

ASX Announcement

Regeneus 2018 Half-Year Results and Business Update

Sydney, Australia – 20 February 2018

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today released its Half-Year Report for the 6 months to 31 December 2017.

The past 6 months has been a period of positive developments for the business. In Japan, we have made significant progress on the transfer of Progenza technology to AGC with AGC having established a mirror production capability at their Yokohama R&D Centre.

We have advanced our discussions and due diligence on securing our first clinical partner for Progenza in Japan. We are working closely with AGC in relation to securing a licensing partner and expect to make an announcement about this by the end of the financial year.

Japan continues to be the most active market for corporate and licensing activity for regenerative medicine technologies with two acquisitions by major Japanese pharmaceutical companies in this quarter. Takeda announced the acquisition of TiGenix for US\$620m in January and Astellas announced the acquisition of Universal Cells for US\$102m in February. Both these target companies have donor stem cell technology platforms.

The appointment of our new Japan based director Leo Lee will give the Board greater insights and capabilities as we grow our business in Japan. Leo is an executive with senior experience in the Japan pharmaceutical industry including as current President of Merck Serono, Japan and previously the President of Allergan.

To assist with funding of our development programs, we have put in place a new \$2m R&D tax incentive debt facility. The securing of a clinical partner in Japan will provide further funding and will release additional milestone funding from our AGC collaboration. These funding sources will contribute to the longer-term success of Regeneus' product development and licensing strategy.

Other business highlights include:

- STEP trial manuscript accepted for publication in Q3 FY18
- Sygenus preclinical study shows a strong analgesic effect outperforming morphine for pain relief
- Sygenus gel shows positive results in acne study
- Recruitment closed for RGSH4K ACTIVATE trial and to be reported H2 FY18
- Strengthening of the patent portfolio with patents granted for the treatment of acne using the Company's stem cell secretions technologies

The financial highlights for the reporting period included:

- Licence revenues of \$0.4m in line with prior comparable period (excluding AGC licence fees of \$7.6m)
- Operating loss of \$2.71m (FY16 profit of \$3.76m including AGC licence fee)
- Cash burn averaging \$1.79m per quarter (FY16: \$1.53m per quarter)
- Net cash used in operating activities of \$0.97m (FY16: \$0.32m)
- Receipt of \$2.61m R&D tax incentive for FY17 (\$2.73m for FY16)
- \$2m R&D tax incentive debt facility being finalised

Regeneus' primary focus is to license Progenza for osteoarthritis in Japan in FY18 and over the next 12 months we will also look to licence Progenza for OA in other major markets including the US and Europe. We will also be seeking to licence Progenza for other indications in Japan and other major markets.

Regeneus 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:

- Secure initial clinical partner for Progenza for osteoarthritis in Japan - FY18
- Advance clinical partnering discussions for Progenza for other indications in Japan and other major markets – ongoing
- STEP Trial manuscript publication – Q3 FY18
- Further Sygenus product development to target specific pain and dermatological indications - ongoing
- Explore early licensing opportunities for Sygenus for pain and dermatology - ongoing
- Complete recruitment and report on ACTIVATE clinical trial – H2 FY18
- Advance clinical partnering discussions for RGSH4K with Phase 1 data – ongoing
- Complete recruitment and report on CryoShot canine OA trial – FY19
- Complete recruitment and report on Kvax canine B cell lymphoma trial - FY19

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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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