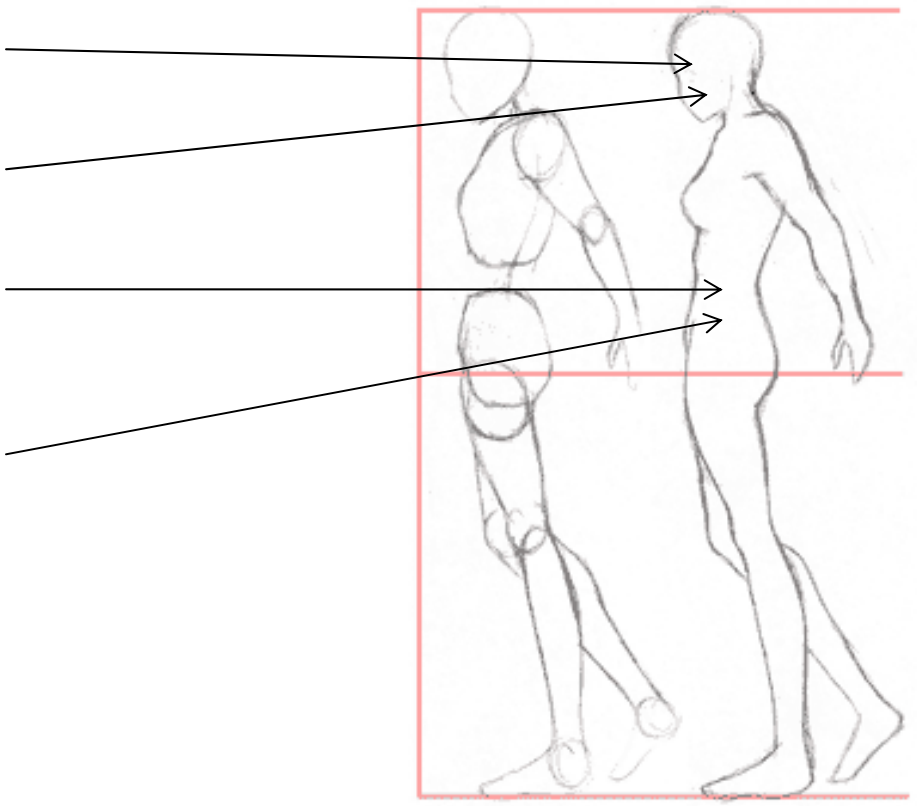
Multiple products from each pig

NTCELL for Parkinson's
Huntington's
Hearing Loss

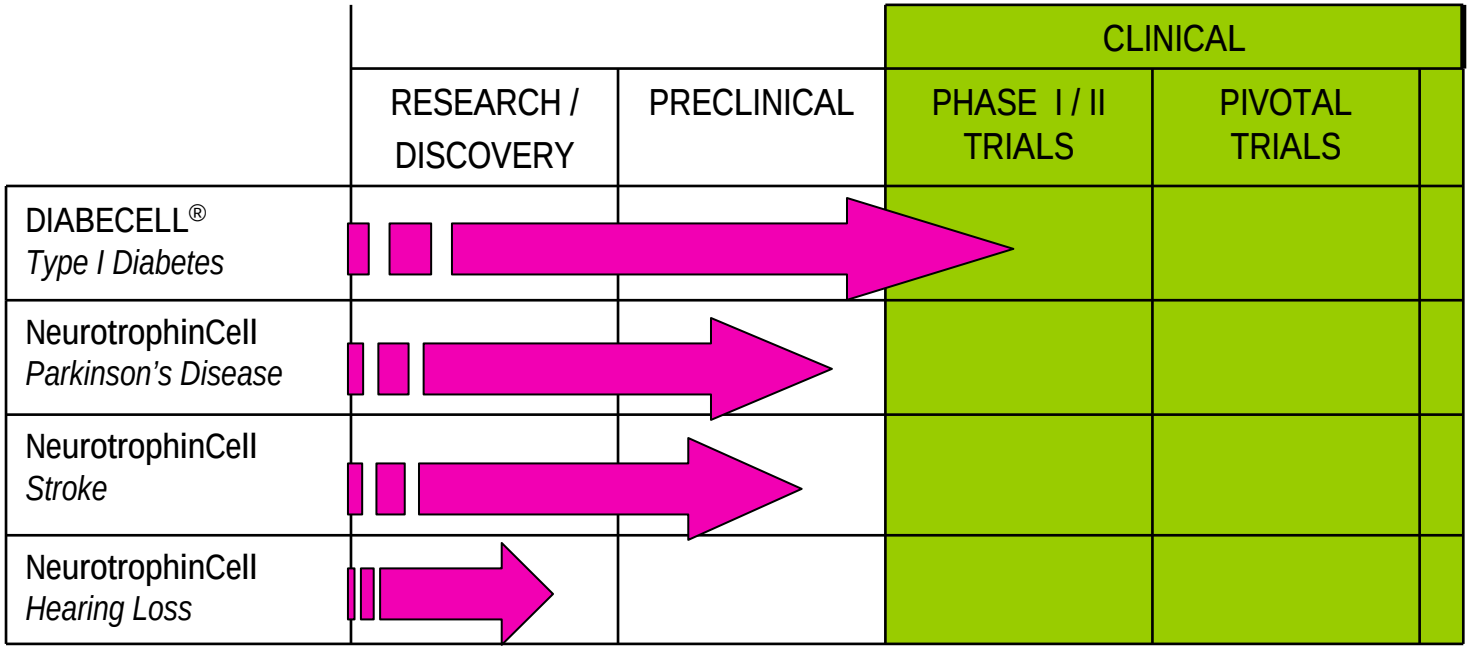
DIABECELL® for type 1 diabetes

Liver Cells
Fac8Cell for Bleeding Disorders

Porcine BioMaterials (Partner)
Heart valves, collagen, Biologics



LCT's Product Pipeline

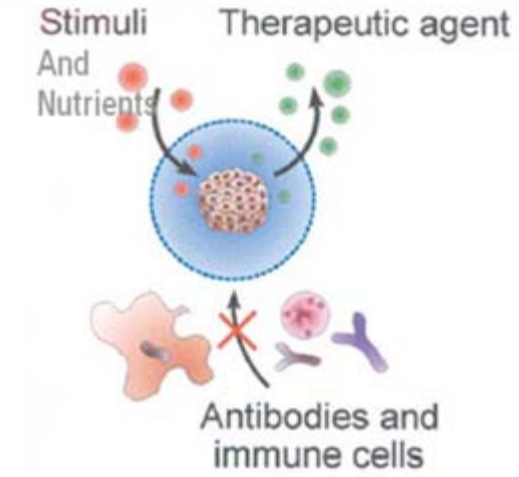


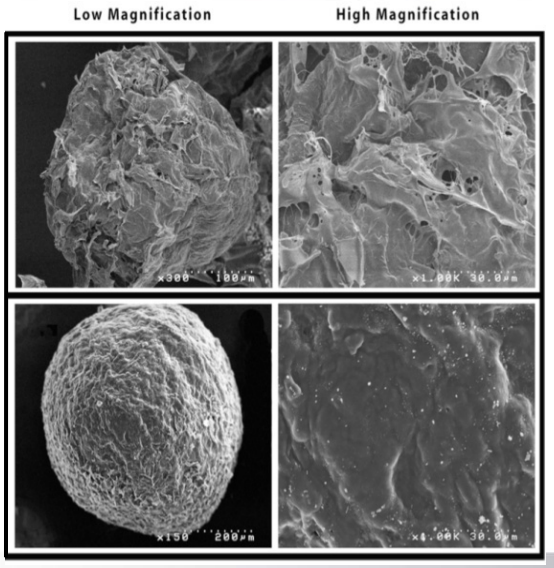
- **NeurotrophinCell** – porcine choroid plexus cells encapsulated in alginate and implanted to act as neuroprotectants for a range of neurological disorders
- **Encapsulation Technology** – LCT manufactures GMP alginate for cell encapsulation

Encapsulation Technology

Protecting cells in capsules

- avoids immune rejection
  without immunosuppressive drugs
- long term durability
- applicable for other cells
- LCT manufactures ultrapure alginate
- patent filed and potential for licensing
- collaboration with Centocor R&D Inc (J&J)
- commercial alginate supply



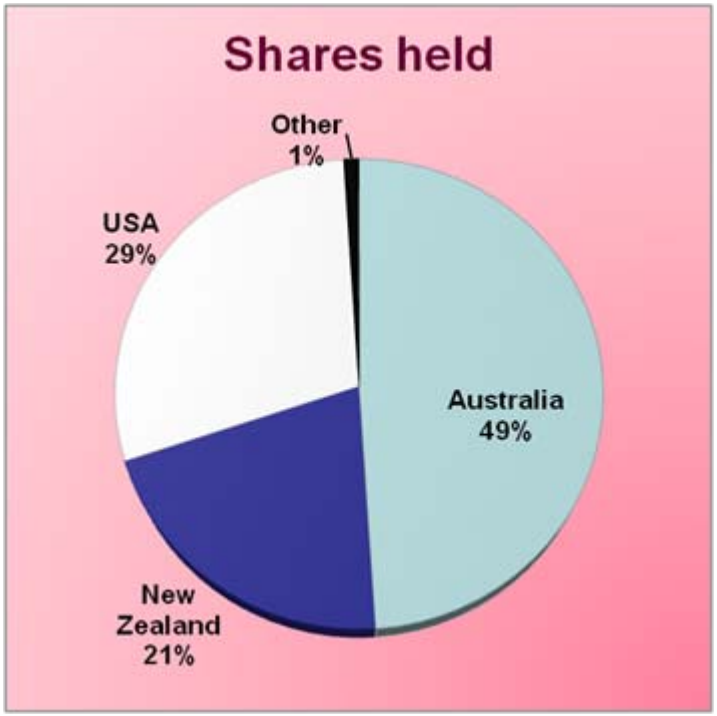


LCT Capital Structure

- Formed in 2003
- Acquired NZ operation, IP & 17+ years of R&D
- Listed on ASX September 2004
- Listed on OTCQX June 2008

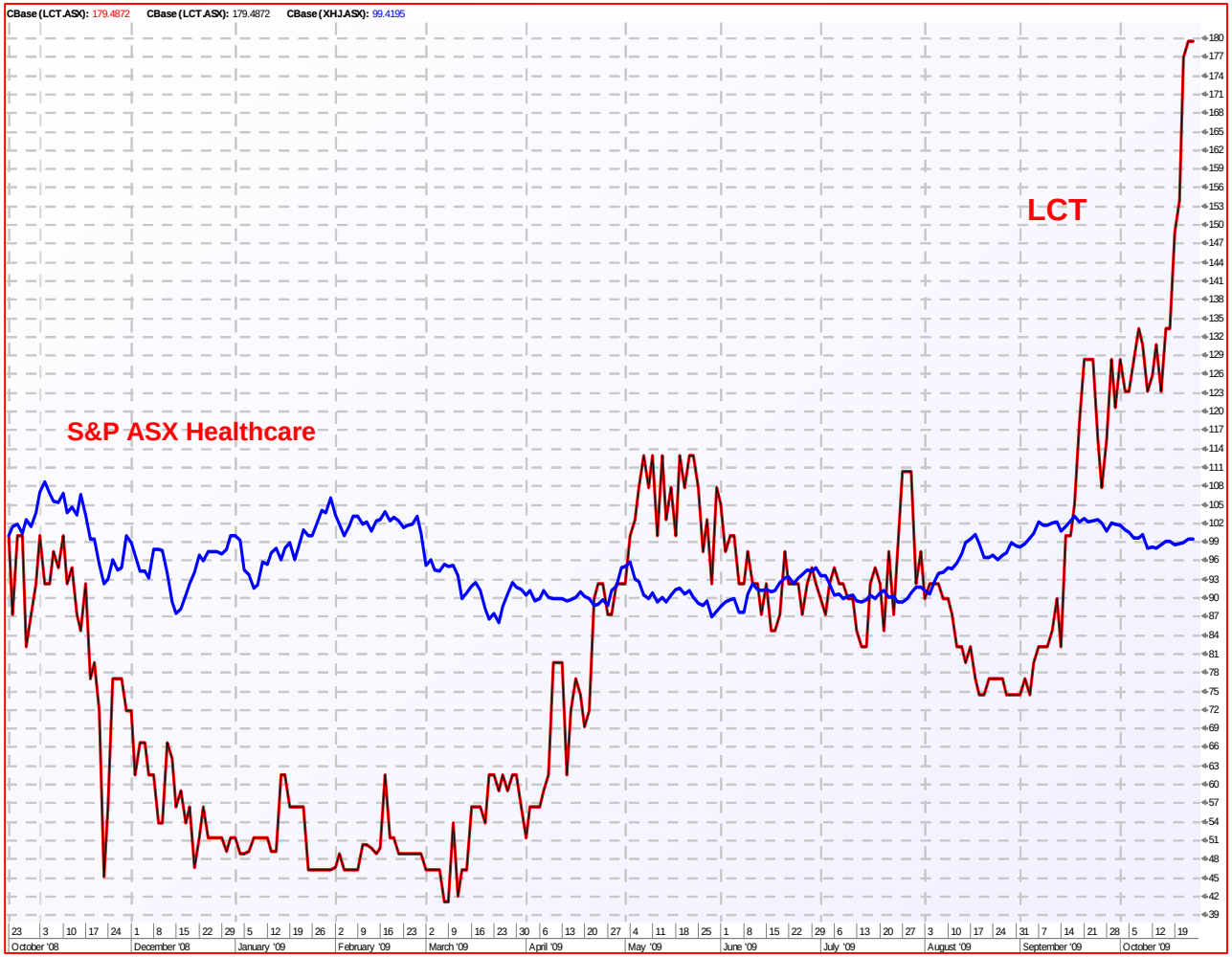
- Shareholding : August 2009

Australia	129,143,483
New Zealand	55,260,280
USA	76,679,042
Other	2,740,947
	263,823,752



- Cash: 2.8M (Jun 09) + 4.2M (Jul 09)
- Market Capitalization (22 Oct 09) 84.3 M
- Total equity investment 53.7 M
- Total government grants: 5.2 M

LCT Relative Share Price Performance
October 2008 - 2009



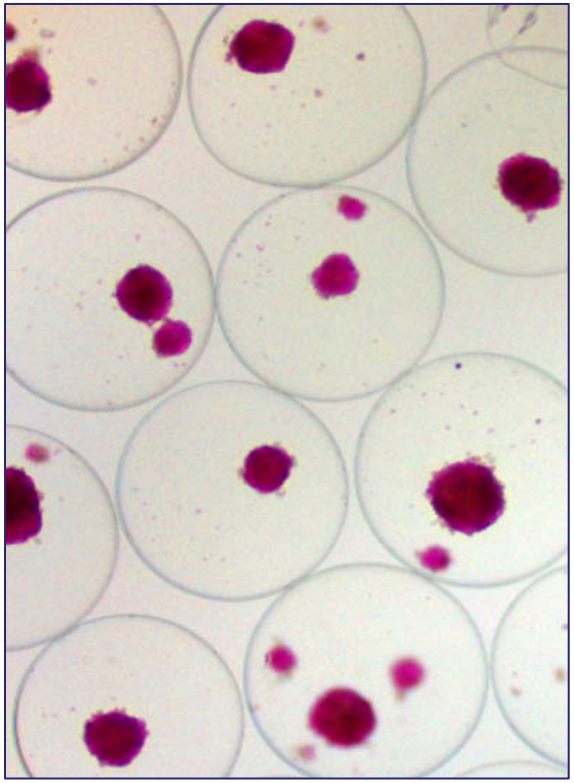
Market Position For DIABECELL®

Medical need to deliver insulin-on-demand

DIABECELL® for insulin dependent type 1 diabetes

- Normalize blood glucose: HbA1c<7%
- Eliminate life-threatening hypoglycaemic events
- Reduce insulin dose or insulin independence

- No immunosuppressive drugs
- Simple laparoscopic procedure
- Adult first then children



Intellectual Property and Patent Families

- method of breeding pigs
- use of neonatal piglets
- methods of preparation
- encapsulation
- treatment of diabetes

Near Term Milestones To Enhance Value

From Pigs to Clinic

2009

Q3 Start NZ trial
Commission new pig facility (50 pigs)
Q4 Establish commercial team in Moscow
Register capsule as delivery device
Complete Phase I/IIa Russia implants
Submit application for pivotal Russia trial

2010

Q2 Report Phase I/IIa – 4 patients from NZ trial
Q3 Pivotal trial in Russia underway
Q4 Report Phase I/IIa – 8 patients from NZ trial
Apply for NZ pivotal trial

2011

Manufacturing facility – further upscale
Expand pig breeding
Completion of pivotal data

Type 1 Diabetes : large burden and market

- About 20 million people globally with insulin dependent type 1 diabetes
  - Australia 100,000; New Zealand 15,000
- Increasing numbers: new cases per year
  - Australia 1,800; USA 30,000
  - Children aged <15 years 65,000 world wide
- Burden of disease
  - Life-long treatment costs approximately $1,000,000 per patient
  - USA 132 billion per yr direct and indirect cost of diabetes types I & II
- Diabetes market (Decision Resources) type 1 diabetes 2008
  - USA: US$1.25 billion and EU US$ 0.6 billion

DIABECELL® : a high value product

- Significant revenue from initial market penetration
- Assuming price at AUD 150,000 per treatment
- Breakeven point: treatment of 78 patients
- Projected Net Income Before Tax

  Taking into account revenue, cost of production, admin costs

Treatment of 100 patients	3.7M
250	21.3M
1000	109.6M

- Comparisons:

  cost of human islet transplant US $250,000 per patient

DIABECELL® Commercial Model

Manufacturer & Supplier

Breed pigs

Manufacture DIABECELL®

Supply DIABECELL®

Train Clinical Teams

Test for potential infections and maintains implant register

Negotiates re-imbursement with public and private funders

Clinical Service Provider

Establish Clinical Center of Excellence

Diabetes Physician refers patients and conducts pre-implant tests

Surgeon implants to LCT-approved procedure

Surgical facilities and DIABECELL® handling and short-term storage

Diabetes Physician Follow-up of recipient

Commercial Opportunities

LCT as Manufacturer and supplier

Client
Clinical Service Provider

Partner
License DIABECELL®
With Supply Agreement

Integrated Business

Local business and reimbursement practice

Medical Tourism

Commercial Route

Clinical

2009 commence 8 patient New Zealand study

2010 complete Phase I/IIa Russian study

2011 complete pivotal studies requirement

Pivotal Trial: Efficacy Data from 50 patients from multiple centres conducted to international standard for product registration in multiple jurisdictions – Russia, New Zealand, others

Registration

2012 Earliest registration and market - Russia

Operations

2009 Breed adequate numbers of pigs – complete new facility

2010 Back up Manufacturing Clean Room to supply for clinical trial

Upscaling manufacturing for commercial supply

Scale Up to Meet Market Demand

All LCT Cell Products Use Porcine Cells

- Scale-up issues known in pig industry
- Modular facilities for stepped expansion
- Fifteen (12 – 18) piglets required for each patient
- Breeding program will provide sufficient cells for commercial volume within 3 yrs
- 1,200 patients could be treated within 3 yrs of expansion from 100 sows

Year	Sows	Piglets	Female piglets (for breeding)	Male piglets (used for cells)	Patients treatable* scale up phase
1	100	1,000	500	500	30
2	600	6,000	3,000	3,000	200
3	3,600	36,000	18,000	18,000	1,200

*The number of piglets required to treat one patient depends on the weight of the patient and the dose.

Integrating Operations For Commercialization

PRODUCT DEVELOPMENT → **COMMERCIAL**

PIG BREEDING IN NZ

20 Sows for supply to Phase I/IIa Trials → 50 Sows for supply to Pivotal Trial → New Site for 500 Sows and Replicate optimum units

GMP MANUFACTURING IN NZ

Pilot GMP Facility → Scale-Up for supply to Pivotal trial → Scale-Up & Set-Up of New Site for Product Manufacturing

CLINICAL TRIALS

Phase I/IIa Trials 18 Patients → Pivotal Data Patients N = 50 → **Approval of Non-Human Islet Cell Implant 2012**

2008-2009 **2010-11** **2012-13**

End of Part 2

Summary for Investment Portfolio

Financial Value

Peak year sales
- Over $ 1 billion potential

Years to Commercial
- Near term: 3 years

Market exclusivity
- Long term
- Not easily replicable

Corporate Strategic Value

Unique selling proposition:
- World leader

Scientific innovation
- Unique, next generation

Fits with broad markets
- Diabetes
- Parkinsons

Success Probability

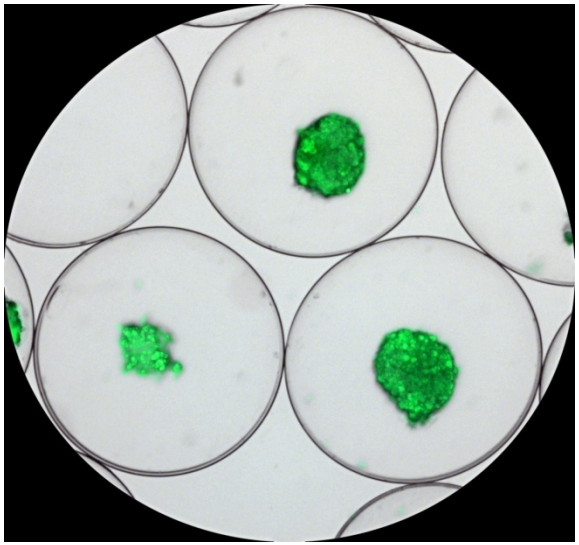
Development Costs
- $60 M invested to date

Technical Risk
- Positive clinical data

Regulatory
- NZ government
- International Review

LCT Company Assets & Value

David Brookes - Chairman

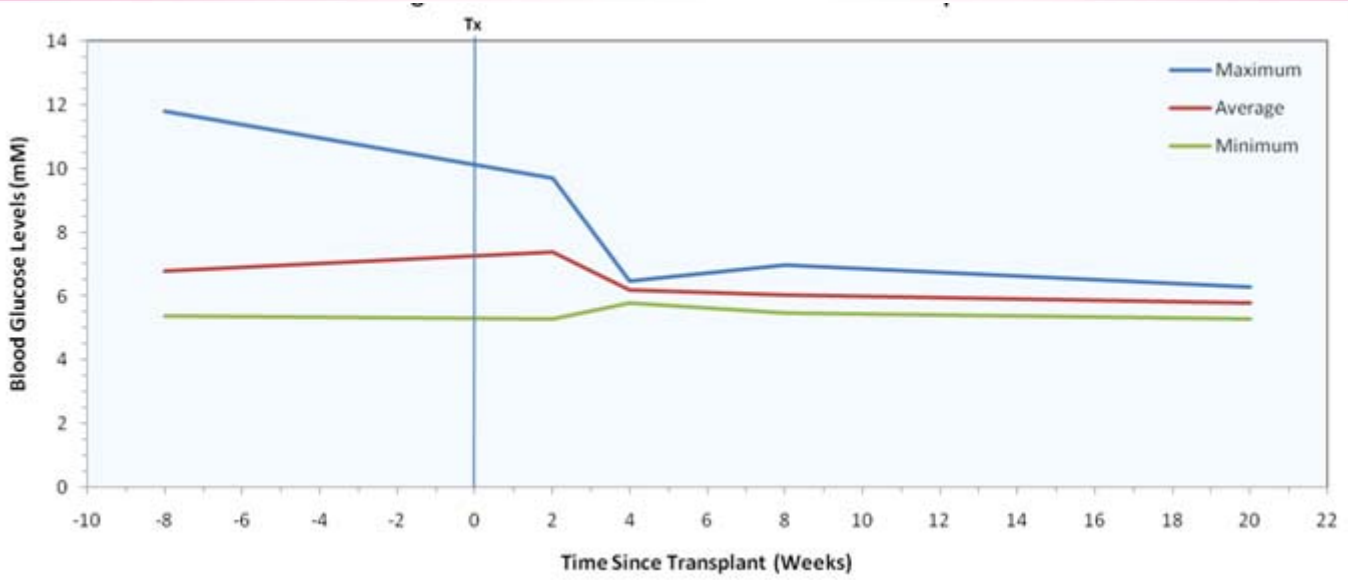


Encapsulated Porcine Islets

Benefits of DIABECELL®

- Safe, physiological (self-regulating) replacement therapy for insulin-dependent diabetics
- Independence from insulin injections possible & ideal
- Patients & families want FREEDOM from unstable blood glucose levels
- Registration of treatment to reduce insulin dose, improve blood glucose control (without hypoglycaemia) and improve quality of lifestyle. These improvements reduce long term disease complications (heart attacks, strokes, blindness, kidney failure ,amputations etc)
- Diabetics want “real control” of their blood glucose with minimised need for finger prick testing.

Function of DIABECELL®



- Reduction in Mean Blood Glucose and Range of Excursions despite minimal post implant Insulin dose reduction
- Islet Cell Transplants (insulin and glucagon secreted)
- Tight control with no hypoglycemia
- Alternative insulin delivery mechanisms not self regulating and require regular finger prick testing of blood sugar levels

Unique Assets

LCT owns unique virus free pig herds

- US FDA Guidelines
- Cash sows (selectively bred)

Laboratory and Manufacturing Plant

- International Accreditation & New Zealand certified
- GMP certification
- Dedicated, stable scientific team

Management Team

- Dr Paul Tan, CEO
  15 years in biotechnology and international clinical trials

- Prof Bob Elliott, Medical Director
  established track record as medical pioneer

Milestone: NZ Clinical Trial Approval

Approval 2009 by New Zealand Minister of Health for clinical trial has drawn world wide attention:

- LCT program reviewed by international experts
- Supported by key opinion leaders such as

  Professor G Eisenbarth (USA Diabetes Physician of Year 2009);
- Increasing interest in xenotransplantation:

  World Health Organization international meeting resulting in consensus for pig islet implants - Changsha Communique Nov 2008

Commercial Considerations

DIABECELL® - a mainstream product for private patients and health system reimbursement

Insulin Dependent Diabetes Type1 is a huge market

- 20 million people world wide with type 1 diabetes
  Example: 250 DIABECELL® transplants would supply approx. 2% NZ IDDM
- New cases every year: Australia 1,800 and US 30,000
- Niche product: Early significant revenue from small market penetration
- QALY="quality adjusted life year " which is defined as a year of perfect health

(approx /less than $50K pa considered cost effective treatment)

Encapsulation Technology used for DIABECELL® has the potential to be a separate commercial platform

Licensing and distributorships

Adapt commercial model to local markets

Medical tourism

Overview

- Leaders, innovators, dedicated team
- Assets: GMP facility; “clean” pigs
- Cell therapy company with porcine xenotransplant focus- DIABECELL® lead product to open pathway for other indications
- Cell encapsulation technology for commercialization
- Intellectual Property: broad applications
- Now in trial phase on historical spend of $60m
- Progressing to complete pivotal numbers of patients for product registration
- Now at value inflection point with trials, changing sentiment etc

World First

Patient from Russia with Diabetes for 15 years now off insulin after DIABECELL® without Immune suppression [photo used with permission]