

ASX Announcement

22 July 2019

Revised Strategy Focuses on Delivering Regenerative Therapies for Global Pain Market

Highlights

- Immediate priority to complete a Phase 2 clinical trial and commercialisation of Progenza for osteoarthritis, targeting Japan product launch in 2023
- Poised to secure Japanese commercialisation deal, representing a major milestone in bringing Progenza for osteoarthritis to market
- Focussed on addressing the large, growing global pain market and developing regenerative therapies that treat pain and the underlying diseases which cause it
- Scientific partnership model will support the funding and activities required to develop therapies using Progenza and Sygenus, targeting additional indications
- Capital to be redeployed to support redefined strategic priorities and drive long-term value creation for shareholders

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, is pleased to provide an update of its revised strategy and focus to commercialise regenerative therapies that address the large and growing global pain market.

Revised focus and strategic direction to address a US\$69 billion¹ global pain market

Following his appointment in late January 2019, Chief Executive Officer Leo Lee has driven a review of the Company's operations, assets and strategy to ensure Regeneus is positioned to maximise the value from its existing assets and has a clear strategy in place to deliver positive commercial outcomes and long-term shareholder value.

The Company has redefined its vision and purpose, with a key focus on developing therapies to treat pain and modify the underlying diseases which are the cause of pain.

Key to accomplishing this, the Board and executive team have identified its key priority as being the commercialisation of Progenza for osteoarthritis in Japan, ahead of commercialising in additional markets, and exploring additional therapies in pain utilising the Company's Progenza and Sygenus technologies.

Completion of Phase 2 and commercialisation of Progenza in Japan

As its number one priority, Regeneus' focus is on the commercialisation of its most mature technology platform – Progenza – and the completion of a Phase 2 clinical trial for the treatment of osteoarthritis, to bring the product to market.

The Company has already demonstrated early success with Progenza for osteoarthritis through a successful Phase I study meeting primary end points in safety and secondary end points in pain

¹ Source: Datamonitor Healthcare – Neuropathic Pain Market Spotlight 2018.

reduction and cartilage protection. Now on the cusp of securing a commercial licensing deal with a major Japanese company to take the product through a Phase 2 clinical trial – as a significant milestone towards bringing a commercial product to market by 2023.

Following this, Regeneus' focus is to bring Progenza for osteoarthritis to market in the US and Europe, with both regions representing a large and growing opportunity. The Company will leverage the experience and industry contacts of the Board and executive team, including recently appointed Non-Executive Directors, John Chiplin, PhD and Alan Dunton, M.D. who are based in the UK and US respectively. Dr Chiplin's proven success in sourcing global capital and Dr Dunton's extensive experience in global drug development, commercialisation and pain management will be invaluable in driving this strategy forward, and in identifying commercial partners to bring Progenza for osteoarthritis to market in these regions.

Over the longer-term, the Company will focus on licensing Progenza for osteoarthritis globally, with Asia, the Middle East and Eastern Europe the markets next prioritised after Japan, the US and Europe.

Scientific partnerships to develop additional therapies from Progenza and Sygenus

Pre-clinical animal studies for both Progenza and Sygenus have demonstrated positive outcomes in the treatment of pain, disease modification and showing strong potential to be developed into therapies that address a broad range of other indications in pain.

Supporting the continued research and development of Progenza and Sygenus and expanding the commercial opportunity from the Company's most mature assets, the Company will seek scientific partners – including with leading university bodies – to identify a second indication for Progenza and a first indication for Sygenus, for commercialisation.

Regeneus will benefit through access to funding and the existing capabilities of an established scientific partner to support its ongoing research and development of Progenza and Sygenus under a collaborative, cost effective model.

RGSH4K and Animal Health platforms

With the Company's focus clearly prioritised on the global pain market, the best immediate use of the Company's internal resources and capital is in support of commercialising Progenza for osteoarthritis in Japan. As such, the Board and executive team are currently considering a range of options to monetise its RGSH4K cancer vaccine and animal health platforms in order to extract the value already created.

Outlook

With strategic priorities now redefined, the Company is focussed on delivering its first commercial product – Progenza for osteoarthritis – to market, targeting Japan in 2023 and is redeploying capital and aligning resources to support this immediate priority. The Company is currently finalising negotiations with a major Japanese company for a commercial licensing deal, which will take Progenza for osteoarthritis through a Phase 2 trial to commercialisation, and expects to announce a positive outcome from these discussions in the near term.

As part of its strategic review, the Board is also finalising a range of initiatives to ensure costs and operations are aligned to execute its revised strategy in an efficient and effective manner, and these will be implemented in early FY2020.

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About Regeneus Ltd

Regeneus Ltd (ASX:RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell technologies to develop a portfolio of novel cell-based therapies to address significant unmet medical needs in the human health markets with a focus on osteoarthritis and other musculoskeletal disorders, neuropathic pain and dermatology.

<http://www.regeneus.com.au>

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