



Financial Year 2015
Full-Year Results and
Business Update

Sydney 31 August 2015

"Improving quality of life through innovative cellular therapies"

Important Notice



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Overview



- 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
 - RGSH4K 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

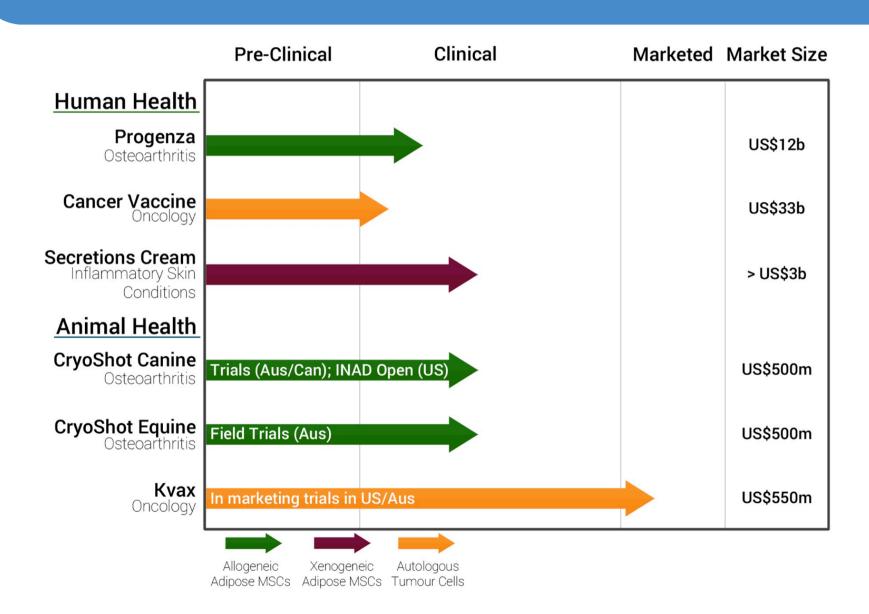
Product Pipeline Update





Product Pipeline & Market Opportunity

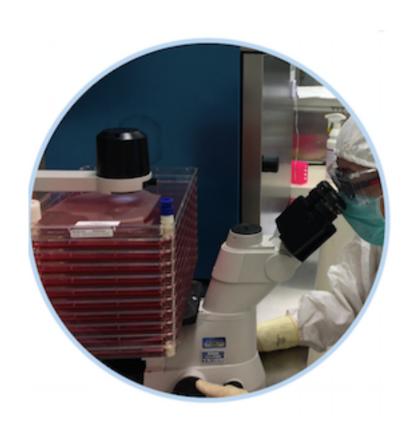




Progenza FY15 Achievements



- 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

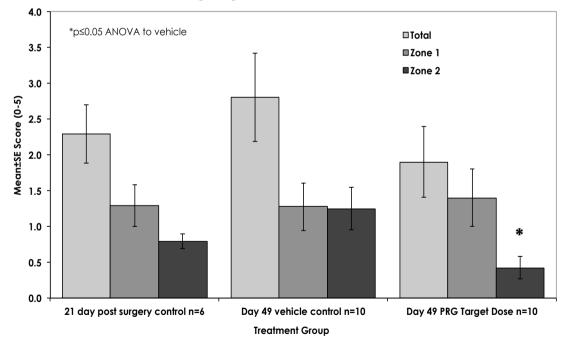


Progenza - Positive Preclinical Results



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

Cartilage Degeneration Scores-Lateral Femur



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 x10⁵ 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 – RGSH4K

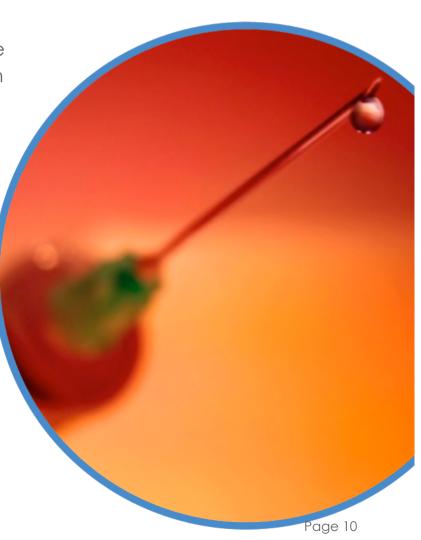


FY15 Achievements

- ✓ 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

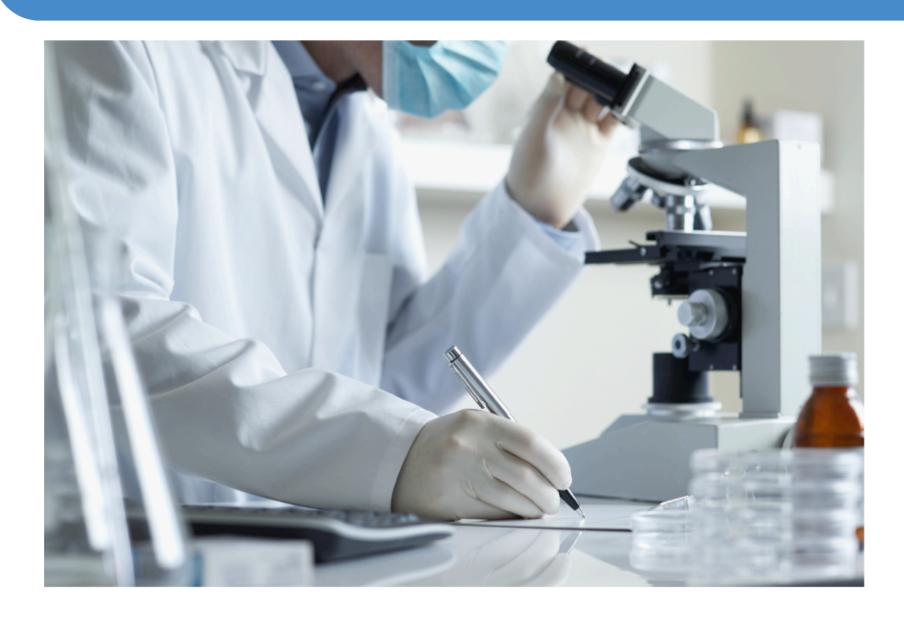


Australian Granted Patents

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	
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



Secure manufacturing and commercial partners for Progenza in Japan H1FY16 First patient treated in human cancer vaccine trial H1FY16 Secure global sales and marketing partner for CryoShot Canine H1FY16 Interim safety report on STEP trial for Progenza in Q2FY16 Complete enrollment in human cancer vaccine safety trial H2FY16 Complete Canine CryoShot pre-pivotal US trial H2FY16