

ASX Announcement

22 December 2021

Market Update

Highlights

- R&D rebate of A\$830,000 received from the Australian Government's Research & Development tax incentive program
- Regeneus signs a Variation Agreement with Kyocera reducing Regeneus' future financial commitment and providing more clarity on responsibilities on its Progenza™ development program
- Next milestone payment of US\$3.0 million to be received by Regeneus in Q2 CY2023
- Further patent for Progenza™ has been allowed in Japan protecting the Company's product until September 2036
- Termination of Subscription Agreement with New Life Sciences as the Company explores more favourable non-dilutive growth funding

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, today provides the following update to the market.

Following the release of its Annual Report on the 26th October 2021 citing a net profit of A\$2.76 million the Company has delivered a number of strategic milestones as it progresses its clinical program for its proprietary technology platforms Progenza™ OA and Sygenus.

Receipt of R&D Tax Refund

Regeneus is pleased to advise that it has received approximately A\$830,000 from the Australian Government's Research & Development tax incentive program for activities conducted during the 2021 financial year.

Variation Agreement secured with Kyocera Corporation

As part of the Company's long-term growth strategy, it has secured a Variation Agreement with Kyocera Corporation (**Kyocera**, TYO:6971) pertaining to the licence and collaboration agreement signed in August 2020 (Ref announcement 11 August 2020).

Under the terms of the original agreement Kyocera will exclusively develop and commercialise Regeneus' lead stem cell platform technology Progenza™ for the treatment of Knee Osteoarthritis (Knee OA) in Japan. The Variation Agreement now clarifies the specific responsibilities of both Kyocera and Regeneus and reduces the Company's future financial commitment to the development program.

The Agreement also provides increased visibility and certainty for obtaining conditional Pharmaceuticals and Medical Devices Agency (PMDA) approval in Japan.

The Agreement retains the milestone payments due to Regeneus on the completion of certain milestones through the development program. The next milestone payment of US\$3.0 million will be received by the Company in Q2 CY23 and which was previously expected in December 2022.

To date Regeneus has received JPY 100 million and US\$4.0 million in milestone payments from Kyocera upon signing the agreement and delivering the initial data package.

Regeneus expects to receive a further US\$13.0 million in milestones payments from Kyocera for the duration of the agreement as well as single to high double-digit royalties on all future Progenza™ OA product sales in Japan based on future reimbursement prices.

Securing this Variation Agreement represents a significant achievement for the Company by reducing its financial commitment to the program and demonstrates the commercial potential of Progenza™ in the global market for advanced treatment of knee osteoarthritis, representing a US\$6.1 billion market opportunity.

Further Japanese patent allowed

Additionally, and as part of the ongoing development program with Kyocera, Regeneus is pleased to announce that a new patent has been allowed in Japan (file number JPO 2018-530940) protecting the Company's Progenza™ product until September 2036. The patent focuses on product composition and will enable the Company to protect Progenza™ market exclusivity for an extended period.

Termination of placement arrangements with New Life Sciences

Regeneus' Board of Directors together with New Life Sciences Capital, LLC ('**New Life Sciences**') have mutually agreed to terminate the Subscription Agreement relating to a three-stage placement (the "**Placement**") which was entered into in May 2021 (Ref announcement 7 May 2021).

As originally announced, the Placement was for up to A\$4.5 million of the Company's ordinary shares ("**Shares**") to US based institutional investor, New Life Sciences.

An initial placement of A\$1,590,000 of Shares to raise A\$1,500,000 occurred on 12 May 2021, with Regeneus receiving a prepayment of A\$1,500,000 from New Life Sciences. Since receipt of this prepayment, A\$200,000 has been converted into Shares, with 2,898,551 Shares at 6.9 cents per Share being issued to New Life Sciences on 14 October 2021.

New Life Sciences and Regeneus have mutually agreed to terminate the Subscription Agreement, with no further investments to be made by, or Shares to be issued to, New Life Sciences under the Subscription Agreement.

Under these termination arrangements, Regeneus will repay New Life Sciences A\$1,262,700 in respect of the balance of the prepayment amount received by Regeneus on 12 May 2021, after netting the 1.9 million Shares issued to New Life Sciences on 7 May 2021 against Regeneus' obligations, at a deemed issue price of 6.7 cents per Share. This amount of A\$1,262,700 will be paid to New Life Sciences on 4 January 2022.

As the Company announced a net profit of A\$2.76 million for FY2021 it is currently in advanced discussions with alternative non-dilutive funding partners to secure growth funding on more favourable terms for its shareholders. Regeneus will update the market in due course upon completion of these discussions.

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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 Chairman and Company Secretary of Regeneus Ltd

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