

ASX Announcement

30 April 2021

Quarterly Cashflow Report & Business Update – Period ending 31 March 2021

Highlights

- Key Progenza™ patents awarded in the quarter for treatment of pain in Japan and Europe.
- Kyocera collaboration on Progenza™ OA in Japan has moved forward, with some additional nonclinical and manufacturing process work now to be undertaken prior to commencement of Phase 2 clinical trials.
- Cash balance of A\$3.2M at 31 March 2021 with a continued focus on streamlining of costs within business while progressing pipeline development.
- Australian Department of Defence to provide A\$300k funding for Sygenus first in human study on pain.

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, today released its quarterly cash flow report and business update for the period ending 31 March 2021 (the quarter).

The Company is focused on bringing its stem cell technology platform Progenza™ to market in Japan through its partnership with Kyocera Corporation (Kyocera), and is progressing the development of Sygenus for dermatological conditions.

Progenza™

Regeneus continues to work with Kyocera to progress the application for regulatory approval of Progenza™ for the treatment of knee osteoarthritis (OA) in Japan. That work has identified some additional nonclinical and manufacturing process work will need to be undertaken prior to the commencement of Phase 2 clinical trials in Japan.

The Company is now working with Kyocera to outline the additional nonclinical and manufacturing process work required, the respective responsibilities and the likely timelines for such work. Allowing for the additional work required and subject to confirmation, the next milestone payment of US\$3.0m is expected to be received December 2022.

In the quarter, the Company was awarded patents for Progenza™ for the treatment of pain in Europe and Japanⁱ. The patents extend Progenza™ protection to 2032 in both markets, supplementing previously granted patents for inflammatory conditions. These key patents expand Regeneus' intellectual property portfolio into the \$85.5 billionⁱⁱ global

pain market. The patent granted in Japan falls under the Company's agreement with Kyocera.

Sygenus

Post quarter end the Company has announcedⁱⁱⁱ a partnership with the Australian Department of Defence to develop Sygenus, Regeneus' stem cell bioactive secretome technology, for combat casualty care. Funding of A\$300,000 will be used to optimise the Sygenus formulation for combat casualties and conduct a first in human study on pain, with the research conducted with Professor Mark Hutchinson's group at Adelaide University.

Sygenus will be used as an analgesic gel applied to damaged tissue. Regeneus has previously reported how the analgesic effect of Sygenus is more potent and longer lasting than morphine^{iv} which is the current mainstay for acute severe battlefield pain.

The funding is part of the Defence Industry Competitive Evaluation Research Agreement (ICERA^v) which will fund eligible Australian SME's with up to A\$300,000 per project for up to 18 months. ICERA is focused on projects with the ability to support Australian Defence Force capability priorities, providing A\$36 million over six years in a series of funding rounds with selected projects then considered for potential further funding. ICERA is funded through Next Generation Technologies Fund which focuses on the research and development of emerging and future technologies.

Financial update

The Company's cash balance at 31 March 2021 was A\$3.2M. Net operating cash outflow for the quarter was A\$0.9M which is attributed to continuing R&D activities, staffing and corporate costs.

The Company has maintained its focus on streamlining operational costs over the quarter while ensuring key R&D activities and work to develop new market opportunities are fully supported to drive the successful development of ProgenzaTM and Sygenus.

Regeneus is now operating on a reduced burn rate and will maintain its strict focus on operating costs.

Further to the information in the Appendix 4C under 'Payments to related parties of the entity and their associates' (item 6), Regeneus confirms that aggregate payments to related parties of A\$163k for the quarter includes three months payments of non-executive Directors fees and payments to Mr. Karolis Rosickas (Consulting CEO).

In other business, Dr Alan Dunton stepped down as Non-Executive Director from the Regeneus Board during the quarter^{vi}. Chairman Barry Sechos thanked Dr Dunton for his valuable contribution during what has been a transformation period for the Company.

Outlook

Regeneus CEO Karolis Rosickas said, "I'm pleased to provide this update to shareholders at the close of this quarter as we continue to streamline operating costs and focus on pipeline delivery. Development of Progenza™ for knee osteoarthritis in Japan continues to move forward through our constructive collaboration with Kyocera. The recently announced funding and partnership with the Australian Department of Defence to develop Sygenus for treatment of combat casualties is a significant milestone in our successful 5-year research partnership with Adelaide University. I remain confident in our anticipated pathway to success in launching through partnerships for Progenza™ and the longer-term potential of our platform and pipeline candidates."

-ENDS-

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

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ⁱ ASX Announcements on 9 February 2021 (Japan) and 16 March 2021 (Europe).

ⁱⁱ Allied Market Research, Global Opportunity Analysis and Industry Forecast, 2019–2027 (2020): Pain Management Drugs Market by Drug Class, (NSAIDS, Anesthetics, Anticonvulsant, Anti-Migraine Drug, Antidepressant Drugs, Opioids, and Non-Narcotic Analgesics) and Indication (Arthritic Pain, Neuropathic Pain, Cancer Pain, Chronic Pain, Post-Operative Pain, Migraine, and Fibromyalgia)

ⁱⁱⁱ ASX Announcement on 29 April 2021

^{iv} ASX Announcement 26 Sep 2017: Sygenus technology shows more potent and longer lasting effect on pain than morphine <https://regeneus.com.au/wp-content/uploads/sygenus-lasting-effect.pdf>

^v About ICERA: <https://www.dst.defence.gov.au/icera>

^{vi} ASX Announcement on 25 February 2021

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Regeneus Ltd

ABN

13 127 035 358

Quarter ended ("current quarter")
31st March 21

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	7,659
1.2 Payments for		
(a) research and development	(225)	(395)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	(2)	(5)
(e) staff costs (including Directors)	(463)	(2,137)
(f) administration and corporate costs	(248)	(2,131)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(0)	(275)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	567
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	938	3,283

1.2 Staff costs includes past due Directors fees

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(8)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	(8)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options (including proceeds from shareholder loan)	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(1,100)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	-	(1,100)

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,095	982
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(938)	3,283
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(8)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(1,100)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	3,157	3,157

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	3,157	4,095
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	3,157	4,095

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current
quarter
\$A'000

163

-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

6.1 Aggregate payments to related parties of \$163k includes 3 months payments of non-executive Directors fees and payments to Mr. Karolis Rosickas (Consulting CEO)

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 Unused financing facilities available at quarter end

-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

As per announcement on the 30th October the loan facility of \$4.0 million provided by Paddington St Finance and Leo Lee have been cancelled, following a final principal repayment of \$1.1m

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9) (net of receipt)	(938)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	3,157
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	3,157
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	3.36

Note: If the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6

If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 30th April 2021

Authorised by: By the board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.