

ASX Announcement

Regeneus reports half-year results

Sydney, Australia – 29 February 2016

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today reported financial results and operational highlights for the 6 month period ended 31 December 2015.

Financial Highlights

The financial highlights for the reporting period included:

- Loss from ordinary activities (before tax) down 46% to \$3.1m
- \$3.4m R&D tax incentive received for FY15 (\$3.7m for FY14)
- Cash at 31 December 2015, \$3.4m
- Net operating cash outflows (prior to R&D tax incentive of \$2.8m), compares favourably to outflows of \$5.7m during the previous half-year corresponding period

Operational Highlights

During the reporting period, the company continued to make good progress on the clinical development of its portfolio of cell-based therapies for the treatment of osteoarthritis and other musculoskeletal disorders and oncology disease in humans and animals.

Operational highlights for the reporting period included:

Human Health – clinical trials

- Completed enrollment and positive safety review of Cohort 1 for STEP trial for knee osteoarthritis
- First patient dosed safely and commenced treatment of new enrolments for ACTIVATE immuno-oncology trial

Animal Health – clinical trials

- Commenced pre-pivotal trial for CryoShot for canine osteoarthritis at University of Pennsylvania
- Commenced trial for Kvax for canine lymphoma at Small Animal Specialist Hospital in Sydney

Commercial and IP developments

- Entered into agreement with top 5 animal health pharma to partner the development and commercialisation of CryoShot Canine
- In-licensed rights for development and commercialisation of next-generation stem cell identification and selection technology for high potency secreting stem cells developed at Centre for Nanoscale BioPhotonics at Macquarie University
- Advanced discussions for licensing of Progenza stem cell technology for development, manufacture and commercialisation in Japan
- Australian patent granted for allogeneic stem cells for osteoarthritis and other inflammatory conditions in human and animals
- Australian patent granted for cancer vaccine technology for humans and animals

Looking forward

Over the next 12 months, the company will seek to unlock value in its clinical and technology assets through achieving milestones including:

- Complete enrollment of Cohort 2 and report on preliminary safety in STEP trial – H2FY16
- Enter into an agreement for the licensing of Progenza in Japan - H2 FY16
- Report on Kvax osteosarcoma trial – H2 FY16
- Report on CryoShot canine trial – H1FY17
- Complete recruitment of ACTIVATE trial – H1FY17

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company developing 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.

The company has two product candidates in Phase 1 trials: Progenza is an allogeneic off-the-shelf adipose stem cell therapy to treat osteoarthritis and other musculoskeletal conditions and RGSH4K is an autologous therapeutic cancer vaccine to treat a wide range of tumour types. The company is developing a stem cell secretions based cream targeting acne and other inflammatory skin conditions. The company has two therapies targeting animal conditions: CryoShot is a clinical-stage allogeneic off-the-shelf adipose stem cell therapy for the treatment of canine and equine osteoarthritis and other musculoskeletal conditions and Kvax is an autologous therapeutic cancer vaccine in clinical trials.

Contact for further information:

Investors:

Sandra McIntosh
Company Secretary
Regeneus Ltd
T: +61 2 9499 8010
E: investors@regeneus.com.au or go to <http://www.regeneus.com.au>

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