

ASX Announcement

28 January 2022

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

Highlights

- Feedback received from the FDA Office of Tissues and Advanced Therapies advances the preparation for the IND Application submission
- Appointment of Dr Scott Bruder as Board Advisor to drive Regeneus' US growth strategy
- Next milestone payment of US\$3.0m from Kyocera to be received in Q2 CY2023 following variation agreement signed in November 2021
- Further patent for Progenza™ has been allowed in Japan protecting the Company's product until September 2036
- Next step discussions commence with the Australian Department of Defence with the near completion of the first preliminary study at the University of Adelaide
- Termination of agreement with New Life Sciences Capital, LLC as Regeneus explores further non-dilutive funding for growth
- Cash balance of A\$1.66 M at 31 December 2021, with continued focus on capital efficiency

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 December 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 pain management and dermatological conditions.

US Strategy update and IND filing

Regeneus had a Pre-IND consultation (Type B meeting) with the FDA in November 2021 with the objective to file an Investigational New Drug (IND) application and initiate a Progenza OA Phase 2 clinical trial in the US. The Company received Informative feedback from the FDA Office of Tissues and Advanced Therapies (OTAT) which will enable it to move forward with the preparation for the IND application submission.

As part of the Company's US strategy, it is focusing on and prioritising securing a strategic partner in the US and today announced it has appointed Scott Bruder MD, PhD as Board Advisor.

Dr Bruder is a leading US based physician-scientist executive in the regenerative medicine and orthopedics industry who provides strategic consultancy in technology, product and market development, clinical and regulatory affairs, reimbursement and health economics, and commercialization strategy for regenerative medicine companies via his company, Bruder Consulting & Venture Group.

Regeneus and Bruder Consulting & Venture Group commenced a strategic relationship agreement in 2021 and his appointment as Board Advisor will assist the Company in accelerating its strategic partnering discussions in the US.

Partnership with Kyocera Corporation

Further to the execution of a Variation Agreement in September 2021, Regeneus and Kyocera continue collaborating on commencing manufacturing of Progenza in Japan and launching a Phase 2 trial. Setting up manufacturing is in progress and the Company will update the market on developments in due course.

Under the terms of the agreement, the Company's next milestone payment of US\$3.0m remains on track to be received in Q2 CY2023.

Additionally, and as part of the ongoing development program with Kyocera, a new patent has been allowed in Japan (file number JPO 2018-530940) protecting the Company's Progenza™ product until September 2036.

First Department of Defence animal study concludes

Regeneus concluded the first animal study in Sygenus development partnership with the Australian Department of Defence for combat casualty care research. The study was conducted by Prof. Mark Hutchinson at the University of Adelaide.

Regeneus and the Department of Defence have now engaged in further discussions and will update the market in due course.

Financial update

As announced during the quarter, the Company's Board of Directors together with New Life Sciences Capital, LLC mutually agreed to terminate the Subscription Agreement relating to a three-stage placement that was entered into in May 2021, and as such no further investments are to be made by, or shares issued to, New Life Sciences under the Subscription Agreement.

This comes as the Company announced it is in advanced and ongoing discussions with alternative non-dilutive funding partners to secure growth funding on more favourable terms for its shareholders.

Regeneus is also 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.

The Company's cash balance at 31 December 2021 was A\$1.66 M. Net operating cash outflow for the quarter was A\$758k which is attributed to research and development costs as well as staffing and corporate costs. The Company continues to maintain its strict focus on operating costs with efficient capital spend and a reduction in overhead costs.

Aggregate payments to related parties of \$304k includes payments of Directors fees, payments to Mr. Karolis Rosickas consulting CEO role plus \$125k bonus and rent paid to a company associated with one of the directors.

Outlook

2022 will represent a year of strategic importance for Regeneus' growth and clinical development as it continues to support Kyocera with the set up of manufacturing operations and the design of a pivotal phase 2 clinical trial in Japan.

Furthermore, in order to materially progress its US development strategy, the Company is focused on securing a strategic partner to develop Progenza osteoarthritis for the US market.

-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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Appendix 4C

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

Name of entity		
Regeneus Ltd		
ABN	Quarter ended ("current quarter")	
13 127 035 358	31 st December 21	
Consolidated statement of cash flows	Current quarter \$A'000	Year to date (.....months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	20
1.2 Payments for		
(a) research and development	(498)	(1,138)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	(11)	(22)
(e) staff costs (including Directors)	(554)	(932)
(f) administration and corporate costs	(524)	(878)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	829	829
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(758)	(2,121)
1.2 (a) Research and development costs in relation to the production of Progenza and Sygenus technologies		
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(8)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (.....months) \$A'000
(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	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
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	-	-

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	2,422	3,793
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(758)	(2,129)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (.....months) \$A'000
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)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	1,663	1,663

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	1,663	2,422
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)	1,663	2,422

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	304
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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 \$304k includes payments of Directors fees, payments to Mr. Karolis Rosickas consulting CEO role plus \$125k bonus and rent paid to a company associated with one of the directors.

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
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.		

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)	(758)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,663
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,663
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.2
<i>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.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 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:	
8.6.2 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:	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer:	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

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:28 January 2022.....

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.