

ASX Announcement

Regeneus reports 2015 full-year results and business update

Sydney, Australia – 31 August 2015

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today reported its 2015 financial results and business update.

During the year, the company made significant progress on the development of its portfolio of cell-based therapies for the treatment of osteoarthritis and other musculoskeletal disorders, oncology and dermatology diseases for the human and animal health markets.

CEO, John Martin said: “last financial year was an important one for the company. We achieved a number of significant clinical, manufacturing and business milestones that should set the foundations for unlocking value in the business in FY16 and beyond”.

Key Achievements for FY15

Key achievements during FY15 included:

- Obtaining approval for commencement of first-in-human trials for:
 - Progenza – our allogeneic “off-the-shelf” stem cell therapy for osteoarthritis
 - RGS4K – our cancer vaccine
- Demonstrating our capacity to manufacture millions of doses of Progenza from a single donor
- Progressing our partnering and licensing discussions:
 - for the manufacture, clinical and commercial development of Progenza in Japan
 - for global sales and marketing of canine CryoShot, our allogeneic stem cell therapy for canine OA
- Substantial growth in our intellectual property portfolio including:
 - granting of 10 new patents and our 1st US granted patent
 - securing the exclusive rights to the human cancer vaccine developed at the Kolling Institute of Medical Research

Strategic focus on Progenza

Over the last year, the company has made significant clinical and manufacturing progress in the Progenza program. This progress, together with the lack of scalability and regulatory certainty of the HiQCell business model, has contributed to the Board’s decision to focus the company’s resources on the development of Progenza and reduce the expenditure on the commercialisation of HiQCell. Allogeneic “off-the-shelf” stem cell products, like Progenza, are the preferred business model of pharmaceutical companies because of scalable production and distribution. The company will assess the licensing options for HiQCell once there is greater regulatory certainty for autologous stem cell products.

Financial Highlights for FY15

The financial highlights for FY15 as reported in the company's financial statements included:

- Revenues of \$2.06m in line with last year's revenues (FY14: \$2.09m)
- Net loss down 12% to \$6.6m (FY14: \$7.5m)
- Net operating cash outflows of \$5.9m (FY14:\$6.2m)
- Successful capital raising completed in August 2014, net of costs of \$6.17m
- Receipt of \$3.73m R&D tax incentive for FY14
- Cash at 30 June 2015, \$3.0m with \$3.4m R&D tax incentive to be received in October

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company developing a portfolio of cell-based therapies to address significant unmet medical needs in the human and veterinary health markets with a focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology diseases.

The company has two product candidates in Phase I trials: Progenza is an allogeneic "off-the-shelf" adipose stem cell therapy to treat osteoarthritis and other musculoskeletal conditions and RGSH4K is an autologous therapeutic cancer vaccine to treat a wide range of cancer types. The company has a stem cell secretions based cream targeting acne and other inflammatory skin conditions and has developed and licensed technologies for the use of autologous adipose stem cells for the treatment of osteoarthritis (HiQCell). The company has two therapies targeting animal conditions: CryoShot is a clinical-stage allogeneic off-the-shelf adipose stem cell therapy for the treatment of canine and equine osteoarthritis and other musculoskeletal conditions and Kvax is an autologous therapeutic cancer vaccine in clinical trials.

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