regeneus
living regenerative medicine

ASX Announcement

2015 Annual General Meeting
Chairman's Address

Sydney, Australia – 9 November 2015

Good afternoon everyone, and thank you for attending the Regeneus 2015 Annual General Meeting.

Let me introduce my fellow Directors. To my right, John Martin, our CEO; next to John is Dr Graham Vesey, co-founder and Chief Scientific Officer; then introducing our non-executive director Barry Sechos. Unfortunately, Dr Glen Richards is unable to join us today due to prior commitments.

We are pleased to report that FY15 has been a productive and positive year for our company. We have achieved a number of significant research and development, clinical and business milestones that have put the company in a good position to unlock value in our regenerative medicine technology and clinical assets in FY16 and beyond.

Strategic focus on Progenza

Over the last financial year we have increased our strategic focus on our Progenza allogeneic "off-the-shelf" stem cell technology platform. We successfully manufactured Progenza for use in our positive pre-clinical study and showed that the technology is scalable by demonstrating our capacity to produce millions of doses from a single donor. This work underpinned the approval and commencement of our first-in-human Progenza trial for osteoarthritis. The first cohort of trial participants should be treated by the end of this year.

Progenza is a key technology platform for our company as it has the potential to be used as an off-the-shelf treatment option for a wide range of musculoskeletal disorders, other than osteoarthritis, and inflammatory or immune-mediated conditions that have limited treatment options. Over the next year we will continue to explore how we can leverage this platform through technology and clinical partnering. In particular, we are hopeful that we can take advantage of the new and attractive regulatory regime in Japan for regenerative medicine by converting our business development initiatives over the last year into positive partnering outcomes.

We are also exploring ways with R&D partners to innovate around allogeneic cell technologies to develop next generation cell therapies.

Our success with the development of Progenza and the lack of scalability and regulatory uncertainty for our autologous HiQCell technology, lead to the Board's decision in late 2014 to focus our efforts and resources on Progenza. Our experience with the development and manufacturing of HiQCell technology, our engagement with specialist clinicians and the significant clinical data generated relating to osteoarthritis will prove invaluable as we develop and exploit the Progenza technology. The company will assess the licensing options for HiQCell technology once there is greater regulatory certainty for autologous cell therapies.

Secured cancer immunotherapy technology

We were pleased to secure the exclusive rights to develop and commercialise the human applications of a new cancer immunotherapy technology (RGSH4K) developed at the Bill Walsh Translational Cancer Research Laboratory at the Kolling Institute of Medical Research located on the grounds of Royal North Shore Hospital. The technology uses the patient's own tumour cells to create a vaccine that stimulates the patient's immune system enabling it to see the cancer cells as foreign.

We had secured rights to the animal health applications for the technology in the 2012.

We were able to translate the work done in demonstrating the safety of the technology for dogs to receiving ethics approval for a first-in-human study in May 2015. We established a tumour bank for existing and prospective tumours and achieved an important milestone in October when the first patient was successfully dosed with the vaccine. The trial is now open for recruitment.

Cells secretions technology – product development phase

We have made progress on identifying a commercial partner for our cell secretions cream for acne and other inflammatory skin conditions. Further work is being undertaken on formulation development, product stability and clinical testing. If the product development is successful then the final phase will be the scale-up of manufacturing technology.

Advancing CryoShot

We continued our clinical development of CryoShot for canine and equine applications. CryoShot is our first allogeneic "off-the-shelf" stem cell technology. Again, we have demonstrated our capacity to produce CryoShot at scale from a single donor.

We explored partnering options for CryoShot Canine and were pleased when we recently announced entering into a development and commercialization collaboration with a US based top 5 animal health company. Our partner will jointly fund a pre-pivotal study on CryoShot for canine osteoarthritis which has commenced this month at the University of Pennsylvania School of Veterinary Medicine. This trial will hopefully pave the way for a full FDA pivotal study.

We were encouraged by the interim results from the CryoShot Equine study at Randwick Equine Centre for early orthopaedic developmental disease in yearling thoroughbreds. Recent published interim results show that CryoShot is having a positive impact on the healing and progression of joint lesions which can lead to bone cysts in young horses. This is exciting news as it shows that cell therapy could potentially be used for early intervention or prophylactic use in human orthopaedic developmental disease.

Kvax – collecting data

As an autologous canine cancer immunotherapy, Kvax can be fast tracked for commercial applications from a regulatory perspective. To maximize Kvax's success and partnering options, our strategy is to generate tumour specific clinical data to prove up the vaccine's effectiveness. We commenced a clinical trial in the US for Kvax to treat osteosarcoma. We expect a readout of the results in Q3 FY16. We also plan to conduct other trials in common canine tumours.

Substantial increase in granted patents

We have seen a substantial increase in granted patents. 10 new patents have been granted during the year, 8 in Australia, 1 in NZ and our first patent in the US.

We now have 14 patents and 35 patent applications across 14 patent families.

Outlook and thanks

On behalf of the Board I thank the Regeneus senior management team and each of our employees and R&D partners for their hard work and commitment over the past year. 2016 is shaping up to be a turning point in the evolution of the company with a number of key R&D, clinical and commercial milestones in sight.

The Board looks forward to capitalizing on our progress and unlocking the value in our technology and clinical assets and gaining market recognition for our successes.

Finally, may I thank you, our shareholders for your support of the company and what we do and showing patience as we develop and seek to partner our regenerative medicine products.

I would now like to ask our Chief Executive, John Martin, to provide further insight into the past year's operational activities and to share with you our plans for the future and specific milestones and catalysts for FY16 and beyond in a slide presentation.

Thank you.

Dr Roger Aston