

ASX Announcement

26 February 2021

Half-Year Results & Business Update

Key highlights:

- Regeneus signed a licence and collaboration agreement with Kyocera to develop and commercialise Progenza™, valued at US\$19M in upfront, development and regulatory milestone payments
- Two milestone payments from Kyocera totalling A\$7M received in H1 FY2021
- Profit of \$4.4M in H1 FY2021, vs. net loss of \$1.2M in pcp
- Cash balance at 31 December 2020 of \$4.1M (H1 FY2020: \$0.8M) due to receipt of funding from Kyocera and \$676k in FY2020 R&D Tax incentives
- New Sygenus patents granted in Canada and U.S., extending technology platform application to additional dermatological indications
- New patent covering use of biomarkers to monitor disease progression in stem therapy granted in Australia
- Experienced executive and healthcare entrepreneur, Karolis Rosickas appointed as CEO

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, today released its Half-Year Financial Results and Appendix 4D for the period ended 31 December 2020 (H1 FY2021).

It was a transformational period for the Company, as it works toward bringing its unique stem cell technology platform Progenza™ to market in Japan and continues to develop Sygenus to treat dermatological conditions.

Regeneus reported revenue of \$7.0M for the half (vs. \$0.8M in H1 FY2020) as the business received licence fee revenue from Kyocera. Profit for the half was \$4.4M, compared to a loss of \$1.2M in the previous corresponding period.

Kyocera agreement

In line with Regeneus' strategy, the Company signed a licence and collaboration agreement during the half, granting Japanese manufacturer Kyocera Corporation (Kyocera, TYO:6971) exclusive rights to develop and commercialise the Company's lead stem cell technology platform Progenza™ for the treatment of knee osteoarthritis (OA) in Japan.

The deal is worth US\$19M overall in upfront, development and regulatory payments from Kyocera, with additional royalties available to Regeneus upon product sales. The first two milestone payments of A\$1.4M and A\$5.6M were received during H1 FY2021 for the completion of execution of the agreement and delivery of the initial Progenza™ OA data package, respectively, with additional milestone payments to be received as the partnership progresses.

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Regeneus CEO, Karolis Rosickas said, "Securing this deal with the highly credible Kyocera is a fantastic endorsement of our technology. Our relationship with Kyocera has remained positive as we progress towards Phase II trials for Progenza™ OA and we are excited by the opportunity the partnership presents us to deliver the first disease modifying treatment for knee OA in the market.

"The global market for osteoarthritis is expected to grow to US\$3.5B by 2026, with the Japanese market alone worth US\$350M¹, representing a significant opportunity."

Progenza™ has already demonstrated in Phase I clinical trials that it is more effective at providing pain relief than existing knee OA treatments, meeting all safety and efficacy endpoints. The higher efficacy of Progenza™ is due to Regeneus' use of a unique combination of stem cells and their bioactive secretome, which not only treat symptoms of pain, but also promote tissue repair and disease modification.

Expanding patent portfolio

During the period, Regeneus extended its patent portfolio for its second platform technology Sygenus, receiving a new patent to be granted in the United States. The patent expands the application of Sygenus into the US\$53B Aesthetics Therapeutic market,² covering treatment of a broad range of non-inflammatory skin conditions with Adipose-derived cell secretions, including age-spots, sun spots, thinning skin, wrinkles, and other Age-Related Degenerative Diseases.

Further, Regeneus secured a Notice of Acceptance for a patent application covering use of biomarkers to monitor disease progression for stem cell therapy in Australia and a new Sygenus patent granted in Canada for the treatment of acne until 2032.

New CEO appointment

During the half, Regeneus appointed experienced executive and healthcare entrepreneur, Karolis Rosickas as CEO, following the resignation of Leo Lee as CEO.

Karolis Rosickas brings to the Company 15 years' business experience in healthcare, technology and finance, including co-founding SingCell, a stem cell contract development and manufacturing organisation in Singapore. Leo Lee remains on the Board of Regeneus as Non-Executive Director.

Further events of note

One-off costs during the half included interest payments and full repayment of the \$1.1M loan from former CEO Leo Lee, and a one-off cash bonus payment of \$325K to Leo Lee following execution of the agreement with Kyocera.

¹ Osteoarthritis market set to be worth \$3.5 billion by 2026. <https://www.globaldata.com/osteoarthritis-7mm-market-set-to-be-worth-3-5-billion-by-2026>

² Grand View Research, Aesthetic Medicine Market Size, Share and Trends Analysis Report, <https://www.grandviewresearch.com/industry-analysis/medical-aesthetics-market>

The company delivered a profit of \$4.4M in H1 FY2021, vs. net loss of \$1.2M in pcp due to the licensing fees and milestone payments from Kyocera.

During the half, Regeneus received \$676K in R&D Tax incentives from the Australian Tax Office for FY2020. The receipt on the rebate, alongside the A\$1.4M and A\$5.6M milestone payments from Kyocera, strengthened the Company's cash balance of \$4.1M at 31 December 2020 (vs \$0.8M in H1 FY2020).

During the half, a total of 22,459,393 shares were issued to Japan based manufacturer AGC Inc following an agreement to mutually terminate the exclusive manufacturing and joint venture agreement, previously announced on 20 December 2019, making them the largest shareholder.

Outlook

"The business is in a transformational phase as we progress Progenza™ OA's path to commercialisation in Japan, including execution of Phase II trials," said Regeneus CEO, Karolis Rosickas.

"While this anchors much of our activity, we are also exploring co-development and licensing options for Progenza™ to treat neuropathic pain, and Sygenus to treat additional skin conditions, globally.

"Our technologies are extremely unique in being able to not only treat symptoms of pain, but also promote tissue repair and disease modification. This positions us well to deliver market-first treatments with Progenza™ and Sygenus and we intent to utilise our IP to seize commercialisation opportunities and deliver returns for our shareholders."

Investor webcast

Regeneus will be conducting a live webcast and Q&A with Regeneus CEO Karolis Rosickas on Wednesday 3 March at 11:00am Australian Eastern Daylight Time (AEDT).

Investors and interested parties are invited to join the session which will focus on the Company's technology and ongoing strategy. Please note, the webinar will not cover financial updates.

Register for the webcast at the following Zoom link:

https://us02web.zoom.us/webinar/register/WN_YyKYF3USS0WusNbnBlafAQ

Registered participants will receive a confirmation email containing the Zoom access link and alternative phone dial-in details.

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About Regeneus

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. The regenerative therapies seek to address unmet medical needs in human health markets, focusing on neuropathic pain, including osteoarthritis and various skin conditions, with its platform technologies Progenza™ and Sygenus. Visit www.regeneus.com.au for more information.

Authorisation & Additional information

This announcement was authorised by the Board of Directors of Regeneus Ltd

Investor and Media Contact

WE Communications

T: (03) 8866 1200

E: WE-AURegeneus@we-worldwide.com

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