

# Regeneus

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## Regeneus reports first half-year profit, funded for eighteen months

Regeneus (ASX:RGS) reported a \$3.8 million profit in the first half of FY17 after coming off a \$3.1 million loss in FY16.

The profit improvement was driven by the receipt of an upfront licence fee from AGC of Japan (TYO:5201) valued at US\$5.5 million, which supports an 18 month funding runway.

During the half, Regeneus entered into a landmark partnership with AGC, which will see AGC be the exclusive manufacturer of Progenza in Japan and the establishment of a joint venture company 'Regeneus Japan' for the exclusive licensing of the clinical development and marketing rights of Progenza in Japan.

Regeneus is in advanced discussions with a number of potential partners for the clinical development of Progenza for a range of indications outside of osteoarthritis, showing Progenza is a technology platform with other clinical applications.

The Progenza STEP trial read out is expected next quarter and this is anticipated to expedite these discussions in Japan, for clinical development for osteoarthritis as well as other conditions.

### 1H17 financial highlights

The financial highlights for the reporting period included:

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

### Anticipated upcoming milestones

Over the next 12-18 months, Regeneus will continue to focus on unlocking value in its clinical-stage human and animal pipeline products through the following activities:

Progenza:

- Ongoing: Advance clinical partnering discussions for Progenza in Japan;
- June quarter 2017: Commence donor procurement and process development for manufacturing Progenza for Phase 2 trial in Japan;
- June quarter 2017: Report on Progenza osteoarthritis STEP trial; and

**Price:** A\$0.145

**Market Cap:** A\$30.288M

### 1 Year Share Price Graph



### Share Information

**Code:** RGS

**Listing:** ASX

**52 week High Low**  
0.185p 0.071p

**Sector:** Health Care, Equipment & Services

**Website:** www.regeneus.com.au

### Company Synopsis:

Regeneus (ASX:RGS) is a clinical-stage regenerative medicine company developing a portfolio of cell therapies with a focus on musculoskeletal disease, oncology and dermatology.

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- June quarter 2017: Commence chronic pain preclinical study.

RGSH4K:

- Ongoing: Further recruitment on ACTIVATE clinical trial; and
- June half 2018: Complete recruitment and report on ACTIVATE trial.

Secretions:

- June quarter 2017: Undertake preclinical trials for human secretions technology for inflammatory skin conditions.

CryoShot:

- June half 2018: Complete recruitment and report on CryoShot Canine pre-pivotal osteoarthritis trial.

### **AGC deal details**

As per the agreement, Regeneus is to receive US\$16.5 million comprised of \$5.5 million upfront and US\$11 million in specified milestone payments.

This will see AGC be the exclusive manufacturer of Progenza for all indications in Japan and the establishment of a 50/50 joint venture for exclusive licensing of the clinical development and marketing rights of Progenza for osteoarthritis and all other indications for the Japanese market.

With the agreement including the licensing of the clinical development and marketing rights of Progenza for osteoarthritis and all other clinical indications, the door is open to a range of opportunities for clinical partnering in Japan.

Regeneus will be entitled, through its 50% interest in the joint venture, to its share of upfront licence fees, milestone payments and royalties from any sub-licensing.

### **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.

Its flagship asset, Progenza is a patented off-the-shelf stem cell technology developed for the treatment of knee osteoarthritis and other inflammatory conditions.

Regeneus' key human assets are Progenza, RGSH4K, which is a cancer vaccine and secretion technology for inflammatory skin conditions.

Regarding animal health, Regeneus is developing CryoShot to treat osteoarthritis and Kvax, a cancer vaccine.

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