



2014 AGM Presentation

Sydney
28 October 2014

“Improving quality of life through innovative cellular therapies”

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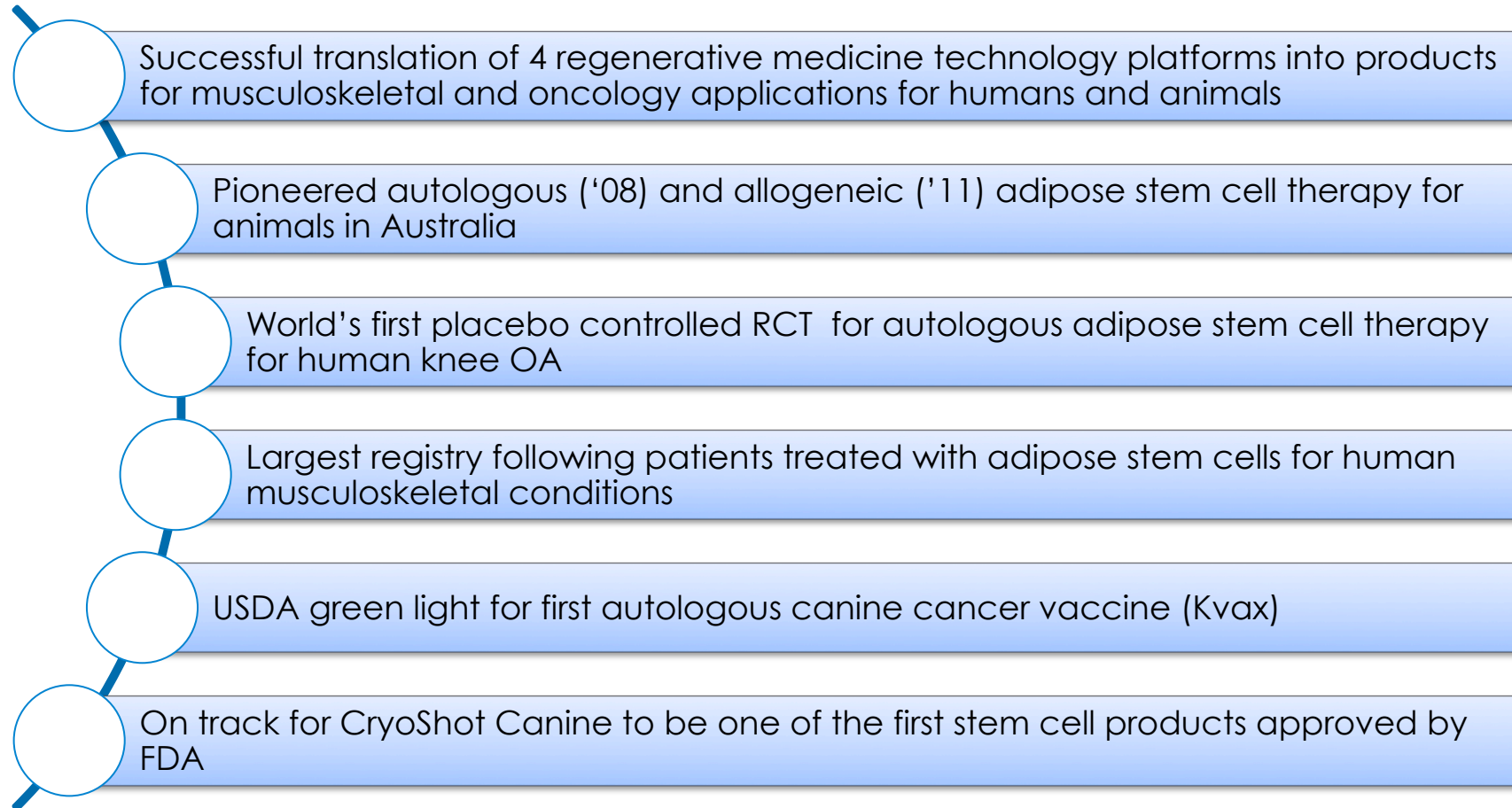
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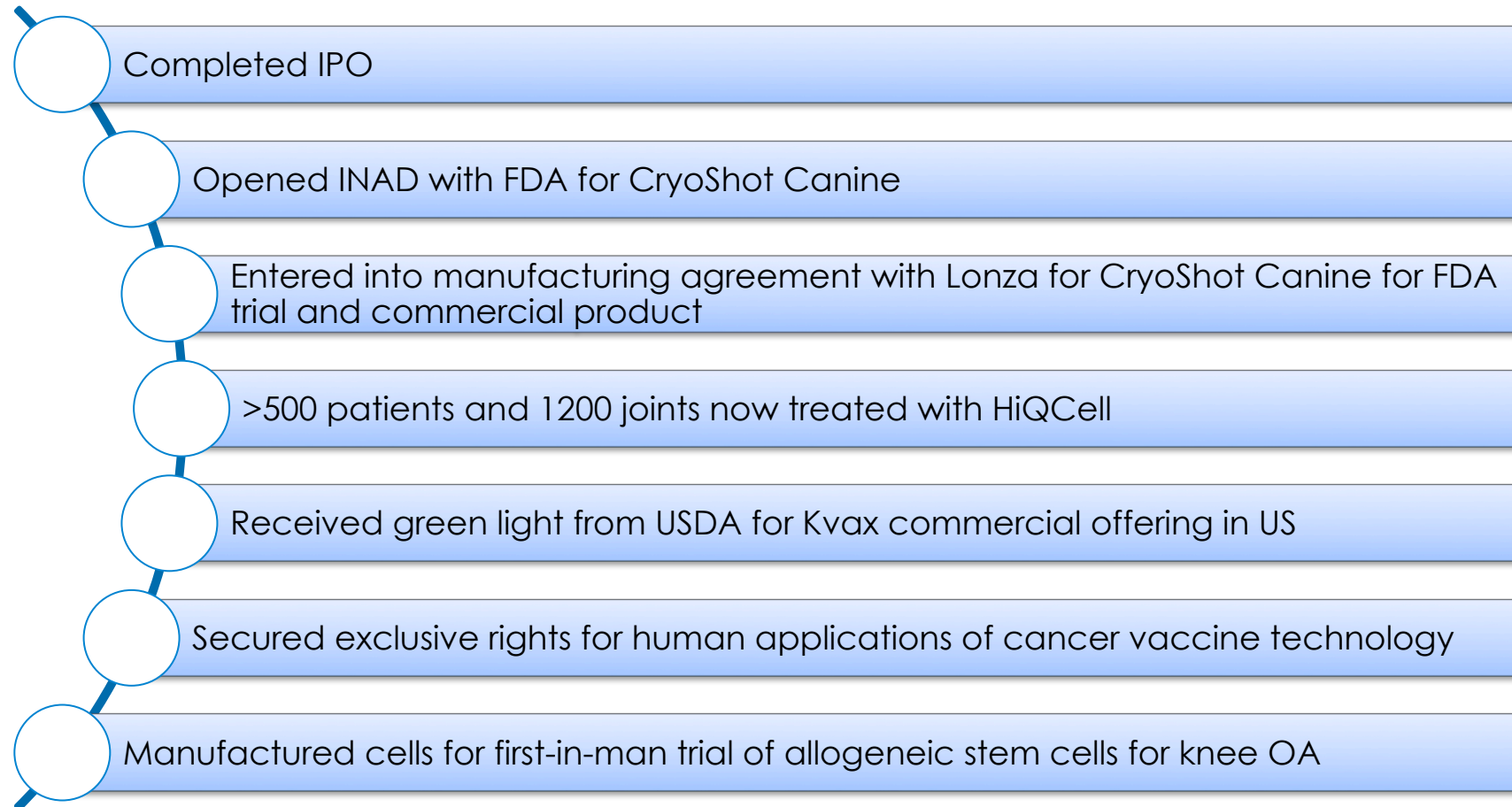
Agenda

1. Significant Achievements to date
2. FY14 Highlights
3. Financial Results
4. Product Pipeline Update and Value
5. FY15 Strategic Imperatives
6. Product Overview
 - FY14 Achievements
 - FY15 Milestones
7. IP Update

Significant Achievements to date



FY14 Highlights



Financial Results



S'000's	2014	2013
Revenue	2,095	1,770
Cost of Sales	(622)	(581)
Gross Profit	1,473	1,189
Other Income (inc R&D incentive)	3,868	2,628
R&D expenses	(5,759)	(4,134)
Selling expenses	(2,253)	(1,784)
Corporate expenses	(3,875)	(2,297)
Occupancy expenses	(628)	(468)
Finance Expenses	(349)	(329)
Loss for year	(7,523)	(5,195)

FY 2014 – Key Financial Highlights

- Revenue up 18% to \$2.1 million
- Targeted R&D expenditure up 39% to \$5.8 million
- R&D tax incentive increased 60% to \$3.7 million
- Successful IPO supported by additional funding Q1 FY15 totalling \$16.5 million
- Cash at 30 June 2014 \$2.5 million

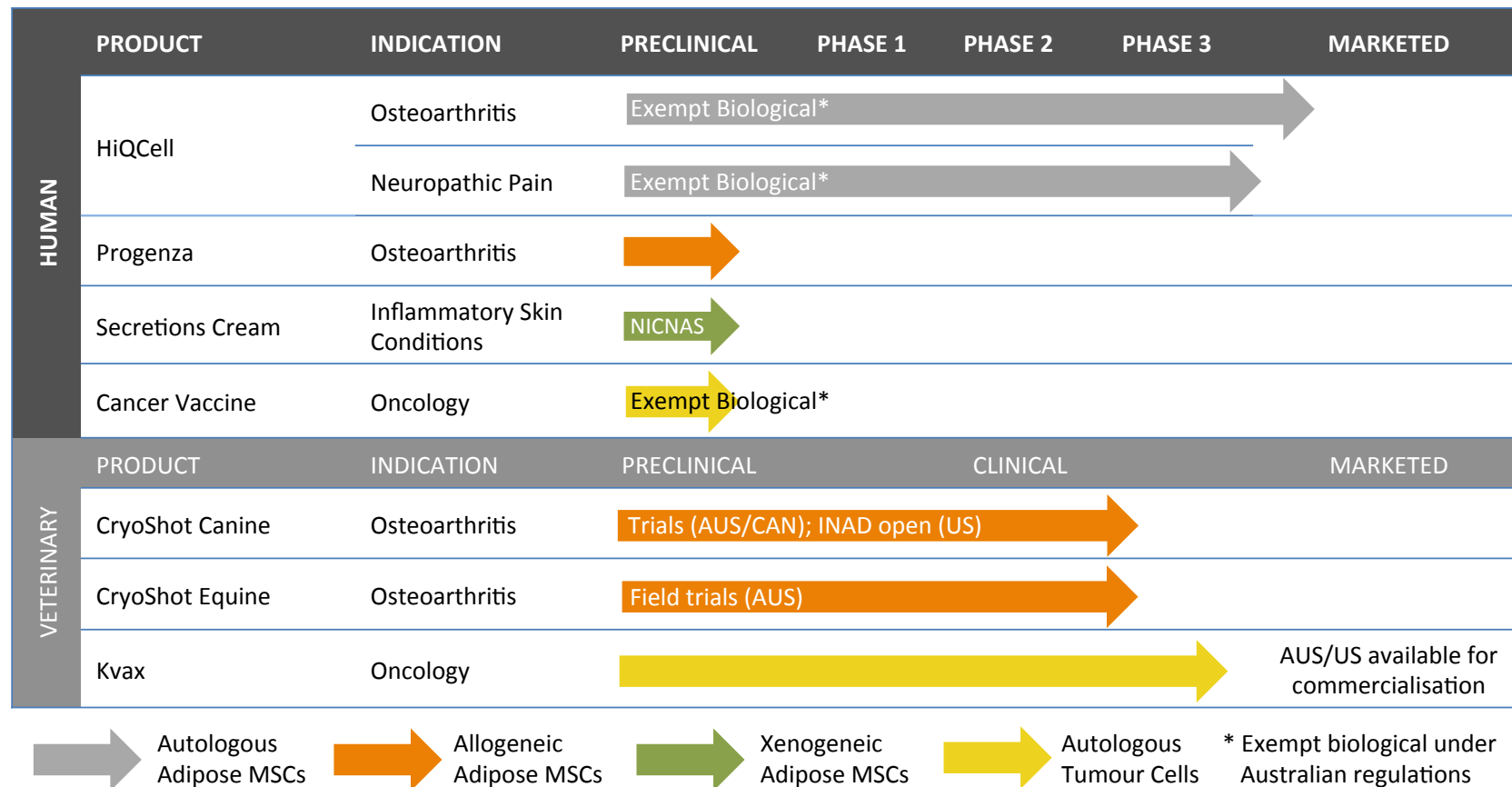
Operating Cash Burn



	S'000's	Q4 FY 15 Target	Q1 FY 15	June 2014	June 2013
Cash on Hand (period end)		3,500+	9,601	2,508	411
R&D Tax Incentive			3,731	2,327	1,679
Normalised Quarterly Operating Cash Burn		1,700	2,558	8,566	6,297

- Accelerated R&D expenditure normalised Q2/Q3 FY 15
- R&D tax incentive of \$2.6+ million received Q1 FY 16 (not included in above)
- Singapore profitable Q4 FY 15
- End FY 2015 'Cash Burn' Quarterly target \$1.7 million (Qtr 1 FY 15 \$2.6 million)

Product Pipeline Update

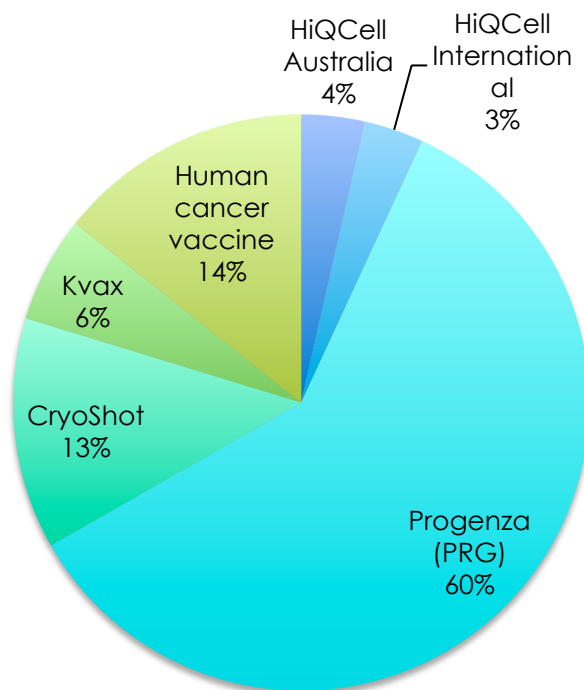


Autologous cells – means a patient's own cells

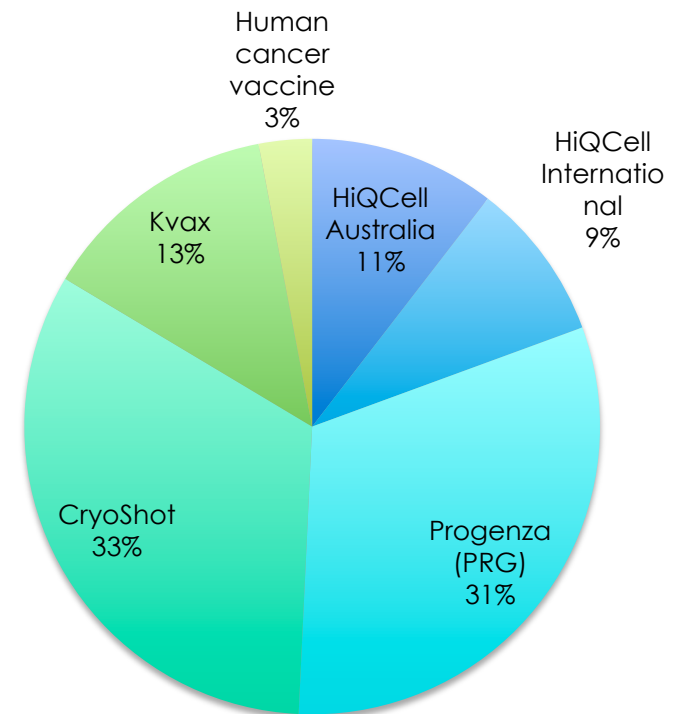
Allogeneic cells – means cells from a donor of the same species

Xenogeneic cells – means cells from a donor of a different species

Relative Value of Products



Net Present Value



rNPV per share

- Analysis based on Edison Investment Research Report 1 October 2014
- Valuation \$0.71c per share or \$148m
- RGS is a research client of Edison

FY15 Strategic Imperatives



HiQCell – cell therapy for OA

FY14 Achievements

- 197 procedures – introduced cryostorage option
- Over 1200 joints and 500 patients now treated
- Launched HiQCell in Melbourne with Sports Med Biologic
- Established processing facility at new East Sydney Day Hospital
- Introduced 4 new treating specialists
- Development and implementation of outbound direct patient marketing and follow-on enquiry handling / recruitment
- Preparation for launch in Singapore in November '14
- Release of latest Joint Registry data
- Publication of HiQCell case study for neuropathic pain patients

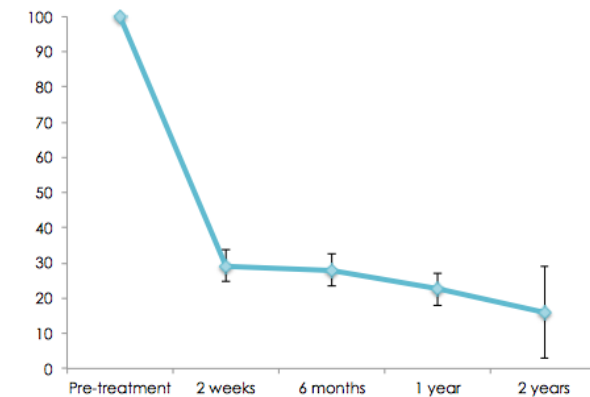


Figure 1b. Pain reduction for responders (95% CI)
Responder: $\geq 30\%$ pain reduction from pre-treatment

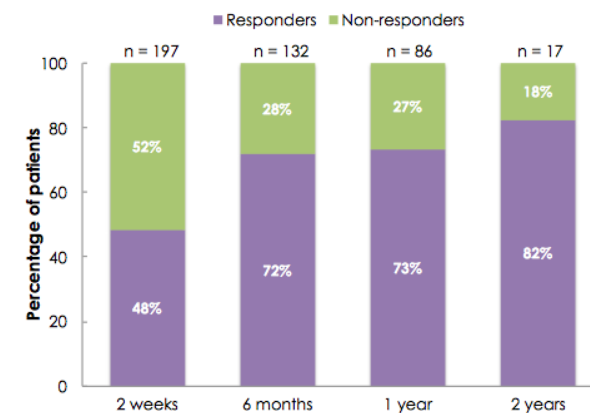


Figure 1a. Responders to treatment
Responder: $\geq 30\%$ pain reduction from pre-treatment

HiQCell – cell therapy for OA



FY15 Milestones

- Further marketing initiatives to referrers, patients and other stakeholders
- Publication of safety and efficacy evidence – OSCARS, Registry, case studies
- Commitment to further clinical studies – important for TMP engagement and further efficacy evidence
- Leverage clinical data and case studies to enhance media understanding
- 3rd party payer / reimbursement exploration – evidence data and pathway forward
- Commence procedures in Singapore
- Explore partnering/licensing options



Kvax – canine cancer vaccine



FY14 Achievements

- Commercially available in Australia September 2014
- USDA sign off for commercialisation in US
- Establish US manufacturing capability with Hennessey Research
- Publication of paper in Cancer Immunology
- Commenced marketing trial with Dr Phil Bergman of VCA, largest US vet services group
- Tech transfer from Kolling to RGS and RGS to Hennessey Research

Cancer Immunology Research

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Streptavidin: A Novel Immunostimulant for the Selection and Delivery of Autologous and Syngeneic Tumor Vaccines

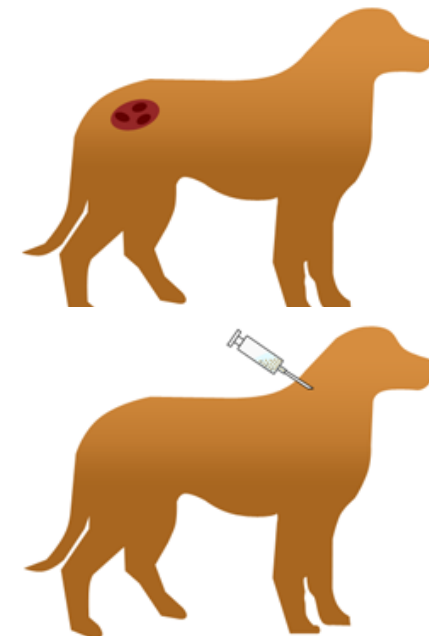
Chris Weir¹, Amanda L. Hudson¹, Elizabeth Moon¹, Angus Ross³, Miles Alexander³, Lyndsay Peters², Veronika Langova⁴, Stephen J. Clarke¹, Nick Pavlaklis¹, Ross Davey¹, and Vilve M. Howell¹

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Published OnlineFirst February 21, 2014; doi: 10.1158/2325-6866.CCR-13-0157
Cancer Immunol Res May 2014 2; 469

» Abstract
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Kvax – canine cancer vaccine



FY15 Milestones

- Increase marketing activities for Kvax in Australia
- Seek global sales and marketing partner
- Confirm market access to UK/EU and Japanese markets
- Commence further marketing trials

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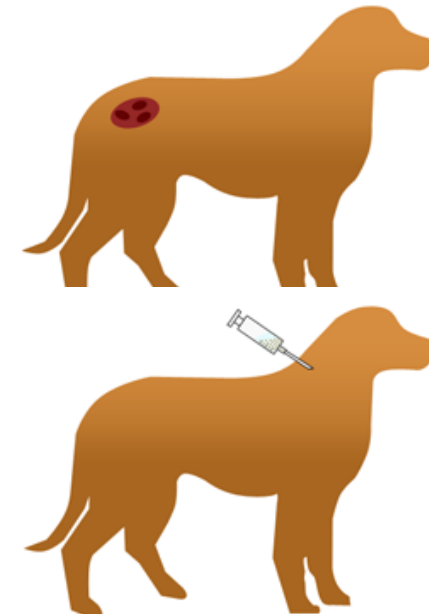
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» Abstract
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Human Cancer Vaccine



FY14 Achievements

- Secured exclusive rights to human applications

FY15 Milestones

- First-in-man trial expected to commence in first half 2015 with lead investigators from RNSH
- Confirm accelerated regulatory pathways as autologous therapy



FY14 Achievements

- INAD opened with FDA for CryoShot Canine FDA registration trial
- Manufacturing agreement with Lonza for GMP product development and trial product
- Further data collected from field trials in Australia
- Commenced RCT in Australia to de-risk FDA trial

FY15 Milestones

- Readout from local RCT
- Sign off on trial design, product characterisation and manufacture for FDA trial scheduled for Q4 2015
- Seek partner for sales and marketing

Progenza (PRG) – targeting Japan



FY14 Achievements

- Development of manufacturing methods for allogeneic adipose derived stem cell product for human OA – using CryoShot platform
- Established production capability at Cryosite for first-in-man trial
- Ethics approved procurement of donor adipose tissue
- Manufacture of seed bank
- Confirmation that PRG would be eligible for conditional approval product approval under new Japanese regulations
- Detailed analysis of Japanese market opportunity

Progenza (PRG) – targeting Japan



FY15 Milestones

- Completion of pre-clinical study
- Ethics approval for first-in man trial
- Commencement of first-in-man trial
- Seek Japanese partner for development and commercialisation in Japan



Patent Portfolio Update



- 11 patent families
- 2 new families since IPO
 - Cancer vaccine licensed from Kolling Institute
 - Biomarkers for monitoring efficacy of cell therapies
- 7 applications have reached Accepted status in Australia
 - Expect these to be granted before July 2015

Patent Portfolio

Patent Family, Title and date of filing of the first application	Subject matter	Related products
1. Therapeutic methods using adipose tissue-derived cell suspensions comprising adipocytes. 22/08/2008	Adipose tissue-derived cell suspensions that comprises adipocytes for use in the treatment of inflammatory disorders and cartilage or bone disorders.	HiQCell™, Secretions
1A. Therapeutic methods. 22/08/2008	Similar to Family 1	HiQCell™, Secretions
2. Therapeutic methods. 17/12/2009	Similar to Family 1 but with the inclusion of additional treatment indications.	HiQCell™, Secretions
3. Cell processing method and device. 15/03/2011	A method of generating a cell suspension from adipose tissue and a tissue processing device for the performance of the method.	HiQCell™
4. Cell free preparation and uses thereof. 14/09/2010	Intra-articular use of a cell-free preparation	Secretions
5. Arthroscopy method. 17/12/2010	The delivery of autologous cells into a joint during an arthroscopy procedure	HiQCell™
6. Pharmaceutical compositions and topical use thereof. 15/03/2011	Topical application of adipose tissue derived cell secretions	Secretions

Patent Portfolio

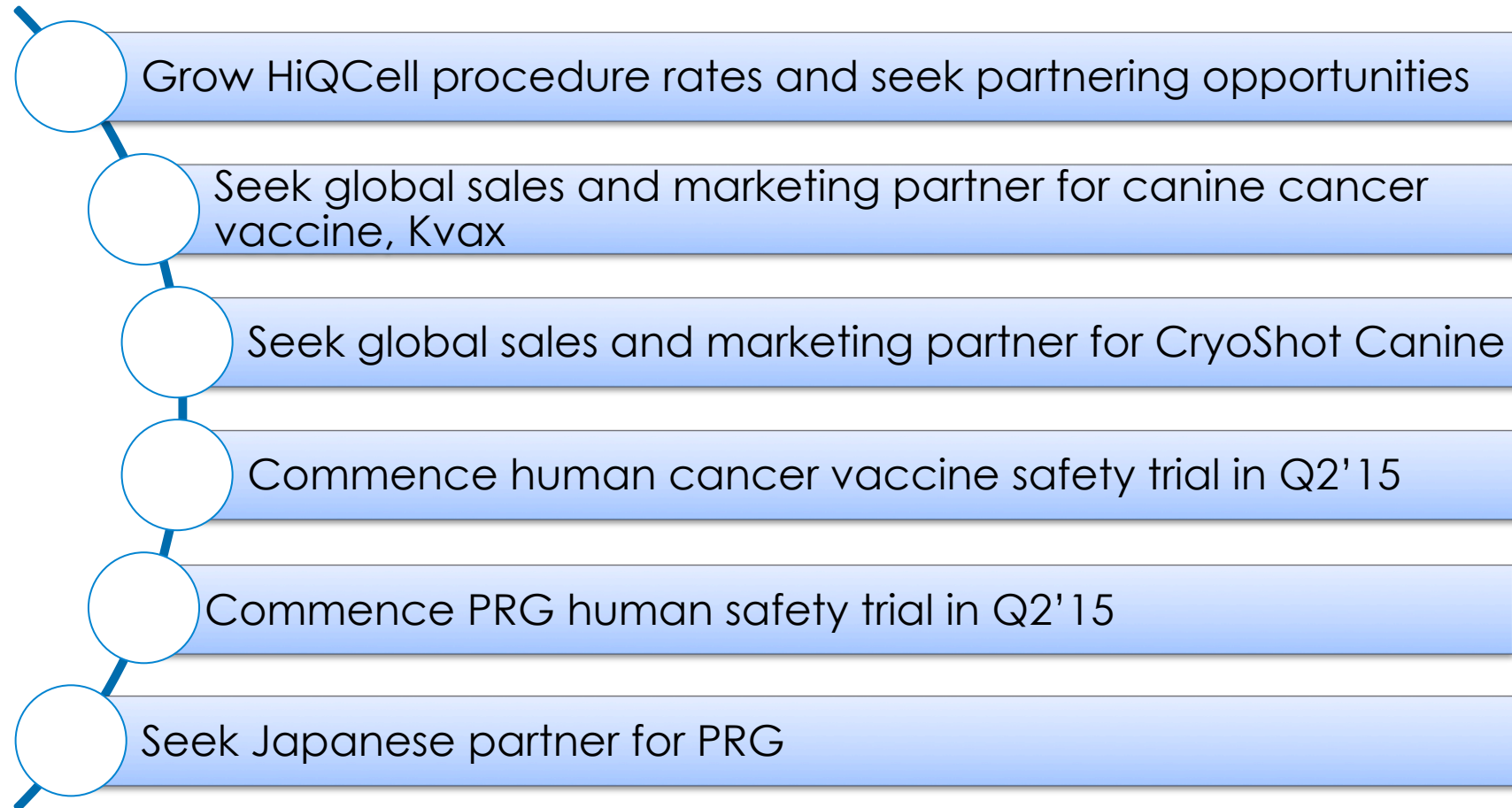
Patent Family, Title and date of filing of the first application	Subject matter	Related products
7. Therapeutic methods and compositions. 23/9/2011	Treatment of various conditions by remote delivery of adipose tissue derived cell secretions or cell suspensions, including treatment of various forms of pain. Also products that comprise a combination of cells and cell secretions.	HiQCell™, CryoShot™, Secretions
8. Therapeutics using multiple injections of cells. 26/9/2012	The patent application has not yet been published and is currently confidential.	HiQCell™
9. Vaccine booster. 24/12/2012	The patent application has not yet been published and is currently confidential.	CryoShot™, HiQCell™
10. Vaccines for the treatment or prevention cancer. 24/12/2012	The patent application has not yet been published and is currently confidential.	Cancer vaccine
11. Biomarkers for cell therapy. 4/10/2013	The patent application has not yet been published and is currently confidential	HiQCell™, Progenza (PRG), CryoShot™

Resolution of Patent Oppositions



- Opposition to an application (AU2009201915) from Family 1 was lodged by Norwood Immunology Ltd
 - Norwood and its sister company Magellan Stem Cells opposed two related applications from Family 1A and three other Regeneus applications
- Reached an agreement with Norwood/Magellan Stem Cells
 - All oppositions are in the process of being withdrawn

FY15 Strategic Imperatives





**Thank you and
questions**

