



Financial Year 2015 Full-Year Results and Business Update

Sydney
31 August 2015

“Improving quality of life through innovative cellular therapies”

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- Key Achievements for FY15
- Product Pipeline Update
 - FY15 Achievements
 - FY16 Outlook
- Patent Portfolio Update
- FY15 Financial Results Overview
- FY16 Catalysts

Key Achievements for FY15



Progress on clinical programs

- ✓ approval for first-in-human trials for
 - Progenza - allogeneic “off-the-shelf” stem cell therapy for osteoarthritis
 - RGS4K – cancer vaccine

Scalable technology

- ✓ demonstrated capacity to produce millions of doses of Progenza from a single donor
- ✓ transition from autologous to allogeneic stem cell technologies

Progress on partnering and licensing discussions

- ✓ progress on partnering discussions
 - for manufacturing, clinical development and commercialisation of Progenza in Japan
 - for global sales and marketing of Canine CryoShot - allogeneic “off-the-shelf” stem cell therapy for osteoarthritis

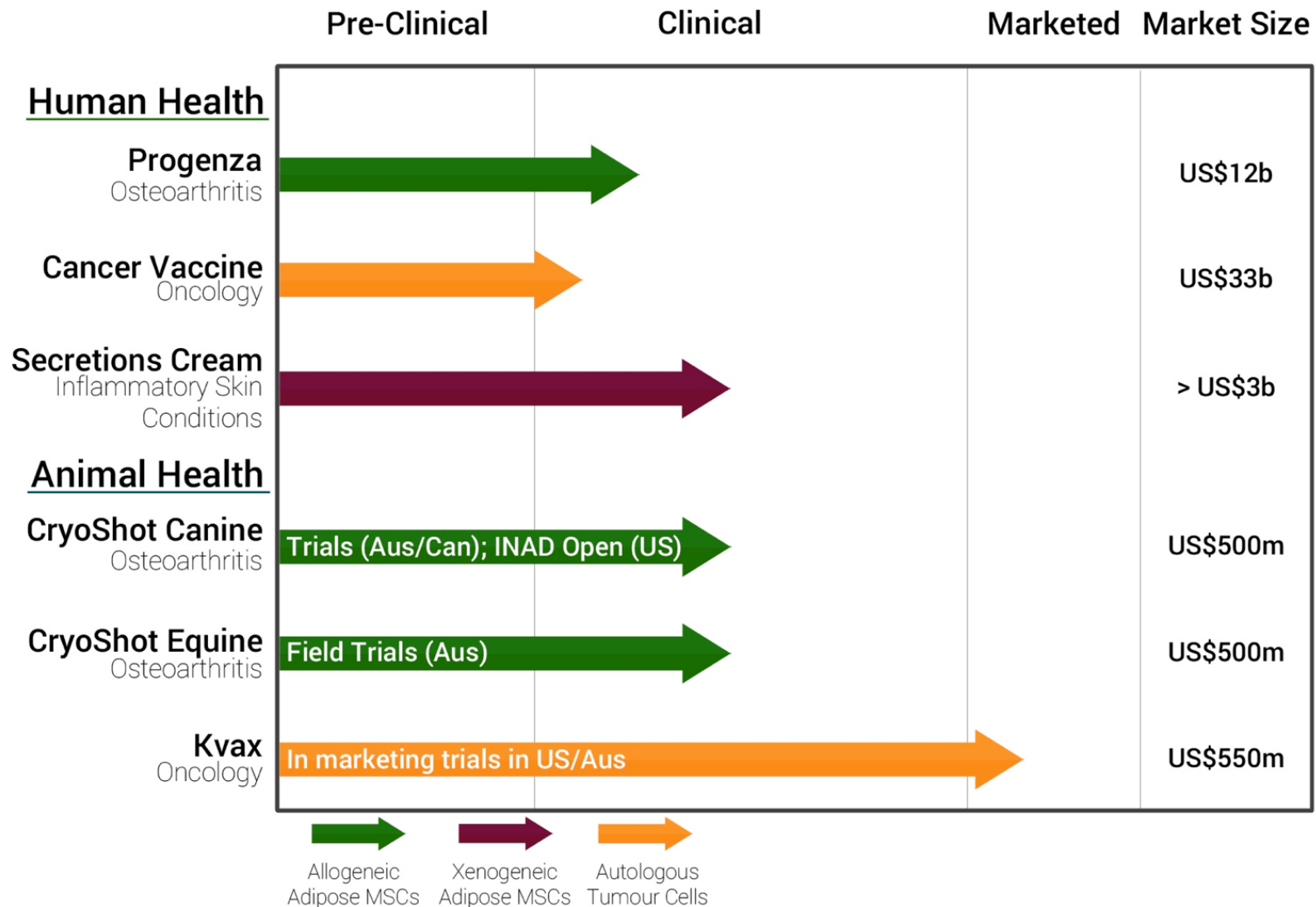
Substantial increase in granted patents

- ✓ 10 new granted patents
- ✓ 1st US granted patent

Product Pipeline Update

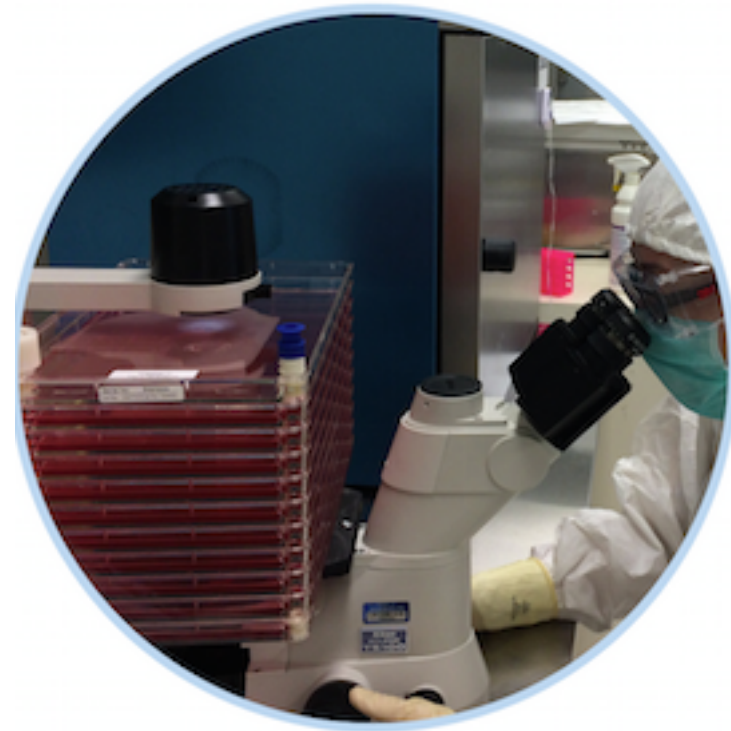


Product Pipeline & Market Opportunity



Progenza FY15 Achievements

- ✓ Successful production of Progenza for trial showing capacity to manufacture millions of doses from single donor
- ✓ Successful completion of preclinical study demonstrating that Progenza prevented cartilage degeneration
- ✓ Ethics approval for first-in-human trial 'STEP' – Safety, Tolerability, Efficacy of Progenza
- ✓ Safe treatment of the first patient in STEP trial
- ✓ Potential Japanese partners engaged for development, manufacture and commercialisation in Japan



Progenza - Positive Preclinical Results



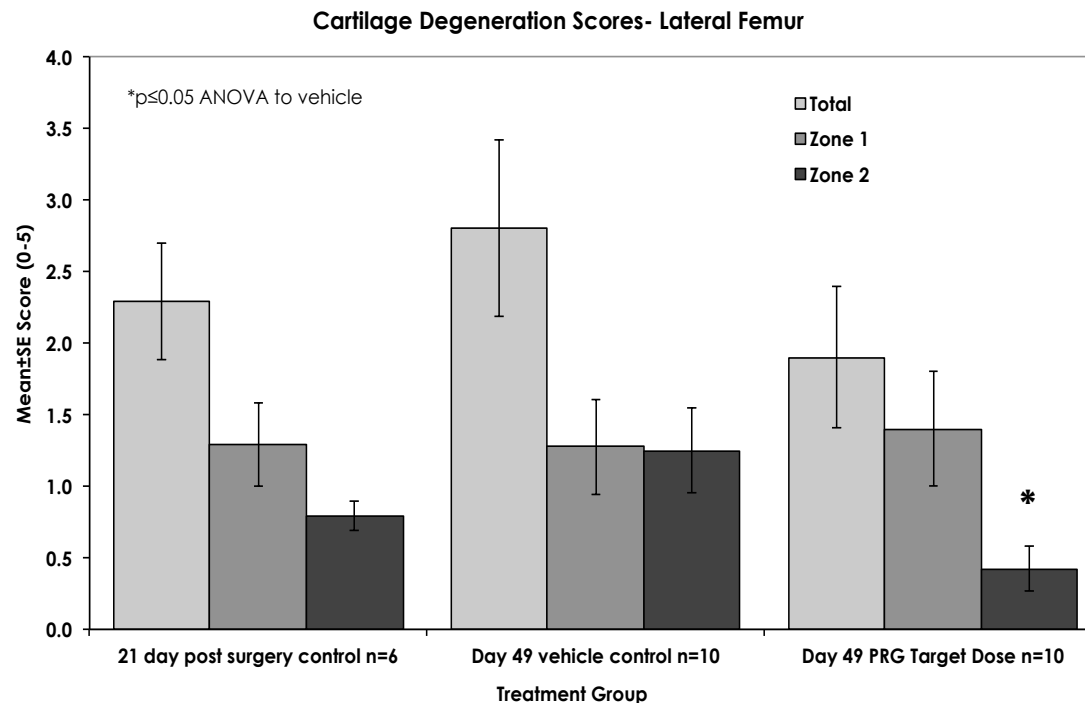
Conducted by independent US research group, a degenerative OA model (partial meniscectomy) in rabbits (n=46; 23M, 23F):

Safety:

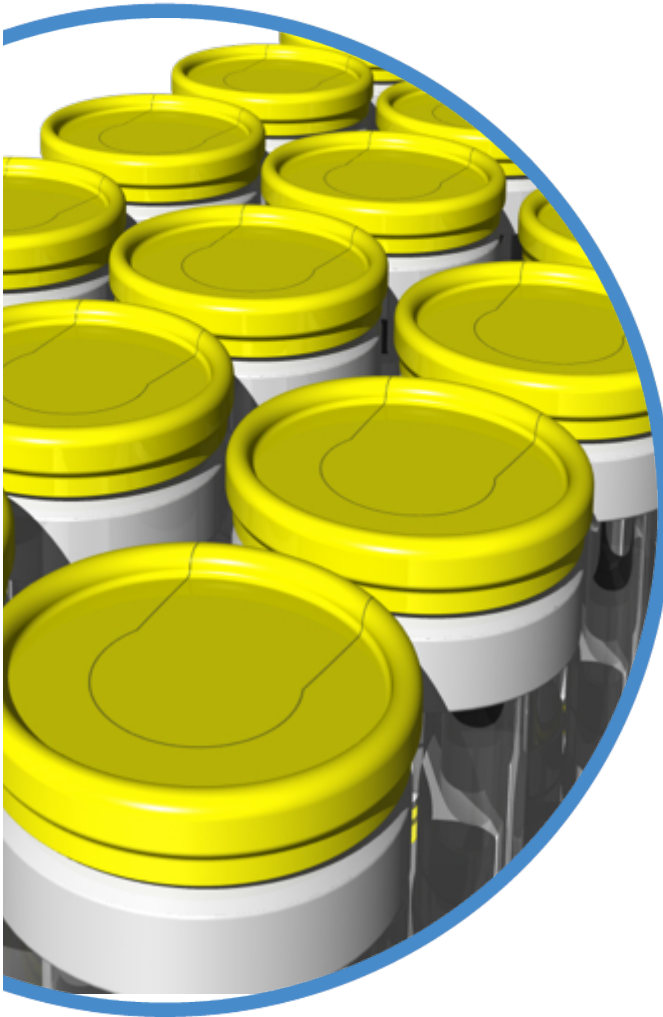
- A single intra-articular injection of >18 million Progenza cells per injection was not associated with any adverse local or systemic effects or toxicities

Efficacy:

- A significant reduction in cartilage degeneration scores of the medial femur in rabbits treated with 9.7×10^5 Progenza cells (rabbit target dose) vs. vehicle control
- Progenza prevented further joint degeneration in the model
- 52% reduction in osteophyte measurements in target dose group compared to vehicle control



Progenza FY16 Milestones



- Complete Phase 1 enrolment in STEP Trial
- Review blinded safety data
- Secure Japanese partner for development and commercialisation in Japan
- Procure donor adipose tissue for Phase 2 and manufacture master seed bank
- Commence PMDA (Japanese regulator) consultations
- Investigate licensing opportunities in US and EU

Human Cancer Vaccine – RGS4K

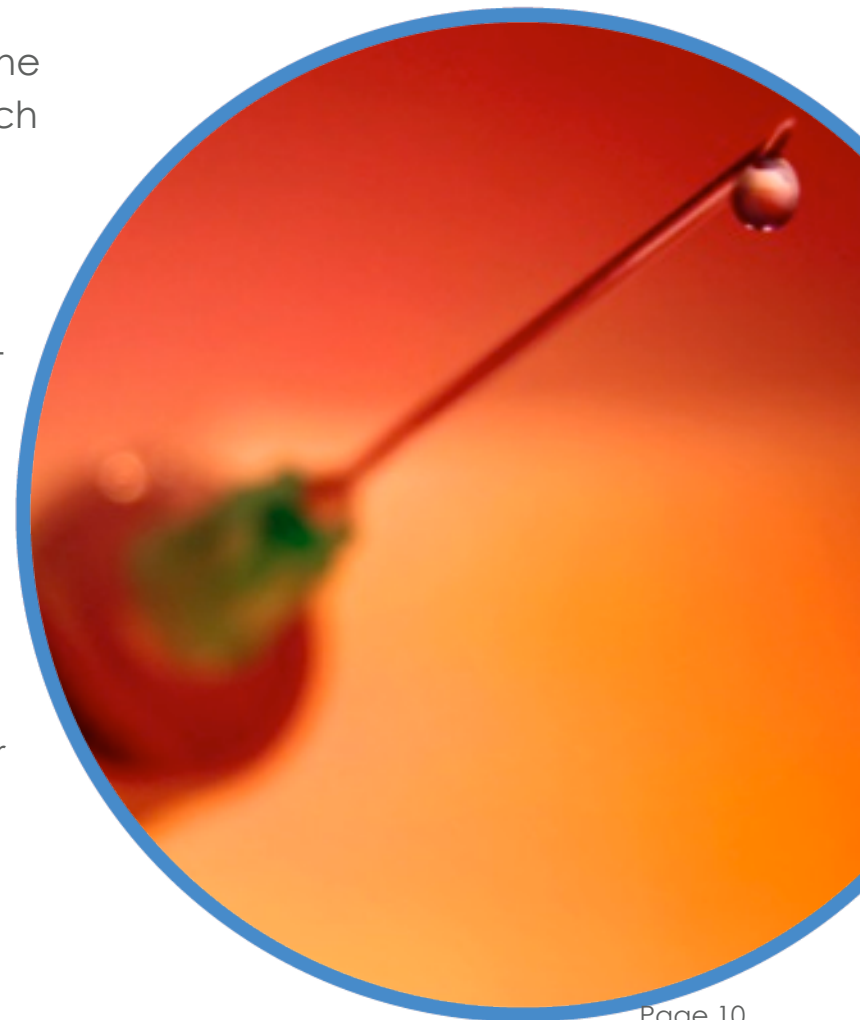


FY15 Achievements

- ✓ Secured exclusive global rights for cancer vaccine developed at Kolling Institute of Medical Research
- ✓ Ethics approval to commence first-in-human 'ACTIVATE' clinical trial obtained in May 2015
- ✓ ACTIVATE trial open for recruitment
- ✓ Ethics approved tumour bank - receiving patient samples to support vaccine manufacture

FY16 Milestones

- Complete enrollment in the ACTIVATE trial
- Assess emerging study data to:
 - Investigate vaccine safety, and
 - Identify a biologically active dose for further studies



Kvax – Canine Cancer Vaccine

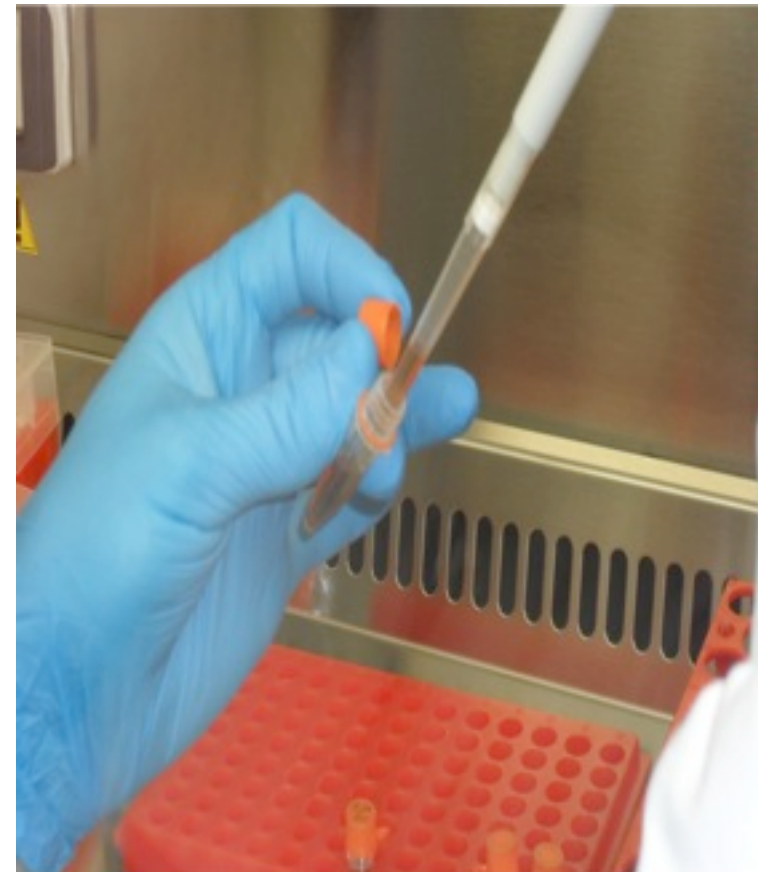


FY15 Achievements

- ✓ Marketing trial with Dr Bergman of VCA, largest US vet services group, fully recruited
- ✓ 1st dog commercially treated outside of the trial in the US
- ✓ >100 dogs treated in Australia

FY16 Milestones

- Commence further marketing trial for lymphoma
- Seek global sales and marketing partner



Canine CryoShot



FY15 Achievements

- ✓ Further data collected from field trials in Australia
- ✓ Local efficacy trial leads to new potential IP for optimising success of treatment
- ✓ Advanced discussions with potential marketing partners
- ✓ Completed preparation for pre-pivotal US trial

FY16 Milestones

- Commence pre-pivotal trial at University of Pennsylvania to de-risk FDA trial
- Secure partner for further development, sales and marketing
- Sign off on pivotal trial design, product characterisation and manufacture for FDA

Patent Portfolio Update



Patent Portfolio Update



- 12 patent families underpinning product portfolio
- 8 patents granted in Australia
- 2 patents granted in NZ
- 1st patent granted in USA
- 1 new family - enhanced cell therapies – Progenza & CryoShot

Patent Portfolio – Granted Patents



Australian Granted Patents

Patent No.	Title	Filing Date	Status
2013203165	Pharmaceutical compositions and topical use thereof	2013-04-09	GRANTED
2013203164	Therapeutics for skin conditions	2013-04-09	GRANTED
2013203072	Therapeutic methods and compositions comprising cells and secretions	2013-04-09	GRANTED
2012229890	Pharmaceutical compositions and topical use thereof	2012-03-15	GRANTED
2011247866	Allogeneic therapeutic methods using adipose tissue-derived cell suspensions	2011-11-08	GRANTED
2009284700	Autologous therapeutic methods using adipose tissue-derived cell suspensions	2009-08-20	GRANTED
2013204930	Therapeutics using multiple injections of cells	2013-04-12	GRANTED
2011342382	Arthroscopy method	2011-12-19	GRANTED

US Granted Patent

9,062,288	Therapeutic methods using adipose tissue-derived cell suspensions comprising adipocytes	2009-08-20	GRANTED
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NZ Granted Patents

591626	Therapeutic methods using adipose tissue-derived cell suspensions comprising adipocytes	2009-08-20	GRANTED
612473	Arthroscopy method	2011-12-19	GRANTED

FY15 Financial Results Overview



FY15 Financial Highlights



S'000's	2015	2014	Change
Revenue	2,061	2,095	(34)
Cost of Sales	(915)	(622)	(293)
Gross Profit	1,146	1,473	(327)
Other income	3,498	3,868	(370)
R&D expenses	(4,945)	(5,759)	814
Selling expenses	(1,678)	(2,253)	575
Occupancy expenses	(757)	(628)	(129)
Corporate expenses	(3,815)	(3,875)	60
Finance Expenses	(56)	(349)	293
Loss for year	(6,607)	(7,523)	916
Non-recurring expenses	1,631	295	1,336
Underlying loss for year	(4,976)	(7,228)	2,252

- Expenditure focused on R&D production and clinical trials
- R&D expenses reduced as manufacture for Progenza clinical trial completed
- Expenditure reduction following strategic review of HiQCell business
- Reduction in FTE from 40+ to less than 20

Operating Cash Burn



	\$'000's
Cash at 30 June	3,013
R&D Tax Incentive	3,418
Cash available	6,431
Quarterly cash burn	1,700+
Cash available	3+ quarters

- Cash Burn for past 2 quarters (ex one-off costs) was \$1.7m
- Slight increase anticipated due to execution of clinical trials
- R&D Incentive of \$3.4m to be received early October 2015

FY16 Catalysts

