

ASX Announcement

Regeneus 2017 Half-Year Results

Sydney, Australia – 22 February 2017

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today released its Half-Year Report for the 6 months to 31 December 2016.

This financial period has been very successful for the company with the efforts of the past 18 months culminating in a strategic collaboration and licensing agreement with AGC of Japan (TYO: 5201), one of Japan's leading biopharmaceutical manufacturers. Under the terms of the collaboration dated 28 December 2016, AGC has the exclusive rights to manufacture Progenza in Japan and a 50% interest in Regeneus Japan, which is the exclusive licensee of the clinical development and marketing rights for Progenza for osteoarthritis and all other clinical indications in Japan. Regeneus received US\$5.5 million as an upfront payment and is entitled to a further US\$11 million upon meeting specific development and approval milestones.

Other key achievements for the first 6 months of FY17 included:

- Advanced discussions with potential partners for clinical development of Progenza for a range of indications in Japan
- Entered into ARC funded collaborative research project with Macquarie University and University of Adelaide to explore Progenza 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

The financial highlights for the reporting period included:

- Upfront licence fee of US\$5.5m received from AGC
- First profit of \$3.8m reported, improvement driven by initial licence fee (FY16 loss \$3.1m)
- Quarterly cash used in operations (excluding R&D tax incentive) maintained at \$1.5m
- Receipt of \$2.7m R&D tax incentive for FY16 (\$3.4m for FY15)
- Secured 18 month funding runway

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 generation of positive clinical data, technology development and partnering through the following activities:

- Advance clinical partnering discussions for Progenza in Japan – ongoing
- Commence donor procurement and process development for manufacturing Progenza for Phase 2 trial in Japan – Q4FY17
- Commence ARC funded Progenza chronic pain study – Q4 FY17
- Complete recruitment and report on ACTIVATE clinical trial – H2 FY18
- Report on Progenza osteoarthritis STEP trial – Q4 FY17
- Meet clinical milestones under AGC collaboration – Q4 FY17
- Undertake preclinical trials for human secretions technology for inflammatory skin conditions - Q4 FY17
- Complete recruitment and report on CryoShot Canine pre-pivotal OA trial - H2 FY18

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell and immune-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.

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