

ASX Announcement

Regeneus Full-Year Results 2017

Sydney, Australia – 22 August 2017

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today released its Full-Year Report for the 12 months ending 30 June 2017.

This financial period has seen the company achieve major milestones that build the foundation for the businesses future success.

Strategic collaboration with AGC of Japan

As part of our Japan strategy, we were successful in securing a strategic collaboration and licensing agreement of our Progenza stem cell technology with AGC of Japan (TYO:5201). AGC is a world-leading glass solution provider and a leading manufacturer of biopharmaceuticals. This is the first collaboration of its type by an Australian biotechnology company in Japan. Under the terms of the collaboration:

- AGC has the exclusive rights to manufacture Progenza in Japan
- AGC will have a 50% interest in Regeneus Japan, which holds the exclusive rights for the clinical development and commercialisation of Progenza for osteoarthritis and all other clinical indications in Japan
- In January 2017, Regeneus received US\$5.5 million as an upfront payment and a further US\$1 million in June upon meeting the primary endpoint in the Progenza STEP trial for osteoarthritis. The company will be entitled to 2 further payments of US\$5m upon meeting specific development and approval milestones.

Successful STEP trial results

On 22 May, we announced the positive results from the Phase 1 STEP trial of Progenza in patients with knee osteoarthritis, meeting the primary endpoint of safety and tolerability.

Other key outcomes from the trial were:

- significant, rapid and sustained reduction in knee pain at both Progenza doses
- significant improvement in cartilage volume compared to placebo
- positive signs of disease modification consistent with preclinical results

Other key achievements

Other key achievements for the period include:

- advanced discussions with potential partners for clinical development of Progenza for a range of indications in Japan and other territories
- patent allowed in Japan covering Progenza technology for the treatment of OA and other inflammatory conditions
- patent allowed in EU, USA and China covering Sygenus stem cell secretions technology for the topical treatment of acne
- commenced Australian Research Council linkage funded collaborative research project with Macquarie University and University of Adelaide to explore Progenza and Sygenus use in the treatment of chronic pain

- completed a successful Kvax study for treatment of canine osteosarcoma with VCA in the USA, which showed Kvax is well tolerated and confers increased progression free interval and survival

Financial Highlights

The financial highlights for the reporting period include:

- licence fee revenues up 715% to A\$9.9m (FY16: \$1.2m) driven by \$8.9m from AGC licence fees
- profit of \$3.3m significantly up from prior year (FY16: \$3.6m loss)
- R&D tax incentive of \$2.6m in line with prior year (FY16: \$2.7m)
- Quarterly cash used in operations (excluding R&D tax incentive) maintained at \$1.7m (FY16: \$1.5m per quarter)
- 30 June cash available \$4.1m

Outlook

Over the next 12-18 months, the company will continue to focus on unlocking value in its clinical-stage human and animal pipeline products through the generation of positive clinical data, technology development and partnering activities including:

- advance clinical partnering discussions for Progenza in Japan and other territories
- report on results of ACTIVATE Phase 1 cancer vaccine trial
- report on results of studies for Sygenus stem cell secretions technology
- report on results of CryoShot canine pre-pivotal osteoarthritis trial

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell and immuno-oncology technologies to develop a portfolio of innovative 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.

Contact for further information:

Investors:

Sandra McIntosh
Company Secretary and Investor Relations
Regeneus Ltd
T: +61 2 9499 8010
E: Sandra.mcintosh@regeneus.com.au
W: www.regeneus.com.au