

Full-Year Results for FY16

Sydney
24 August 2016

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Emerging Leader in Cell Based Medicines



Developing a portfolio of clinical-stage products for human and animal health markets – focus on musculoskeletal, oncology and dermatology

Disruptive technology platforms - allogeneic “off-the-shelf” stem cells, stem cell secretions and immuno-oncology

Scalable technology and cost-efficient manufacturing

Strategic and growing IP portfolio covering methods of manufacture, composition and broad range of uses

Innovation and strategic collaboration across technology R&D, product and clinical development and commercialisation

FY16 Financial Results Overview



FY16 Financial Results Overview

\$'000's	2016	2015	Change
Revenue	1,878	2,061	↓ (183)
Cost of Sales	(292)	(915)	↓ 623
Gross Profit	1,586	1,146	↑ 440
Other Income (inc R&D incentive)	2,747	3,498	↓ (751)
R & D expenses	(4,309)	(4,945)	↓ 636
Selling expenses	(375)	(1,678)	↓ 1,303
Occupancy expenses	(473)	(757)	↓ 284
Corporate expenses	(2,730)	(3,815)	↓ 1,085
Finance Costs	(20)	(56)	↓ 36
Net Expenses	(5,160)	(7,753)	↓ 2,593
Loss for the year	(3,574)	(6,607)	↓ 3,033

- Licence fee revenues up 35% to \$1.2m (FY15: \$0.9m)
- R&D tax incentive of \$2.7m claimed (FY15: \$3.4m)
- Expenditure levels reduced in all categories a key benefit of the strategic changes taken throughout FY15
- Loss from ordinary activities reduced by 45% to \$3.6 m (FY15: \$6.6m)

Operating Cash Burn

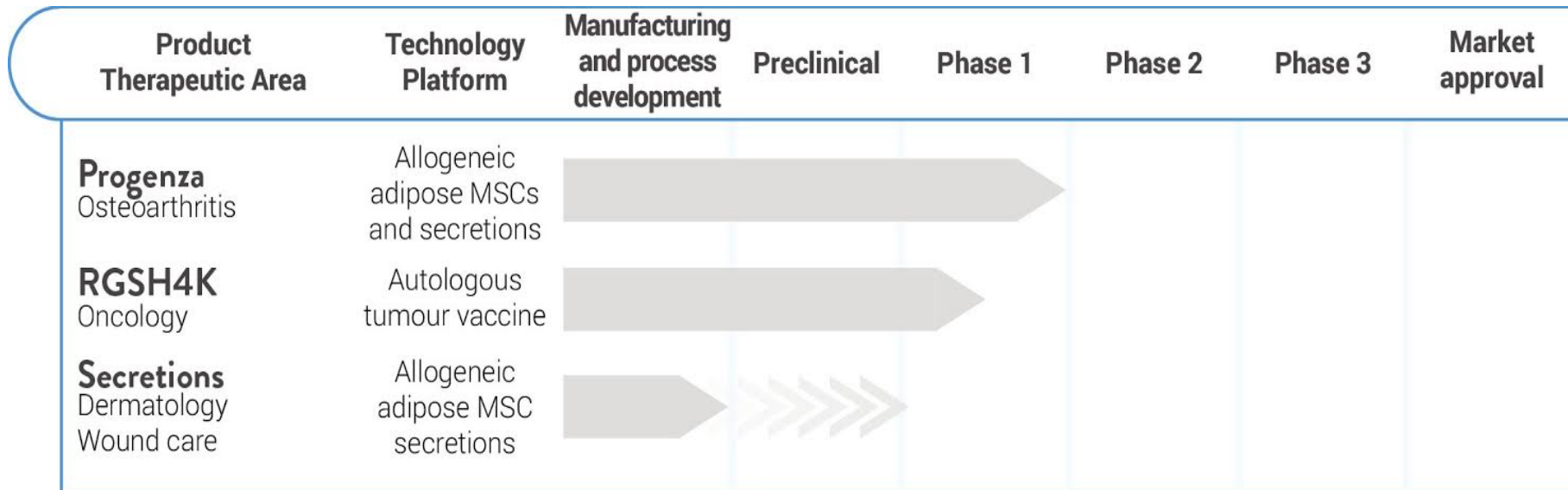
	\$'000's
Cash at 30 June	529
R&D Tax Incentive	2,732
Cash available	3,261
Quarterly cash burn	1,500+
Cash available	2+ quarters

- Quarterly cash burn down 37% to \$1.48m per quarter (FY15: \$2.35m per quarter) – better than stated target of \$1.7m
- Net cash used in operating activities of \$2.25m (including R&D tax incentive) (FY15: \$5.92m)
- \$2m R&D tax funding facility in place
- R&D tax incentive of \$2.7m expected to be received mid September '16

FY16 Achievements, Pipeline and Technology Overview



Human Health Pipeline

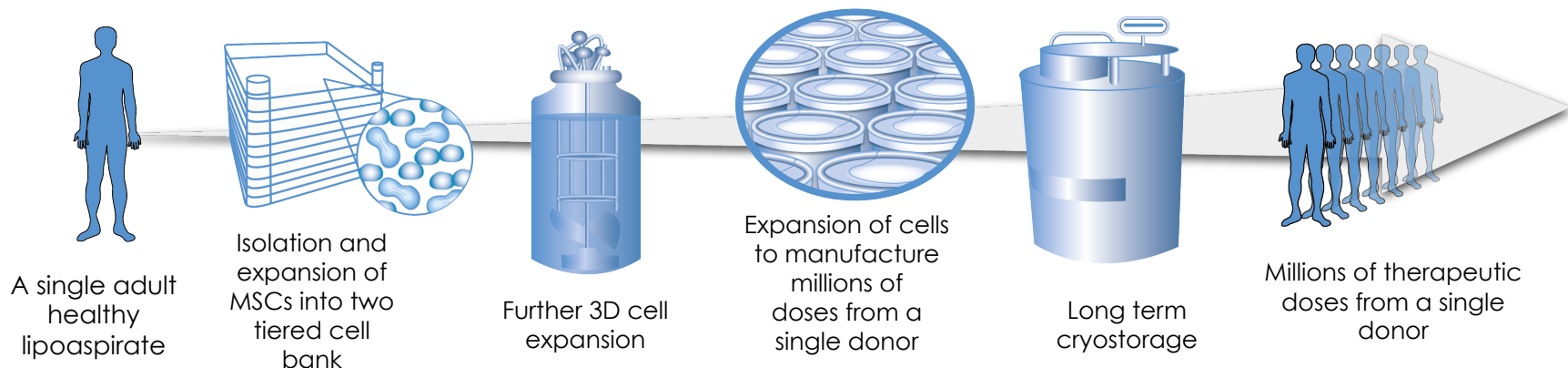


Allogeneic cells - cells from a donor Autologous cells - patient's own cells

Stem Cell Technology Platform

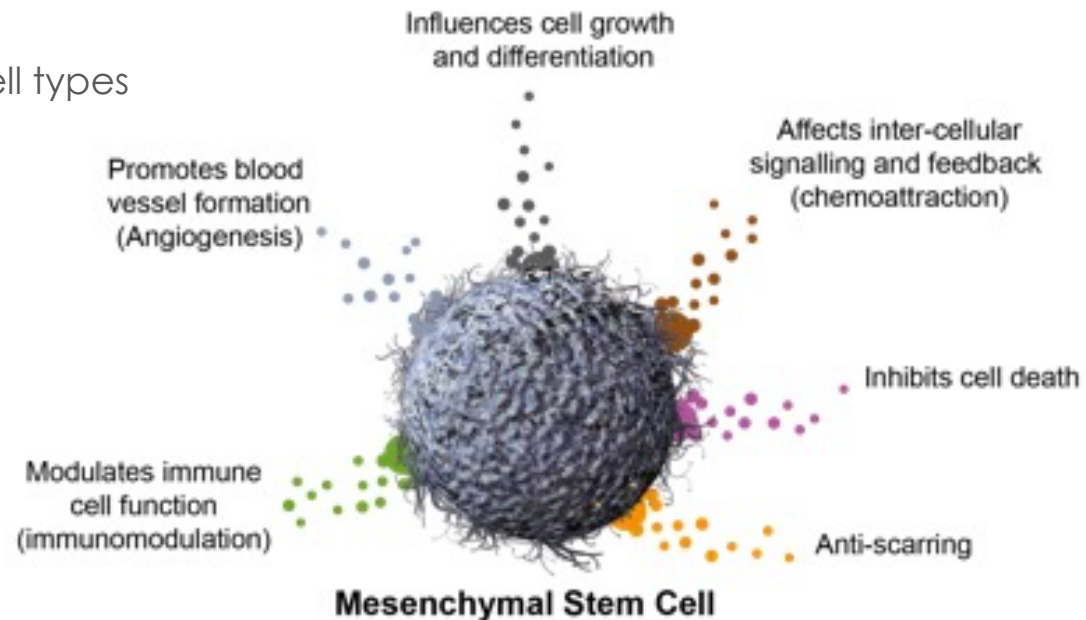


- Our allogeneic stem cell technology platform allows for the scalable production of off-the-shelf cell products with a focus on osteoarthritis and other musculoskeletal disorders – can also be applied to a range of other inflammatory conditions
- Technology underpins both the Progenza and CryoShot product platforms
- Mesenchymal stem cells (MSCs) are sourced from the adipose (fat) tissue of a healthy donor
- Progenza MSCs are expanded using proprietary technology to optimise cell yield – demonstrated capacity to produce millions of doses from 1 donor
- Progenza MSCs are cryopreserved in cell secretions to optimise viability and functionality
- Predictable cell numbers in each dose



Secretions - drivers of therapeutic effect

- MSCs are found in adipose tissue in much greater numbers than other tissue types e.g. bone marrow, blood
- MSCs can differentiate into other cell types
- MSCs respond to signals associated with tissue damage
- MSCs have immune privileges
- MSCs secrete a diverse variety of bioactive factors including cytokines, and growth factors that respond to the local environment and are responsible for reducing inflammation, promoting tissue repair and reducing scarring
- Secretions are the drivers of MSCs therapeutic effect



Progenza FY16 Achievements



STEP Trial Update

- ✓ Commenced and completed recruitment for Progenza Phase 1 Study for osteoarthritis (STEP Trial)
- ✓ Positive safety review for both cohorts
- ✓ 12 month follow up on participants

Collaboration and licensing

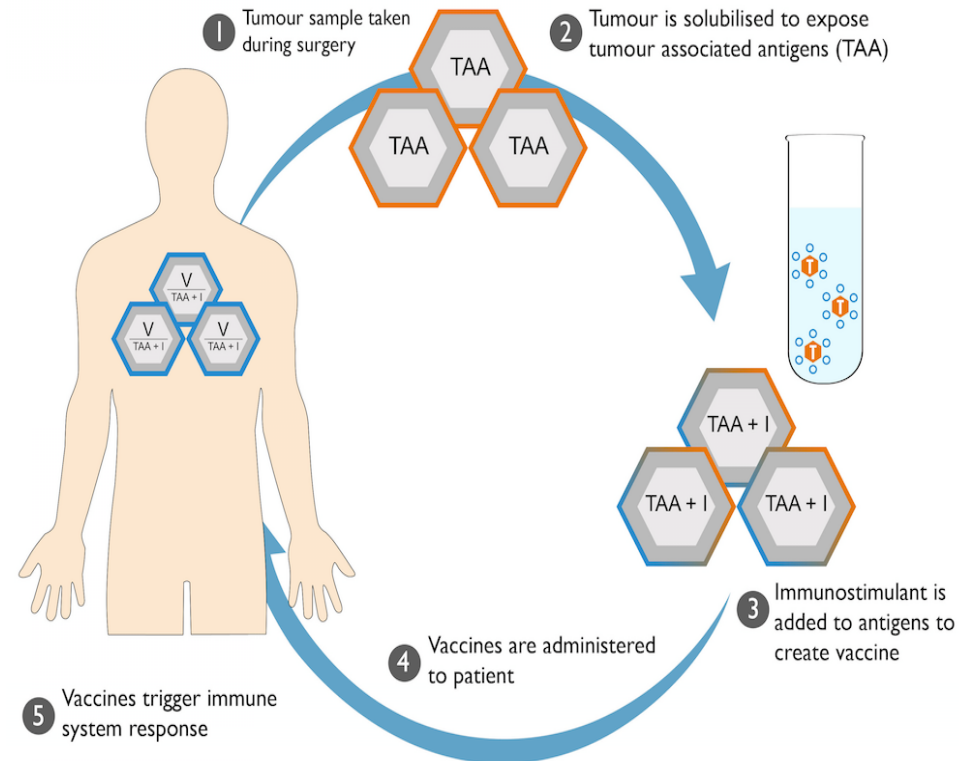
- ✓ Progressed licensing discussions for manufacturing, clinical development and commercialisation in Japan

Product development and scale-up

- ✓ Collaboration with CSIRO on manufacture scale up-technologies
- ✓ Improvements to cell growth media to enhance yield
- ✓ Developed potency and identity assays

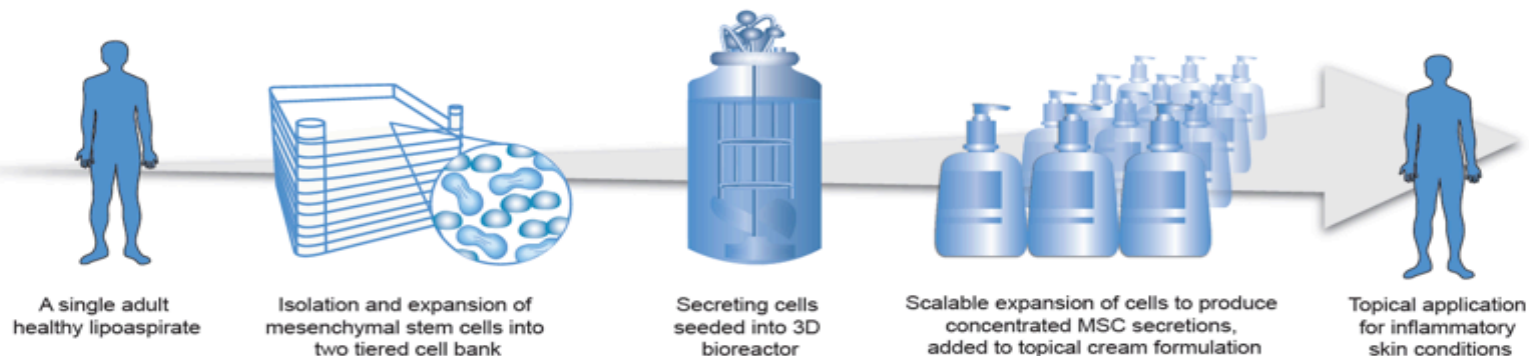
RGSH4K - Human Cancer Vaccine FY16 Achievements

- ✓ Established tumour bank - receiving patient samples to support vaccine manufacture
- ✓ First patient dosed safely Nov '15 – ACTIVATE trial open for enrollment
- ✓ Patients dosed safely in all 3 cohorts
- ✓ Assess emerging study data to:
 - investigate vaccine safety, and
 - identify a biologically active dose for further studies
- ✓ Exploring partnering for combination with check point inhibitors



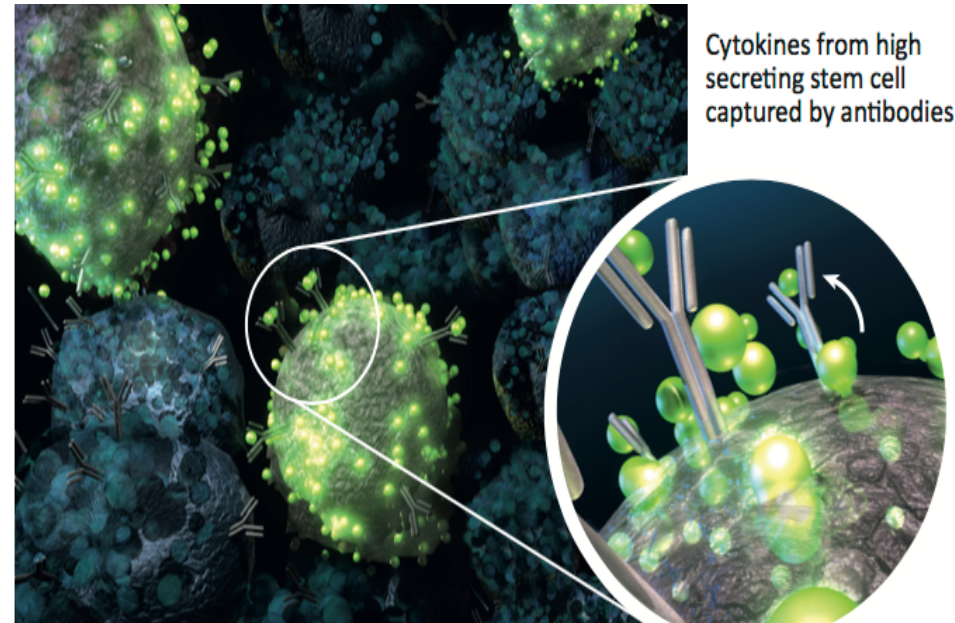
Secretions Technology – emerging platform

- Developed IP for the manufacture and use of bioactive secretions from MSCs for therapeutic purposes
- Secretions used in Progenza to optimise viability and functionality
- Demonstrated safety and efficacy in preclinical inflammatory disease model
- Secretions can be used as a standalone application
- Secretions have shown promise in topical application for the management of acne, wound care and other inflammatory skin conditions
- Optimised formulation
- Collaborating with CSIRO on manufacturing scale-up



High Secreting Cells – next generation cell therapies

- Exclusive licence to develop and commercialise high secreting cells technology for R&D and next generation cell therapeutics
- Developed at Australian Research Council's Centre of Excellence for Nanoscale BioPhotonics – Macquarie Uni node
- Potential for cell therapies to be designed to match secretion profile with target disease
- Collaboration led to successful linkage grant to explore the use of stem cells in treating chronic pain



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Australian Government
Australian Research Council

Animal Health Pipeline



* Autologous animal cancer vaccines are subject to less regulatory requirements in Australia and the USA

CryoShot FY16 Achievements

- ✓ Commenced recruitment for 80 dog pre-pivotal trial at U.Penn to assess CryoShot for canine osteoarthritis more than 30% recruited
- ✓ Entered into agreement with top animal health pharma to partner development and commercialisation of CryoShot
- ✓ Positive clinical results for using CryoShot on early orthopaedic development disease in yearling thoroughbreds
- ✓ Commenced study in assessing CryoShot for strengthening equine tendons



Kvax - Canine Cancer Vaccine FY16 Achievements

- ✓ Completed clinical trial assessing Kvax for canine osteosarcoma as standalone treatment with Dr Bergman of VCA Hospital Inc., largest US vet services group
 - data readout from osteosarcoma trial in Oct '16
- ✓ Commenced clinical trial for Kvax in combination with chemotherapy for canine lymphoma with SASH



Patent Portfolio Update



Patent Portfolio Update

Key patents granted in FY16

- Patent granted in Australia covering Progenza technology – allogeneic stem cells and secretions for the treatment of osteoarthritis and other inflammatory conditions in humans and animals
- Patent granted in Australia covering cancer vaccine technology for the treatment of cancers in humans (RGSH4K) and animals (Kvax)

Overview

- 14 patent families covering products and processes: 11 patents granted in Australia; 2 in NZ; 1 in US and EU
- Pursuing all key territories
- Patents cover:
 - Methods of manufacture
 - Compositions and delivery
 - Use of products for treatment of a broad range of indications

FY17 Milestones

Product or Program	Anticipated Milestone	Timing by Financial Year
Progenza	Secure manufacturing and commercial partner for Progenza technology in Japan	Q1 FY17
Progenza	Advance clinical partnering discussions for Progenza in Japan and other territories	
Progenza	Commence donor procurement in preparation for manufacturing Progenza for Phase 2 trial in Japan	Q1 FY17
Progenza	Commence ARC linkage project on stem cells for chronic pain	Q2 FY17
Secretions	Initiate preclinical and clinical trials for secretions technology	H1 FY17
RGSH4K	Complete recruitment and report on ACTIVATE cancer vaccine trial	H2 FY17
Progenza	Report on Progenza osteoarthritis STEP trial	H2 FY17
CryoShot	Report on CryoShot Canine pre-pivotal trial	H2 FY17

Further Information

ASX: RGS

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