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Regeneus Ltd

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Regeneus Ltd secures patent in Europe to tackle $3B acne market

Regeneus Ltd (ASX:RGS) has been granted a patent providing commercial rights in Europe for the treatment of acne using the company's stem cell secretion technology.

This is the first Regeneus patent to be granted in Europe and follows the granting of this patent in Australia in October 2014.

The global market for acne-based prescription treatments is over $3 billion per annum.

The company is exploring partnering options for the development and commercialisation of the secretions
technology.

The patent is also being pursued for grant in other key territories including USA and Japan.

Background

Regeneus is a clinical-stage regenerative medicine company developing cell-based therapies to treat unmet medical needs for both humans and animals with a focus on osteoarthritis and other musculoskeletal disorders, oncology and inflammatory skin conditions.

In the first half of FY16, the company commenced two first-in-human clinical trials: the STEP trial for its allogeneic stem cell therapy to treat knee OA and the ACTIVATE trial, for its autologous cancer vaccine.

1 Year Share Price Graph

Share Information

Code:	RGS
Listing:	ASX
Sector:	**Medical Supplies**
Website:	**www.regeneus.com.au**

Company Synopsis:

Regeneus Ltd (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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Regeneus has 49 patents or patent applications across 14 patent families relating to its regenerative medicine development products.

Analysis

The granting of this patent represents a milestone for Regeneus as it builds upon its ability to apply its stem cell technology to acne treatment while expanding its patent presence to Europe for the first time.

Skin conditions and wound healing are a promising and near term area for cell-based regenerative medicine products.

With few treatment innovations or improvements in the treatment of acne over the last 10 years, the demand for new improved acne treatments is high.

The company has additional patent applications in the pipeline that cover the use of the secretions technology for other skin conditions.

Regeneus shares are up 35% year to date, currently trading at circa $0.13 per share.

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

During July the company signed a $2 million R&D funding facility and anticipates receiving a $2.5m R&D tax incentive

for FY16 in Q1FY17. These funds will support the clinical trials and operating activities throughout the rest of 2016.

Partnering Progenza in Japan

Regeneus is on track to enter its first significant partnering agreement in Japan by the end of September for its stem cell product, Progenza.

Progenza is an off-the-shelf stem cell product with the first targeted treatment being for knee osteoarthritis.

The company's executive team visited Japan to advance discussions in late May, which have had a positive effect on developing a partnership.

Interest in cell-based regenerative medicine technologies in Japan has grown since regulatory changes in 2014, which allow for an accelerated pathway to approval for regenerative therapies like Progenza.

STEP trial fully recruited

In May, the company announced that that the STEP trial of 20 patients was fully recruited ahead of schedule.

Participants will be monitored for 12 months. The trial is scheduled to report in H2 FY17.

This positive milestone moved the company a step closer to completing its Progenza licensing discussions for the Japanese market.

Progenza development strategy

Regeneus is moving forward with the regulatory registration pathway in 2 jurisdictions, Japan and the U.S.

The initial goal is to progress towards manufacture for a Phase 2 trial in Japan.

This will include donor procurement, process development and technology transfer to a chosen good manufacturing practice facility.

In the U.S., further preclinical studies will build upon the efficacy seen in the rabbit osteoarthritis study.

The results from the Australian Phase 1 STEP trial will also be helpful with the FDA pathway in the U.S.

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