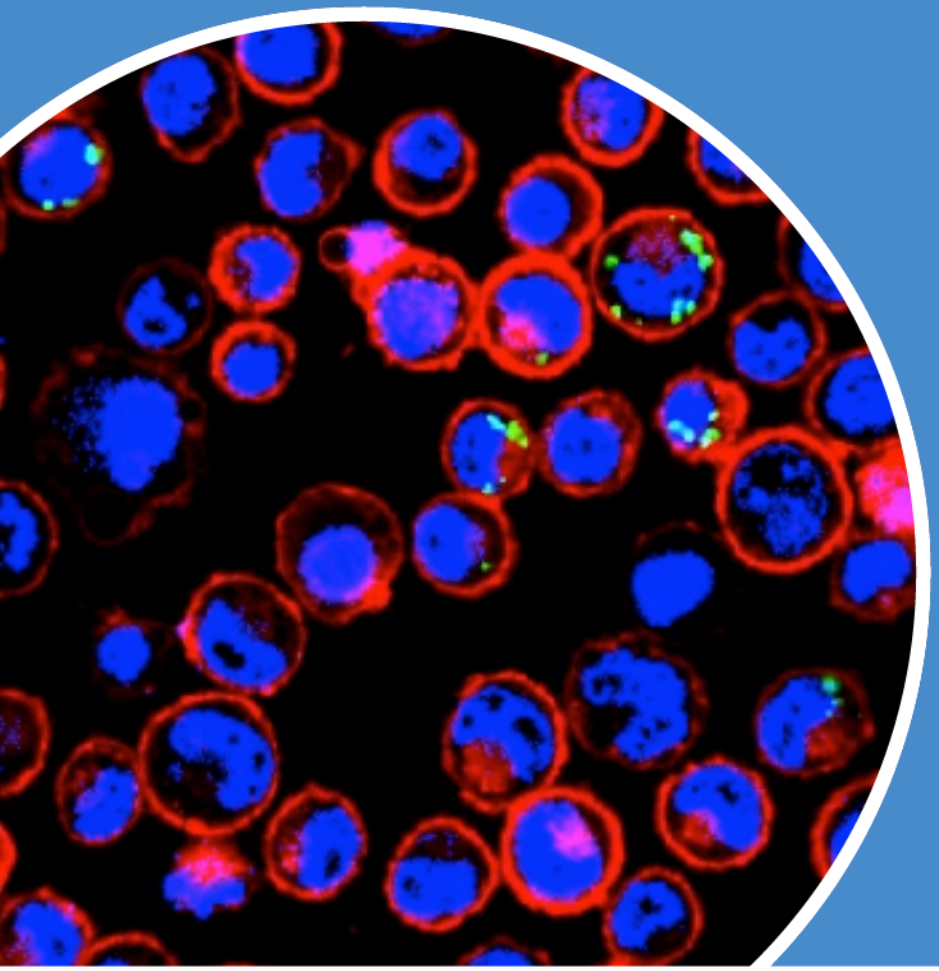
regeneus

living regenerative medicine



Annual General Meeting 2016

Sydney
19 October 2016

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This presentation contains certain statements which constitute forward-looking statements or information ("forward-looking statements"). These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding the general economic and industry conditions in Australia and globally and the operations of the company. These factors and assumptions are based upon currently available information and these forward-looking statements speak only as of the date of the presentation. Although the company believes the expectations and assumptions are reasonable, undue reliance should not be placed on the forward-looking statements as the company can give no assurances that they will prove correct and because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include, but are not limited to: uncertainties and other factors that are beyond the control of the company; global economic conditions; risks associated with biotechnology and regenerative medicine companies; specific risks associated with research and development of the company's products including product development and manufacturing and the funding, conduct and results of clinical trials; regulatory approvals for or applying to the company's products; licensing and commercialisation of the company's products and; risks associated with stock market volatility and the ability of the company to continue as a going concern. The company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by securities laws.

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Agenda

- Vision and Strategy
- Key Achievements for FY16
- Development Pipeline and Technology Overview
- IP Update
- FY17 Milestones
- Summary

Vision and Strategy

Our goal is to build a valuable biotechnology company through the successful development of innovative cell-based regenerative medicines that improve the lives of humans and animals

Our strategies to achieve our goal include:

- Use our proprietary stem cell and immunotherapy technologies to develop innovative cell-based regenerative medicines targeting unmet medical needs in humans and animals
- Focus on clinical development of Progenza - allogeneic MSC based products to optimise licensing prospects particularly in Japan with leading regen med market conditions
- Build on our clinical focus in osteoarthritis, oncology and inflammatory skin conditions
- Optimise scalable and cost-efficient manufacturing
- Develop our products to their next value inflexion point and seek clinical development and commercialisation partners to de-risk products and access non-dilutive funding sources
- Develop new high value clinical applications for our technologies
- Continue to grow our IP portfolio to support product platforms and improve licensing prospects
- Continue to improve technology platforms through innovation and R&D collaborations and licensing

Key Achievements for FY16

Progress on first-in-human clinical trials

- ✓ Progenza STEP trial - allogeneic off-the-shelf stem cell therapy for human osteoarthritis
  - commenced and completed enrollment for trial
  - positive safety review for both dose cohorts
- ✓ RGSH4K ACTIVATE trial – autologous cancer vaccine
  - established tumour bank
  - patients safely dosed in all 3 cohorts

Commencement of clinical trials for animal health

- ✓ CryoShot pre-pivotal trial – allogeneic stem cells for canine osteoarthritis
  - commenced enrollment for trial at PennVet - >40% recruited
- ✓ Kvax trials – autologous canine cancer vaccine
  - completed recruitment of osteosarcoma trial at VCA Hospitals in US
  - commenced enrollment of lymphoma trial at SASH in Sydney

Key Achievements for FY16

Partnering developments

- ✓ entered into agreement with leading animal health pharma for clinical development and commercialisation of CryoShot canine
- ✓ advanced collaboration and licensing discussions for manufacture and commecialisation of Progenza in Japan
- ✓ exclusive in-licence of next generation cell identification and selection technology for high potency cells – Macquarie Uni node of Centre for Nanoscale BioPhotonics

R&D developments

- ✓ secured linkage grant funding for collaborative research into neuropathic pain and stem cells – Macquarie Uni and Uni of Adelaide
- ✓ collaboration with CSIRO on manufacture scale up technologies for Progenza and Secretions
- ✓ improvements in cell growth media to enhance cell yield for Progenza and Secretions

IP developments

- ✓ patents granted in Australia for Progenza and cancer vaccine technologies

RGS: Relative 12 month performance

Regeneus Ltd (ASX:RGS)

Add to portfolio

0.140 0.000 (0.00%)

Oct 18 - Close

ASX data delayed by 20 mins - Disclaimer

Currency in AUD

Range	-	Div/yield	-
52 week	0.07 - 0.19	EPS	-0.02
Open	-	Shares	208.89M
Vol / Avg.	0.00/115,739.00	Beta	-
Mkt cap	29.24M	Inst. own	-
P/E	-		

G+1 0

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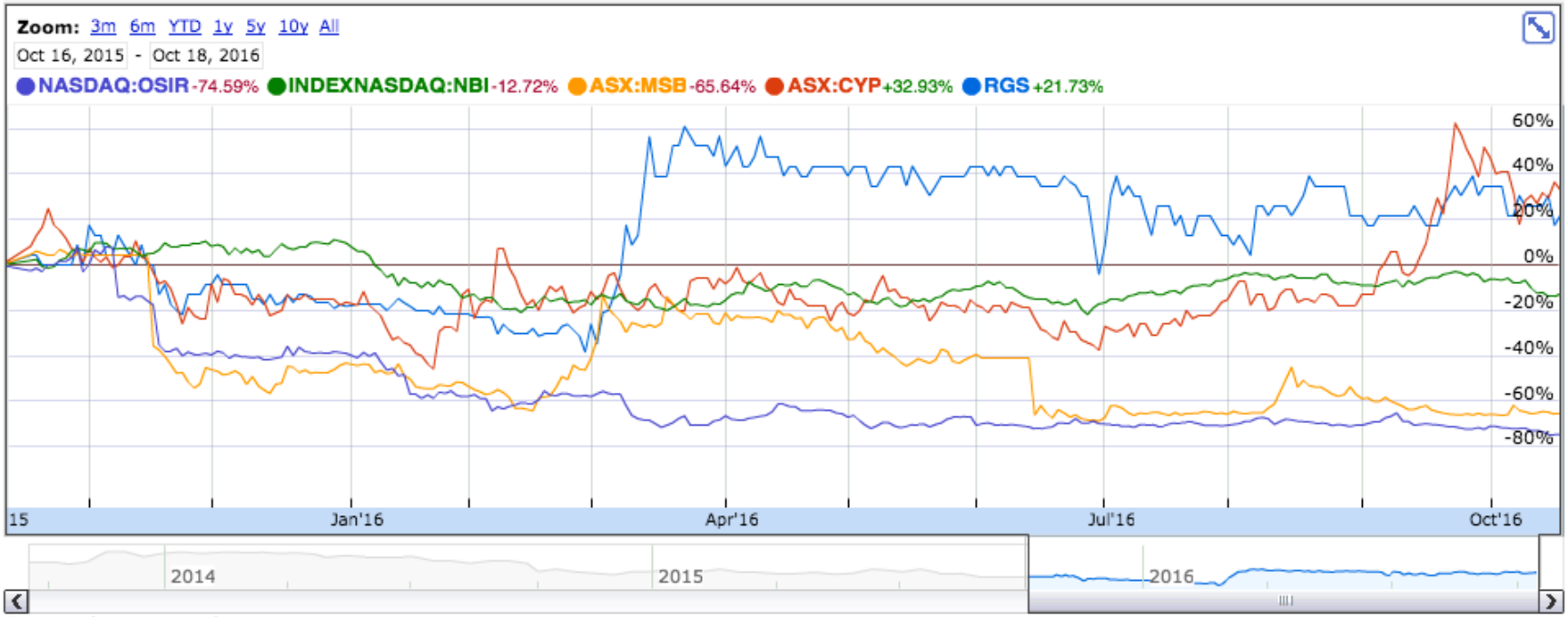
☐ S&P/ASX 200 ☐ PIQ ☐ GBI ☐ SPL ☐ PRM ☐ RAP ☐ SBN ☐ PAA ☐ ACR ☑ ASX:CYP « less

☑ ASX:MSB ☑ INDEXNASDAQ:NBI ☑ NASDAQ:OSIR



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Sources include SIX.

Development Pipeline and Technology Overview

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Human Health Pipeline

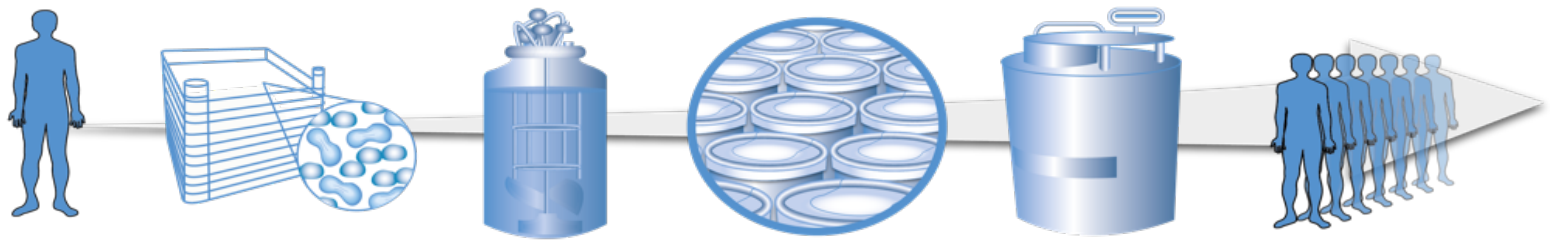
Product Technology Platform	Indication	Manufacturing & Process Development	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Market Size
Progenza	1. Osteoarthritis 2. Other	Allogeneic adipose MSCs						US$12b
RGSH4K	Solid Tumours	Autologous tumour vaccine						US$33b
Secretions	Dermatology Wound Healing	Allogeneic adipose MSC secretions						US$3b (Acne)

Allogeneic cells - cells from a donor

Autologous cells - patient's own cells

Progenza – allogeneic stem cell technology platform

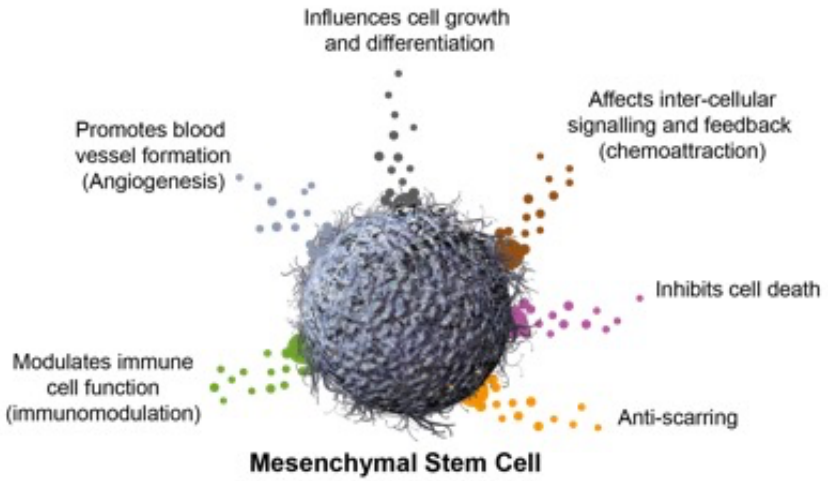
- Allogeneic mesenchymal stem cells (MSCs) are sourced from a healthy adult donor
  - no reprogramming of cells = **safety benefits**
- Adipose (fat) tissue is the source of cells
  - large starting volume, and large number of MSCs in adipose vs. other tissue sources
    - Optimised production using proprietary IP → production of millions of doses from one donor = **scalable technology**
  - immuno-modulatory benefits of adipose derived cells (vs other sources)



Zhu, Y., Liu, T., Song, K., Fan, X., Ma, X., & Cui, Z. (2008). Adipose-derived stem cell: a better stem cell than BMSC. Cell Biochem Funct, 26(6), 664–675.
Melief, S. M., Zwaginga, J. J., Fibbe, W. E., & Roelofs, H. (2013). Adipose tissue-derived multipotent stromal cells have a higher immunomodulatory capacity than their bone marrow-derived counterparts. Stem Cells Translational Medicine, 2(6), 455–463.

Progenza – advantages of secretions

- Secretions are the drivers of therapeutic effect
- MSCs secrete a diverse variety of bioactive factors including cytokines, and growth factors
- Secretions respond to the local environment and responsible for reducing inflammation, promoting tissue repair and reducing scarring
- Addition of secretions with cells (Progenza):
  - **Improve functionality of cells**
    - enhanced ability to secrete and proliferate
  - **Improve therapeutic effect**
    - demonstrated in rheumatoid arthritis model (CAIA) in mice - tested MSC cells alone and MSC cells frozen in cell supernatant
    - average Clinical Arthritis score were significantly lower with cells frozen in cell supernatant compared to cells alone

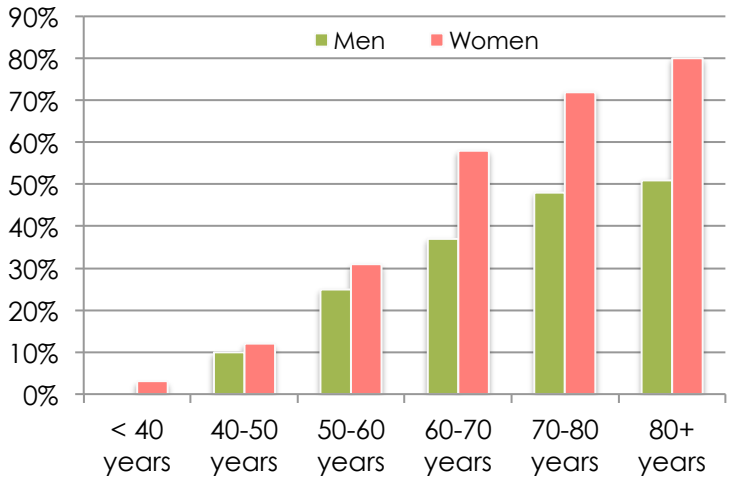


Osteoarthritis – a big issue

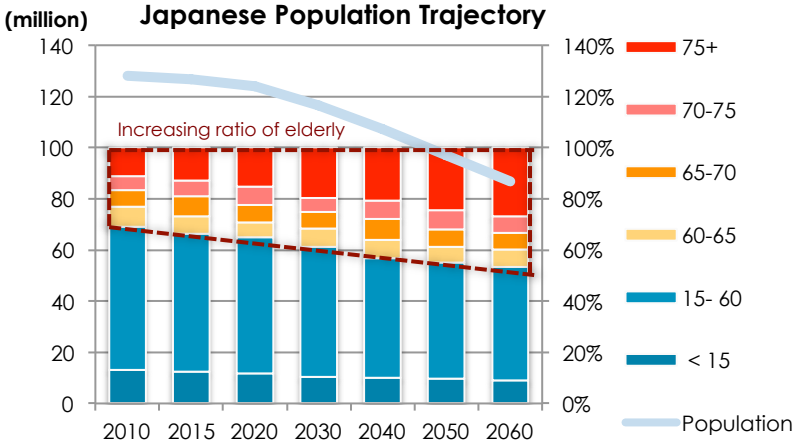
- Single most common cause of disability in older adults
- Fastest increasing major health condition globally
  - driven by ageing population, increased obesity and lack of physical activity[1]
- Japan has a rapidly aging population
- With no cure, and only symptomatic relief, current market in Japan is dominated by pain relief:
  - NSAIDs ~JPY 300,000m (US$3 billion)
  - Hyaluronic Acid ~JPY 80,000m (US$800 million)
  - Total joint Replacement - only used as a last resort ~ 70,000 knee replacements/year

>250m
Older adults affected worldwide

Japanese knee OA prevalence by age group

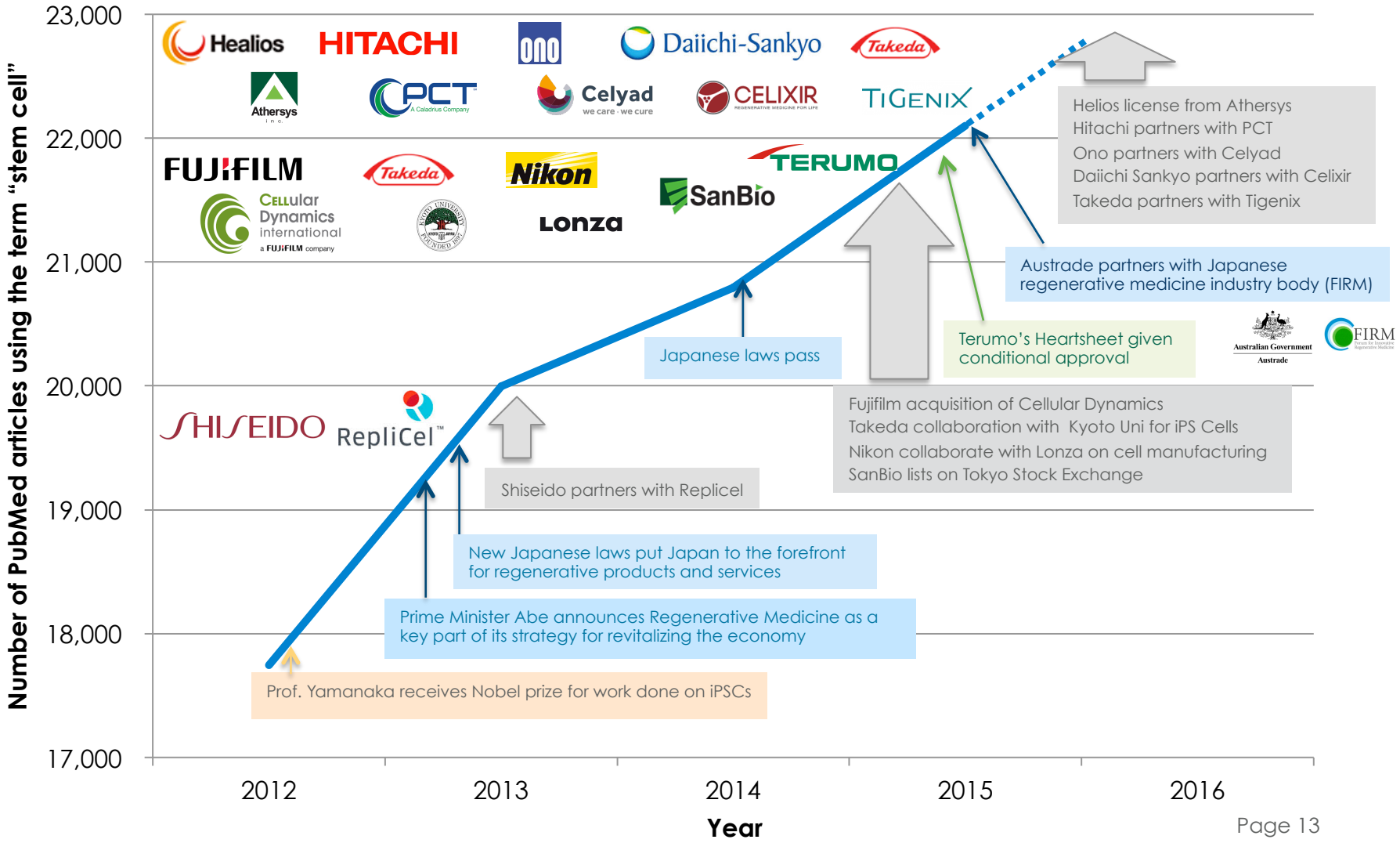


Japanese Population Trajectory



1 The bone and Joint Decade, http://bjdonline.org/key-facts-and-figures/,
Ref: Dr. Noriko Yoshimura "Epidemiology of osteoarthritis in Japan: the ROAD study", the Ministry of Internal Affairs and Communications' "National Census". NIPSSRs "JPN population trajectory", MHLW's "Comprehensive Study of Living Conditions"
Hosaka, K., Saito, S., Ishii, T., Mori, S., Sumino, T., & Tokuhashi, Y. (2011). Asian-Specific total knee system: 5-14 year follow-up study. *BMC Musculoskeletal Disorders*, *12*(1), 251. doi: 10.1186/1471-2474-12-251
http://www.medical-excellence-japan.org/en/hospital/040/index.html (accessed 09/16)

Japan – leading market for Regenerative Medicine



Progenza OA Update

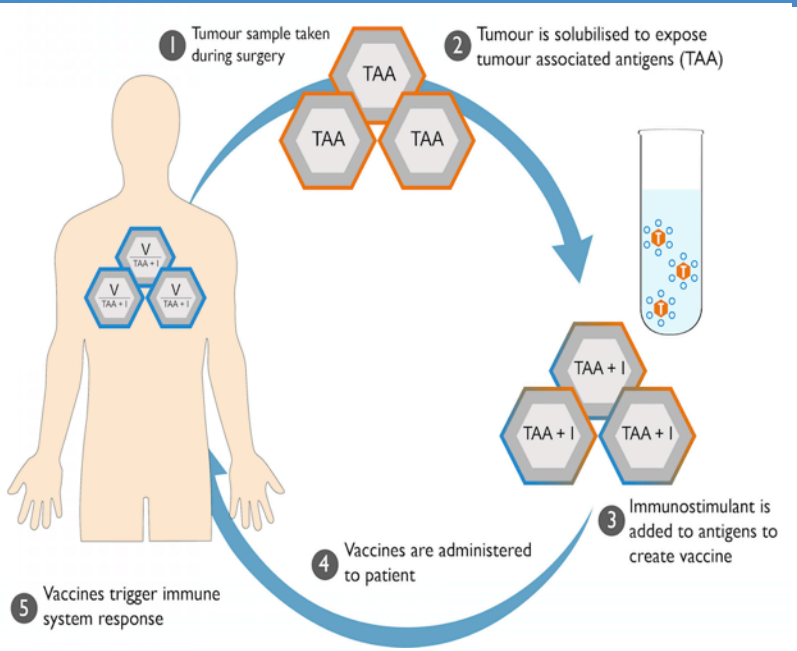
- Progenza Phase 1 Study for OA (STEP Trial) commenced enrolment in Q3 '15
  - Single IA injection with a 12 month follow-up
  - 2 treatment cohorts vs placebo

Activity / Milestone	
STEP trial open for recruitment	☑
Complete enrolment of Cohort 1 & 2	☑
Interim safety results	☑
Last patient last visit	☐
Analysis and final report	☐

- 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
- Progressed licensing discussions for manufacturing, clinical development and commercialisation in Japan (for Phase 2 trial)

Cancer Immunotherapy Platform – RGSH4K

- A clinical-stage, autologous cancer immunotherapy which uses a patient's own tumour as source material for a vaccine, coupled with a bacterial adjuvant for immune recognition
- Addresses tumour heterogeneity as all relevant tumour associated antigens and proteins are included and become potential targets of the immune system
- Immune memory may be effective in reducing risk of tumour recurrence
- Straightforward and rapid manufacturing process
- **Multi-tumour type potential**



	Multiple Relevant Antigens	Potent Immunological Response	Ease of manufacture	Safety Profile	Low COGS
Autologous therapies					
RGSH4K tumour cell vaccine	✓	✓	✓	✓	✓
Dendritic cell vaccine	✗	✓	✗	✓	✗
Peptide vaccine	✗	✗	✓	✓	✗
Allogeneic therapies					
Peptide / HSP vaccine	✗	✗	✗	✓	✗
Gene transfer	✗	✓	✓	✗	✗

Compelling Cancer Market Opportunity

- 8.2 million people die each year from cancer, an estimated 13% of all deaths worldwide.
  - ~ one third of cancer deaths are due to: high body mass index, low fruit and vegetable intake, lack of physical activity, tobacco use, and alcohol use
- Oncology market reached US$100bn in 2014 and set to reach ~US$190bn (2022)
  - Immunotherapy is the most active segment of the market
- RGSH4K is widely applicable to solid tumours with large market size

Colorectal $9.4bn by 2020	Small cell lung $6.9bn by 2019
Ovarian $1.4bn by 2021	Pancreatic $1.5bn currently

- Immunotherapy
  - Several immunotherapies are FDA-approved, e.g. checkpoint inhibitors, and are the new gold standard for certain cancers
  - Checkpoint inhibitors are being used in combination to achieve excellent responses
  - The 2 market-leading products (Yervoy & Keytruda) have estimated sales of $33bn by 2022
  - RGSH4K is appropriate for combination therapy

Forbes May 5, 2015 IMS Institute for Healthcare Information; *Evaluate Pharma - World Preview 2016, Outlook to 2022*. (2016). *Evaluate Pharma - World Preview 2016, Outlook to 2022* (pp. 1–49).
http://www.transparencymarketresearch.com/pancreatic-cancer-market.html
http://canceraustralia.gov.au/affected-cancer/cancer-types/bowel-cancer/bowel-cancer-statistics; Ovarian Cancer Statistics, Cancer Australia,
http://www.prnewswire.com/news-releases/colorectal-cancer-therapeutics-market-worth-94bil-by-2020-in-8-major-countries-289542041.html
http://www.fiercebiotech.com/press-releases/ovarian-cancer-drug-market-will-more-triple-over-next-decade-increasing-460 ;
http://www.transparencymarketresearch.com/non-small-cell-lung-cancer-market.html
http://www.fiercepharmamarketing.com/story/pd-1-wave-report-says-its-33b-tsunami-bms-surfing-first-place/2015-03-04

RGSH4K Update

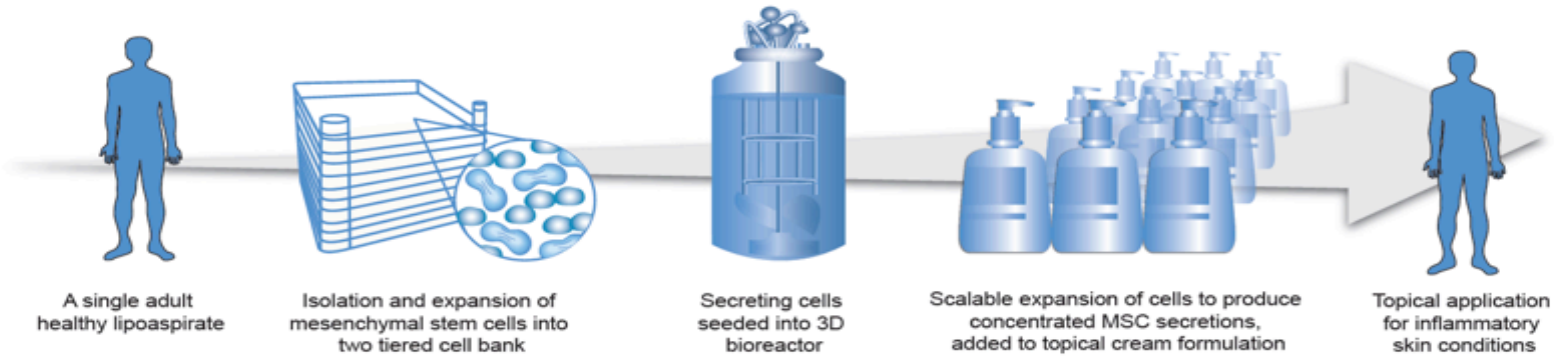
- Phase 1 Study for solid cancers (ACTIVATE Trial) commenced enrolment in Q3 '15
  - Multiple solid tumour types accepted
  - Open to patients with terminal cancer for which no other therapy exists
  - Varying levels of streptavidin to identify biologically active dose

Activity / Milestone	
STEP trial open for recruitment	☑
HREC approved tumour bank	☑
Patients in all cohorts safely treated	☑
Patent granted	☑
Last patient last visit	☐
Analysis and final report	☐

- Exploring partnering for combination with check-point inhibitors
- Assess emerging data to:
  - investigate vaccine safety, and
  - identify a biologically active dose for further studies

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



Animal Health Pipeline

Product	Indication	Discovery	Manufacturing and Process Development	Safety and Efficacy Studies	Pivotal Study	Market Approval	Market Size
Cryoshot Canine	Osteoarthritis	Allogeneic adipose MSCs					US$500m
Cryoshot Equine	Osteoarthritis	Allogeneic adipose MSCs					US$500m
Kvax	Solid tumours	Autologous tumour vaccine					US$550m

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

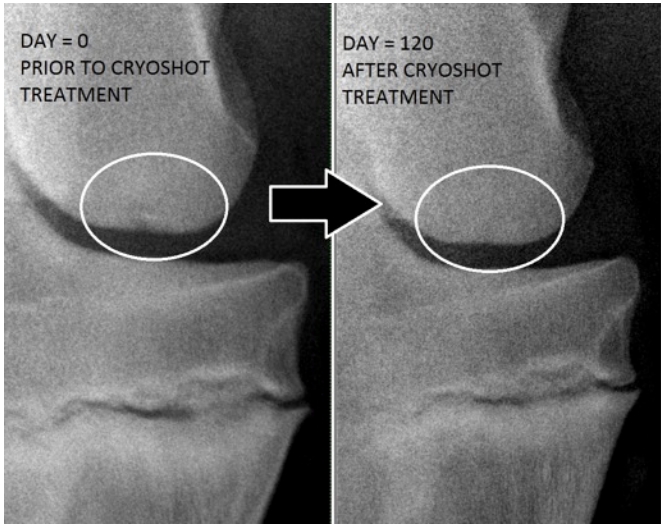
CryoShot – leading allogeneic MSC platform

- Leading in-field, practical experience with allogeneic MSCs in the veterinary field globally with >90 vet practices involved and 3,000+ field trial treatments
- Better pain relief than NSAIDs in uncontrolled studies for osteoarthritis in dogs
- Improved interim clinical results on early orthopaedic developmental disease in yearling thoroughbreds
- Commenced study in assessing CryoShot for strengthening equine tendons

CryoShot

PennVet

Activity / Milestone	
Signed collaboration with top vet Pharma to partner development and commercialisation of CryoShot Canine	☑
Commenced pre pivotal dog trial at U.Penn for osteoarthritis (>40% complete)	☑
Last patient last visit	☐
Analysis and final report	☐



Kvax – Canine Cancer Vaccine

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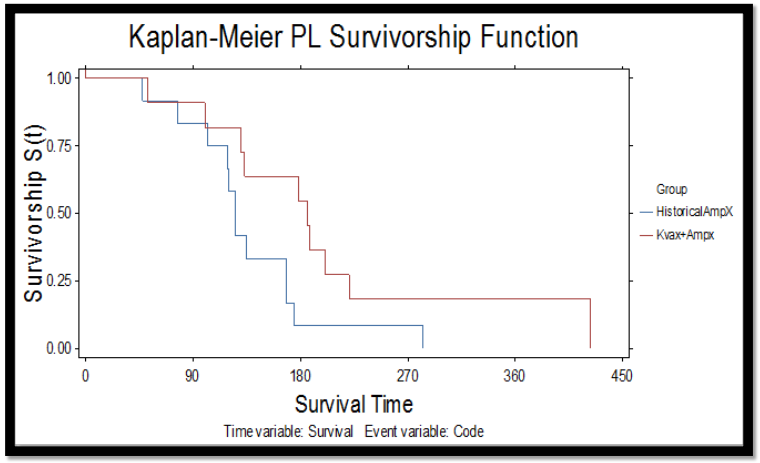
- Clinical trial for osteosarcoma (bone cancer) with Dr Bergman of VCA, largest US vet services group
  - Single arm: post-amputation, Kvax only
  - *"Kvax is well tolerated and appears to confer increased progression free interval and survival compared to historically reported dogs with osteosarcoma treated with limb amputation only."*

VCA



- Initiated canine lymphoma trial in Sydney at the Small Animal Specialist Hospital

sash

  - Lymphoma is most commonly treated cancer in dogs
  - Placebo controlled, conjunction with standard of care chemotherapy
    - hyperlink → Kvax

THE UNIVERSITY OF SYDNEY

BILL WALSH LAB
TRANSLATIONAL CANCER RESEARCH
Working for a cure

KOLLING Institute of Medical Research

Patent Portfolio Update

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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, EU and Singapore

- 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	Q2 FY17
Progenza	Advance clinical partnering discussions for Progenza in Japan and other territories	Ongoing
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

Summary of competitive strengths

☑ **Multiple proprietary technology platforms**
- adult stem cells from adipose tissue for OA and other inflammatory conditions
  - allogeneic and autologous adipose MSCs
- Immunotherapy for oncology
- secretions from adipose MSCs for inflammatory skin conditions and wound healing
- next generation high secreting cells technology

☑ **Diversified portfolio of clinical stage products – human and animal health markets**
- lower technical, clinical and commercial risk
- all product platforms in clinical development
- scalable manufacturing for allogeneic stem cells
- IP has application for OA and a broad range of inflammatory clinical indications

☑ **Catalysts – unlocking near term value**
- near term licensing and partnering in fast growth market of Japan
- clinical trial results readouts in FY17

☑ **Innovation and collaboration – commercially focused and strategic**
- rapid product development and manufacture capability
- successful technology and clinical collaborations
- ability to translate products into the clinic
- strategic and growing IP portfolio to underpin technologies and products

Further Information

ASX: RGS

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