



## Annual General Meeting 2013

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**Andrea Grant PhD, Managing Director**

ASX:LCT | OTCQX: LVCLY | [www.lctglobal.com](http://www.lctglobal.com) |  LCTglobal

# SAFE HARBOR STATEMENT

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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.

# Company snapshot

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## Origins

- ❖ Listed on ASX 2004
- ❖ First clinical trial DIABECCELL started 2007
- ❖ First clinical trial NTCELL started 2013

## Key strategic relationships

- ❖ Otsuka Pharmaceutical factory
- ❖ Callaghan Innovation (NZ government)

## Operations

- ❖ NZ main operating centre
- ❖ Two products in clinical development
- ❖ R&D group generating new IP

# Technology foundation



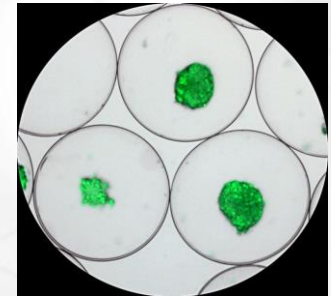
Null virus pig herd



GMP manufacture



Encapsulation



Comprehensive IP portfolio - US, EU, world



Therapeutic products in clinical development  
**DIABECCELL®**

# DIABECCELL: Phase I/IIa trials to date

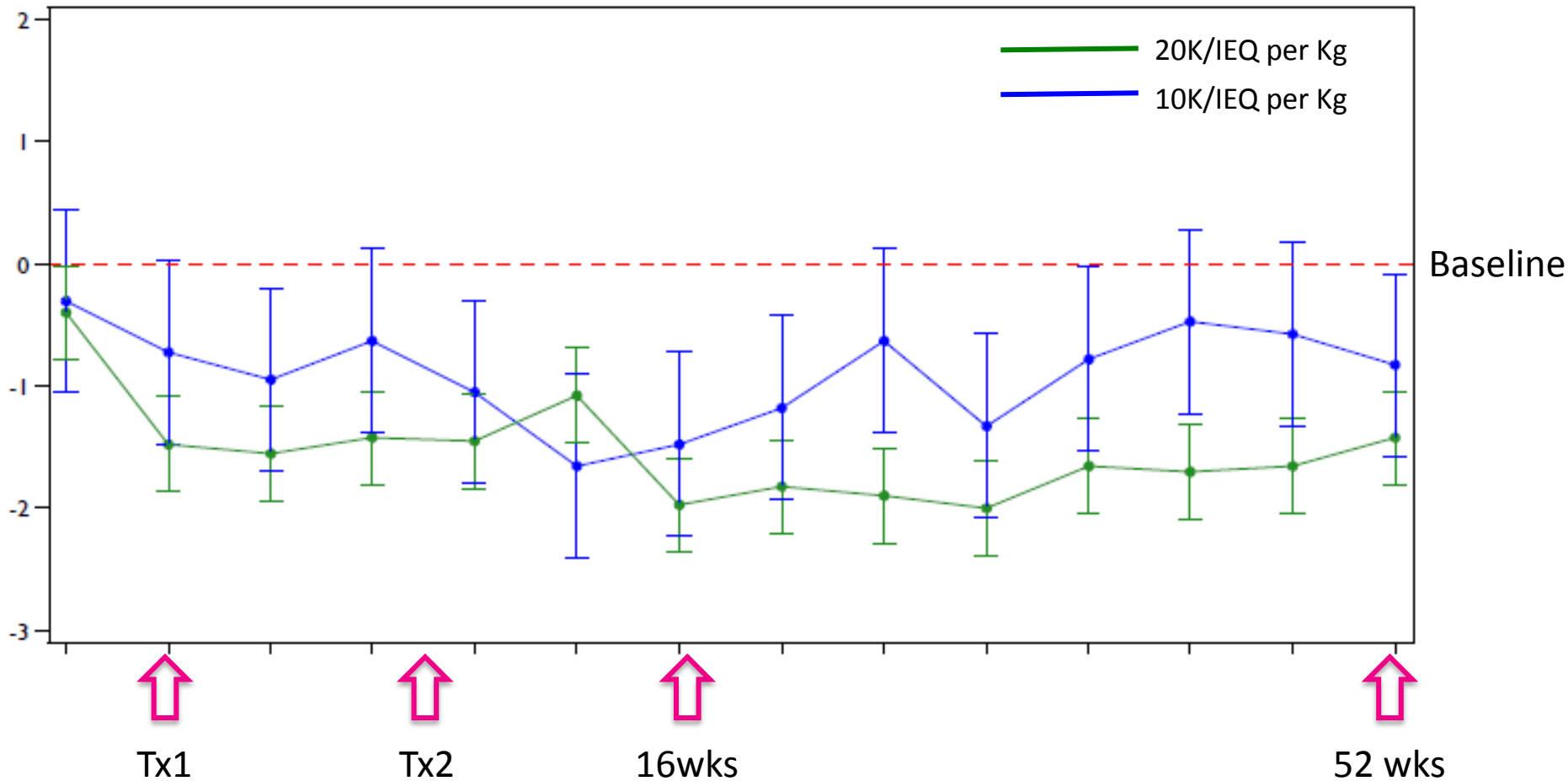
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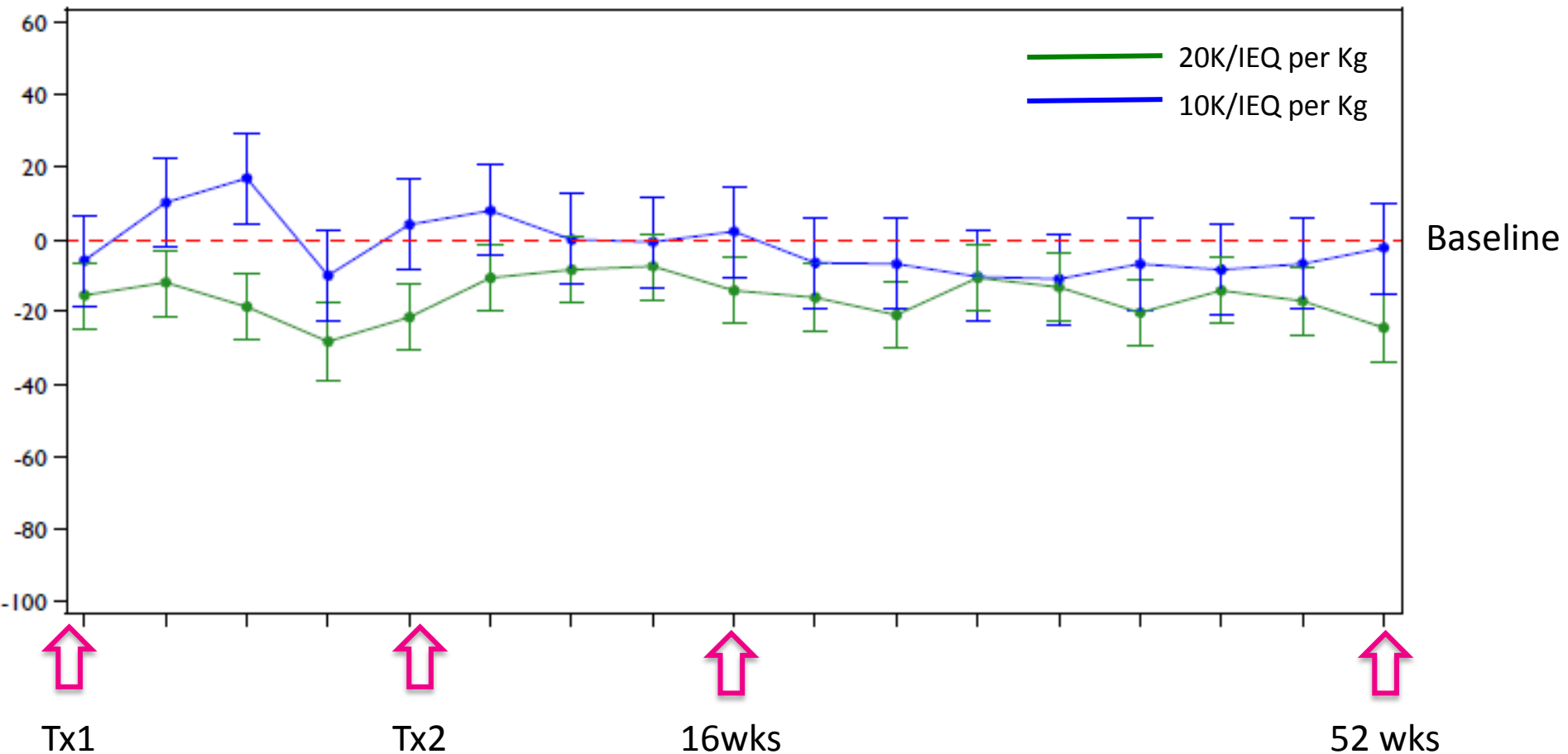
Trial	Endpoint	Country	# patients	Status
DIA-07(R)	Safety	Russia	10	Complete
DIA-06	Safety & dose finding	NZ	16	Complete
DIA-09	Safety & dose finding	Argentina	8	Complete

# Reduction HbA1c: 1.5-2% with 20K dose

*DIA-09 (Argentina, 8 patients)*



# 57% reduction unaware hypoglycaemia with 20K dose *DIA-09 (Argentina, 8 patients)*





# Safety assessments

*DIA-09 (Argentina, 8 patients)*

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## Minor adverse events

- ❖ abdominal pain & fever

## One major SAE

- ❖ bowel, required IV meds.

**Otherwise, well tolerated.**

# DIABECCELL – clinical summary to date

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## Three Phase I/IIa clinical trials

- ❖ Safe
- ❖ Optimum dose: two implants of 10K/IEQ, 3 months between implants
- ❖ Significant reduction unaware hypoglycaemia without increasing in HbA1c

# DIABECCELL – next steps clinical development

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## Strategy prior to August 2013

- ❖ 30 patient study designed to enable registration in New Zealand by 2016

## Strategy post August 2013

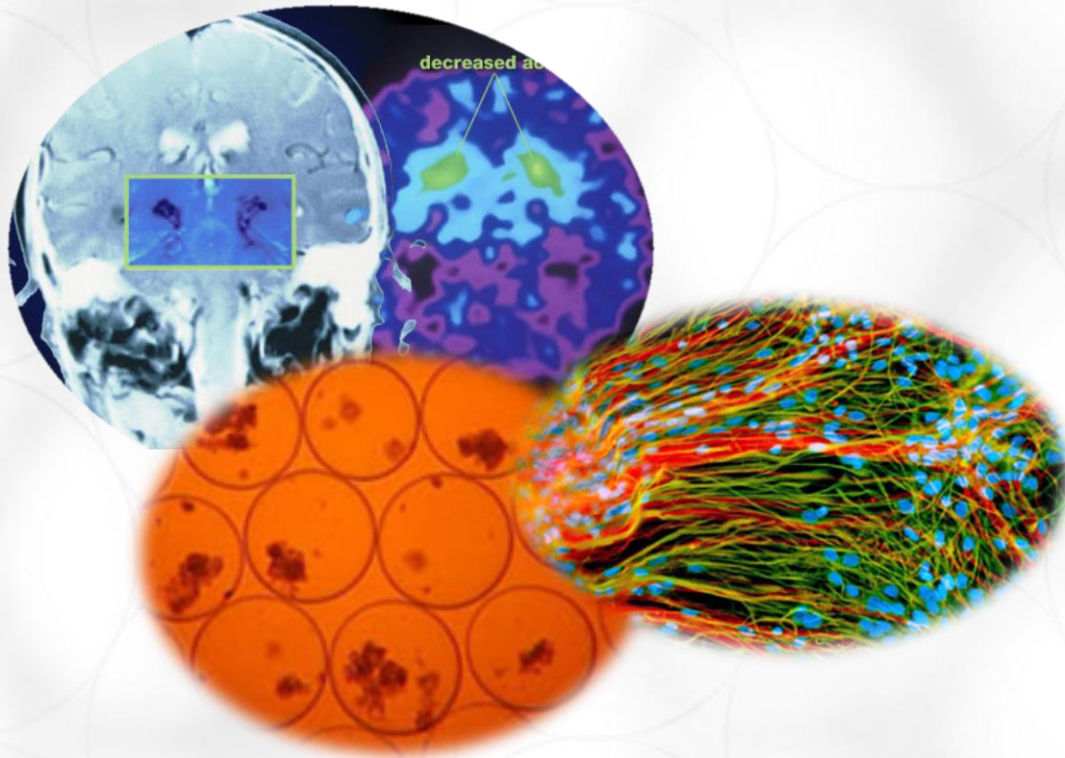
- ❖ Modified formulation  $\Rightarrow$  improved efficacy in *in-vivo* animal studies
- ❖ Re-design clinical development pathway to enable registration in New Zealand, Australia and Singapore
- ❖ Clinical studies in EU and USA also being explored

# DIABECCELL – commercialisation strategy

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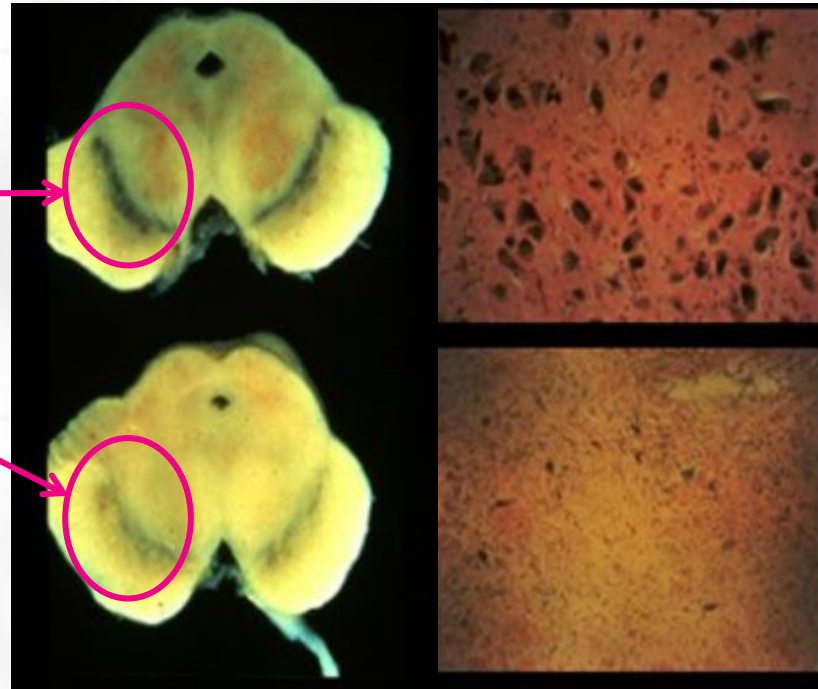
- ❖ DOL is responsible for commercialisation of DIABECCELL
- ❖ Local treatment centres in NZ and Australia to service local markets
- ❖ Treatment centres in Singapore (SG) to service international markets via established medical tourism industry
  - ⦿ Discussions underway with hospital partners with existing medical tourism infra-structure
- ❖ Regulatory strategy for EU and US registration in development
- ❖ Explore additional pig herds to determine suitability as tissue source for xenotransplantation
  - ⦿ Reduces capital required for pig facility scale up
  - ⦿ Discussions underway with multiple parties
  - ⦿ Will seek exclusive access for purposes of live cell therapeutics



Therapeutic products in clinical development

NTCELL®

# Loss of dopamine neurons



**No  
Parkinson's**

**Parkinson's**

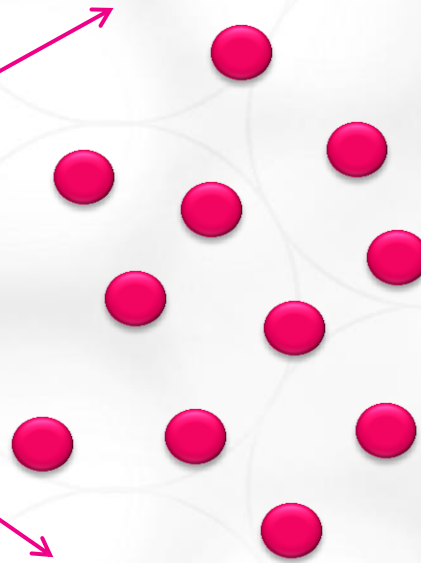
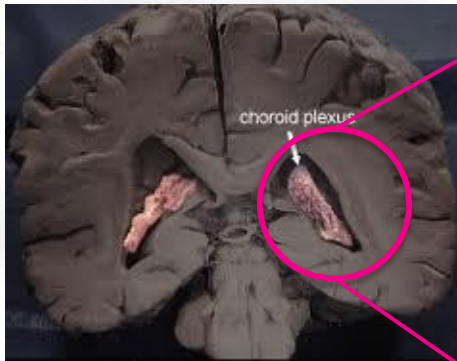
# Parkinson's disease

## "The saddest of all diseases"

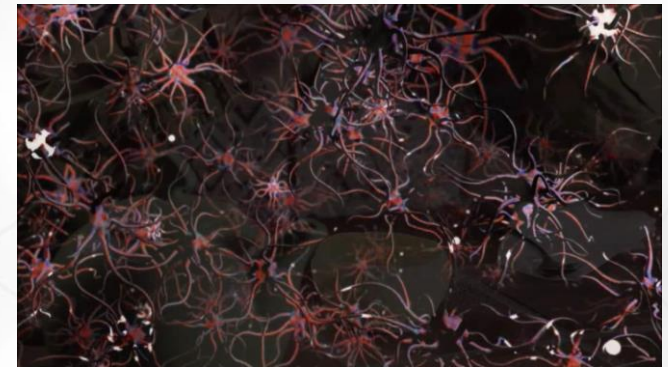
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# NTCELL: a regenerative therapy



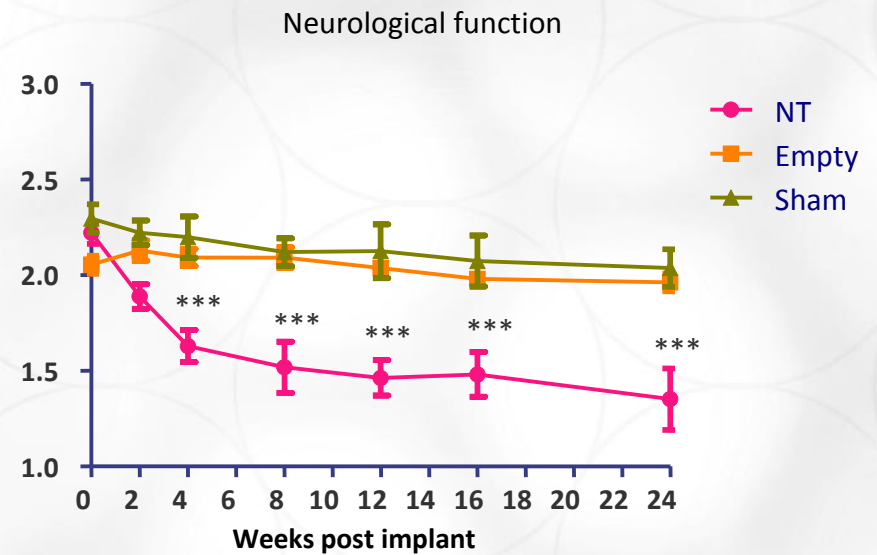
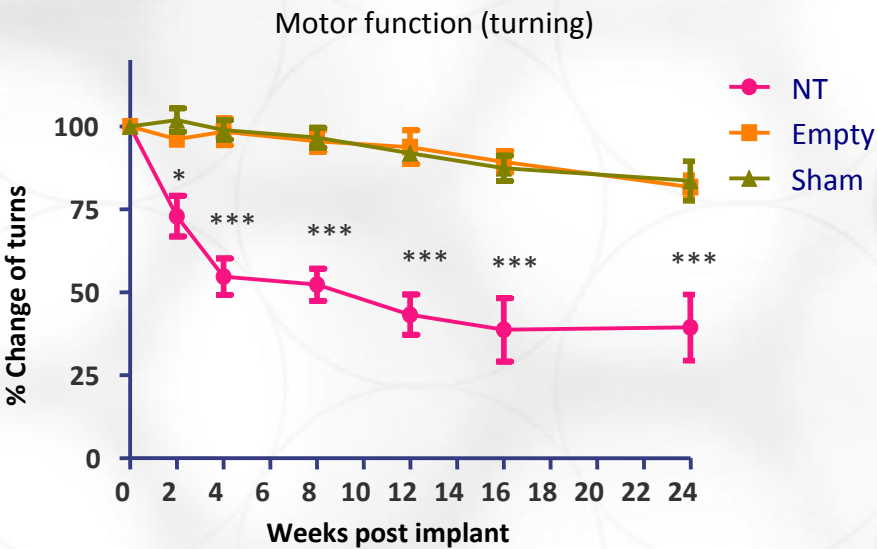
**100's of growth factors**



**Nerve regeneration**  
**Stem cell differentiation**  
**Protection from cell death**



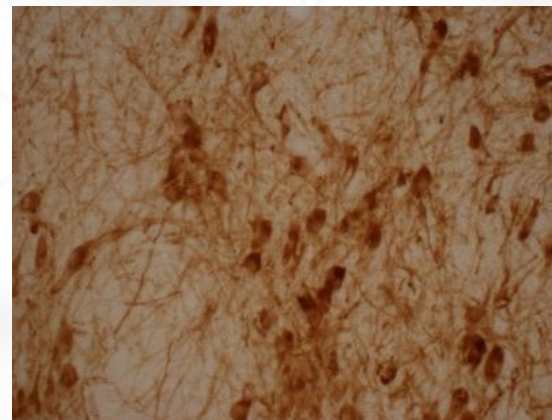
# >50% improvement in primate models



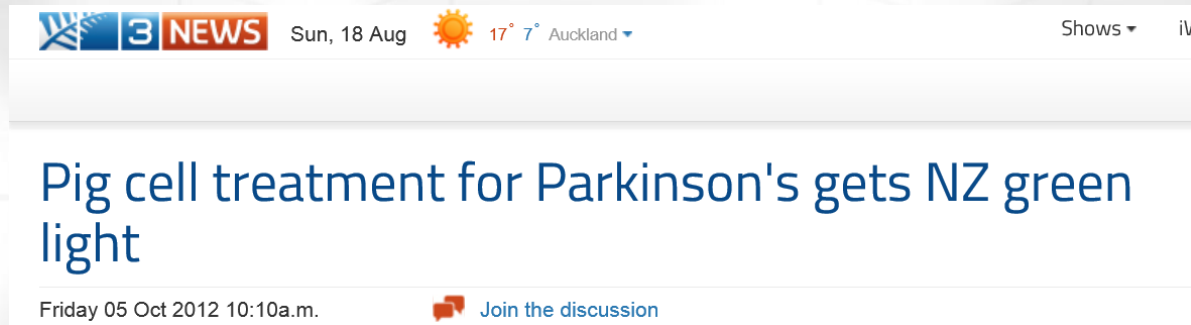
**Control**



**NT**



# NTCELL for Parkinson's Phase I underway



**4 patients – SAFETY study**

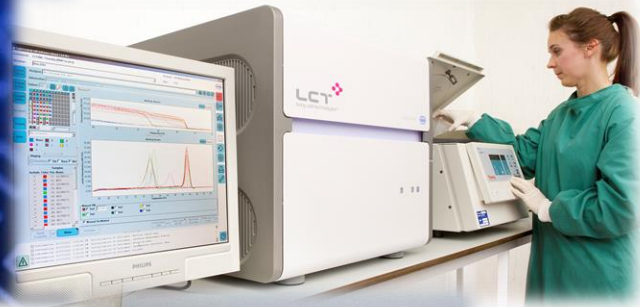
**First implant safely completed Sept 2013**

**Provided safety demonstrated – we will aim for fast track/breakthrough designation with FDA**

# The Otsuka partnership significantly reduces LCT's cash needs for clinical programmes



- ❖ LCT shareholders retain 50% share profits
- ❖ \$25m invested to date for clinical development of DIABECCELL
- ❖ Potential for additional \$20m on exercise of NTCELL option
- ❖ Up to \$5m option fee direct to LCT
- ❖ Enhanced R&D and commercialisation capabilities



New therapeutic candidates in pre-clinical development

# Examples of programs in pre-clinical development



**NTCELL**  
Encapsulated cells

- Neurological conditions: Huntington's, Alzheimer's, hearing loss
- Musculoskeletal

**NTCELL**  
Secreted growth factors

- Wound healing
- Respiratory

**Other cell types**

- Non-liver cells for Factor VIII

# Strategy

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## **Current therapeutic candidates**

- ❖ Adopt expanded regulatory strategy for DIABECCELL
- ❖ Demonstrate safety of NTCELL in Parkinson's and initiate efficacy studies

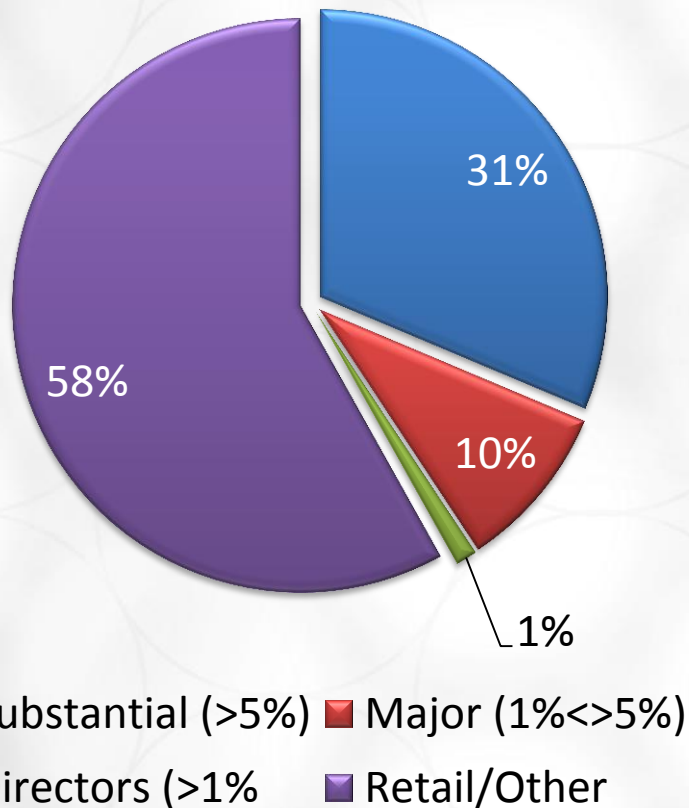
## **Strategy for new therapeutic development**

- ❖ Significant unmet need
- ❖ Powerful justification for cell replacement or regenerative approach
- ❖ Exploit key competencies, whilst diversifying product portfolio

## **Opportunities for new therapeutic development**

- ❖ NTCELL in other neurodegenerative conditions
- ❖ NTCELL secreted products for degenerative & inflammatory conditions
- ❖ Non-pig cell based products exploiting know-how

# Shareholding & financial position



Shares outstanding	357m
Options outstanding	12m
Last close (11 Nov 13)	\$0.09
52 wk range	\$0.04-0.10
Mkt Cap	\$30.2m
Current cash (30 Sep 13)	\$4.8m
Cash utilisation/annum	\$1.2m

# LCT:ASX 12mth chart





# Investment summary

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- ❖ Global pharmaceutical partner substantially invested
- ❖ Two breakthrough products in clinical development for diseases of high unmet need & substantial target populations
- ❖ IP protected technology platform with freedom to operate and develop new technologies
- ❖ Solid cash position with low per annum cash utilisation
- ❖ De-novo R&D identifying new therapeutic candidates
- ❖ Experienced management and governance

# Future news flow

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DSMB decision NTCELL Phase I trial	Dec 2013
Complete implants NTCELL Phase I trial	1H 2014
Interim analysis efficacy NTCELL Phase I	2H 2014
Commence new clinical development DIABECCELL	2H2014
Identification new clinical candidates	2H2014

# Thank you to our partners, staff, management, shareholders and BOD

