

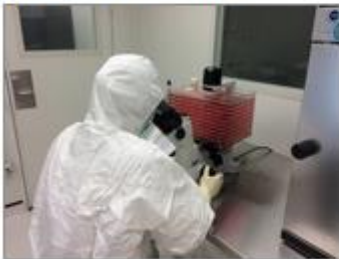
# Regeneus Ltd

15<sup>th</sup> September 2016

## Regeneus Ltd receives \$2.7M for regenerative medicine product pipeline

Thursday, September 15, 2016

### Regeneus Ltd receives \$2.7M for regenerative medicine product pipeline



The \$2.73 million payment from the Australian Government's Research and Development Tax Incentive Program illustrates the financial support Regeneus is capable of receiving from tax incentives as it develops its medical treatments.

[Regeneus Ltd \(ASX:RGS\)](#) has received \$2.73 million from the Australian government as part of a research and development tax refund.

Funds will be used to progress its regenerative medicine product pipeline.

Regeneus commenced two first-in-human clinical trials during FY16, the STEP trial and the ACTIVATE trial.

These Phase I trials are for Progenza (STEP trial), an off-the-shelf stem cell therapy targeting osteoarthritis, and RGSH4K (ACTIVIATE trial), a cancer vaccine.

Regeneus is in the process of securing a manufacturing and commercial partner for Progenza in Japan.

### Background

Regeneus is an emerging leader in cell based medicines for both humans and animals.

It is a clinical-stage regenerative medicine company with a focus on osteoarthritis and other musculoskeletal disorders, oncology (cancer) and dermatology diseases.

In the first half of FY16, the company commenced two first-in-human clinical trials, the STEP trial and the ACTIVATE trial.

Regeneus also has two therapies targeting animal conditions: CryoShot is a clinical-stage stem cell therapy, similar to Progenza, for dogs and horses and Kvax is a cancer vaccine for dogs in clinical trials.

### FY16 result highlights

The financial highlights for FY16 were better than expected and showed substantial progress on the company's R&D, clinical development and commercial goals including:

- Licence fee revenues up 35% to \$1.2 million (FY15: \$0.9 million);
- Loss from ordinary activities down 45% to \$3.6 million (FY15: \$6.6 million);

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- Quarterly cash burn down 37% to \$1.48 million per quarter (FY15: \$2.35 million per quarter); and
- Net cash used in operating activities of \$2.25 million (including R&D tax incentive) (FY15: \$5.92 million).

## FY17 milestones

Over the coming 12 months, the company expects to achieve the following key milestones:

- Progenza: Secure manufacturing and commercial partner for Progenza technology in Japan (Q1 FY17);
- Progenza: Advance clinical partnering discussions for Progenza in Japan and other territories (FY17);
- Progenza: Commence donor procurement in preparation for manufacturing Progenza for Phase 2 trial in Japan (Q2 FY17);
- Progenza: Commence ARC linkage project on stem cells for chronic pain (Q2 FY17);
- Secretions: Initiate preclinical and clinical trials for secretions technology (Q2 FY17);
- RGS4K: Complete recruitment and report on ACTIVATE cancer vaccine trial (H2 FY17);
- Progenza: Report on Progenza osteoarthritis STEP trial (H2 FY17); and
- CryoShot: Report on CryoShot Canine pre-pivotal trial (H2 FY17).

## Analysis

The \$2.73 million payment from the Australian Government's Research and Development Tax Incentive Program illustrates the financial support Regeneus is capable of receiving from tax incentives as it develops its medical treatments.

This support has helped the company achieve its goal of lowering its quarterly cash burn to \$1.7, million, which it convincingly beat in FY16, lowering to \$1.48 million.

This is an important achievement for the company while it develops its medical treatments to their next value inflexion point and seeks clinical and commercialisation partners to de-risk their product pipeline and access non-dilutive funding sources.

Regeneus' allogeneic stem cell technology platform allows for the scalable production of off-the-shelf cell products and this technology underpins both the Progenza and CryoShot product platforms.

The company has a number of key milestones to achieve over the coming 12 months, which are important for the development and growth of the business and the creation of shareholder value.

The company has estimated available cash of \$3.2 million.

Upcoming news is anticipated during the September quarter related to securing a manufacturing and commercial partner for Progenza in Japan.

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