

ASX Announcement

Regeneus reports 2016 full-year results

Sydney, Australia – 24 August 2016

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today reported its 2016 financial results and business update.

During the year, the company made significant progress on the development of its portfolio of cell-based therapies for the treatment of osteoarthritis and other musculoskeletal disorders, oncology and dermatology diseases for the human and animal health markets.

CEO, John Martin said: "last financial year we achieved a number of important R&D, clinical, and commercial milestones that set the platform for unlocking significant shareholder value in the business over the next 12 months".

Key achievements

Progress on first-in-human clinical trials

- ✓ Progenza STEP trial – allogeneic off-the-shelf stem cells for human osteoarthritis
 - commenced and completed enrollment for STEP trial
 - positive safety review for both dose cohorts
- ✓ RGS4K ACTIVATE trial – autologous cancer vaccine
 - established tumour bank
 - patients safely dosed in all 3 dose cohorts

Commencement of clinical trials for animal health

- ✓ CryoShot pre-pivotal trial – allogeneic stem cells for canine osteoarthritis
 - commenced enrollment for trial at University of Pennsylvania – more than 30% recruited
- ✓ Kvax trials – autologous canine cancer vaccine
 - completed osteosarcoma trial with VCA Hospitals Inc. in USA
 - commenced enrollment of lymphoma trial at Small Animal Specialist Hospital in Sydney

Partnering and technology development

- ✓ Entered into agreement with top animal health pharma to partner development and commercialisation of CryoShot for canine osteoarthritis
- ✓ Advanced licensing discussions for manufacturing and clinical development of Progenza in Japan
- ✓ Exclusive licence for next generation cell identification and selection technology for high potency secreting stem cells developed at Macquarie University node of Centre for Nanoscale Biophotonics
- ✓ Secured ARC linkage grant funding for collaborative research with Macquarie University and University of Adelaide into treating chronic pain with stem cells
- ✓ Collaboration with CSIRO on manufacture scale-up technologies for Progenza and Secretions
- ✓ Improvements to cell growth media to enhance cell yield for Progenza and Secretions
- ✓ Optimised Secretions formulation

Key patents granted

- ✓ 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)

Financial Highlights

The financial highlights for FY16 were better than expected and show continuing financial discipline in the management of the company's operations while making substantial progress on our R&D, clinical development and commercial goals including:

- ✓ Licence fee revenues up 35% to \$1.2m (FY15: \$0.9m)
- ✓ Loss from ordinary activities down 45% to \$3.6m (FY15: \$6.6m). These results include R&D tax incentive of \$2.7m (FY15: \$3.4m)
- ✓ 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)

Looking forward

Over the next 12 months, the company expects to achieve key milestones which are important for the development and growth of the business and the creation of shareholder value including:

- ✓ Secure manufacturing and commercial partner for Progenza technology in Japan Q1 FY17
- ✓ Advance clinical partnering discussions for Progenza in Japan and other territories
- ✓ Commence donor procurement in preparation for Progenza manufacture for Phase 2 trial in Japan – Q1 FY17
- ✓ Commence ARC linkage project on stem cells for chronic pain – Q2 FY17
- ✓ Initiate preclinical and clinical trials for secretions technology - H1 FY17
- ✓ Complete recruitment and report on ACTIVATE cancer vaccine trial – H2 FY17
- ✓ Report on Progenza osteoarthritis STEP trial – H2 FY17
- ✓ Report on CryoShot canine pre-pivotal trial - H2 FY17

ENDS

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company using stem cell and immuno-oncology technologies to develop a portfolio of cell-based therapies to address significant unmet medical needs in the human and animal health markets with a focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology diseases.