

ASX Announcement

29 April 2022

Quarterly Cashflow Report & Business Update – Period ending 31 March 2022

Highlights

- Regeneus secures non-dilutive A\$4.0m loan financing against Kyocera's upcoming US\$3.0m milestone payment
- Working together with Kyocera to set up a manufacturing process for Progenza™ in Japan
- Initiated a partnership search processes for Progenza OA in the United States, China, and South Korea
- Continuing animal studies for Sygenus as per the Collaboration Agreement with the Australian Department of Defence
- Strengthens its patent position globally with a new patent granted in China
- Scott Bruder MD PhD appointed as Adviser to the Regeneus Board
- Cash balance of A\$0.5 M at 31 March 2022 with an additional undrawn A\$3.0m loan facility with sufficient runway to earn future milestone payments from Kyocera and commercialise Progenza™ in Japan

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 2022 (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

After the Pre-IND Consultation with the FDA in November 2021, the Company seeks clarifications from the FDA before preparing to submit an IND Application. At the same time, Regeneus is actively searching for strategic partners to co-develop Progenza™ for knee osteoarthritis in the United States.

Partnership with Kyocera Corporation

Regeneus and Kyocera are currently working together to set up a manufacturing process for Progenza™ in Japan. Regulatory discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) are ongoing as they move closer to the launch of the pivotal Phase 2 trial and the commercialisation of Progenza™ in Japan.

Global search for additional partners for commercialisation of Progenza™

In addition to the active partnership with Kyocera in Japan, Regeneus has initiated a structured partnership search processes for Progenza™ OA in the United States, China, and South Korea.

Recently appointed Regeneus Board Advisor Dr. Scott Bruder and his Bruder Consulting team are leading the search in the United States. The Company has also appointed experienced advisors with a track record in executing successful in-licensing partnerships in knee osteoarthritis in China and South Korea.

Department of Defence animal study update

Regeneus is continuing its animal studies for Sygenus as per the Collaboration Agreement with the Australian Department of Defence. The study is being conducted by Prof. Mark Hutchinson at the University of Adelaide and international research collaborators.

The Company will provide updates in due course.

Strengthening global patents

Regeneus continues to strengthen its patent position globally with a new patent granted in China, namely Patent Application No. 201680054321.7 The patent covers cell expansion methods and therapeutic compositions for Progenza™ in China.

Scott Bruder MD PhD appointed as Adviser to the Board

Renowned physician-scientist executive in the orthobiologics industry, Dr. Scott Bruder joined Regeneus as Board Advisor, effective 1 February 2022. Dr Bruder brings more than 30 years leadership experience taking clinical regenerative medicine and orthopedic products through to commercial success.

Financial update

In February, Regeneus received non-dilutive A\$4.0m loan financing from Paddington Street Finance Pty Ltd against Kyocera's upcoming US\$3.0m milestone payment expected in Q2 CY2023. Given the challenges currently facing capital markets for biotechnology stocks globally, this funding structure is competitive and ensures no dilution to Regeneus shareholders.

The remaining balance of the placement of shares instrument was repaid to New Life Sciences LLC in January 2022.

With the revised underlying cost structure of Regeneus and available short-term debt funding, the Company does not expect to raise additional capital to meet its remaining obligations to Kyocera for the commercialisation of Progenza™ in Japan.

Details of the loan facility agreement with Paddington St Finance Pty Ltd are:

- Agreement entered into on 25 February 2022
- The maximum loan value of the facility is the lesser of (i) A\$4.0m; or (ii) US\$3.0m, with an interest rate of 1.0% per month and a 3.0% arrangement fee
- The secured loan will be repaid on or before the earlier of: (a) 30 September 2023; and (b) the date on which Regeneus receives the milestone payment of US\$3.0m under the agreement with Kyocera

Aggregate payments to related parties of \$198k includes

- Payments of Directors fees,
- Payments to Mr. Karolis Rosickas consulting CEO role,
- Rent paid to a company associated with one of the directors and
- \$30k loan arrangement fee paid to a company associated with one of the directors

Outlook

The remainder of 2022 represents a strategically important period of Regeneus as it works closely with its existing partners including Kyocera towards commercialising Progenza™ and seeks licensing partners for Progenza™ in the United States, China and South Korea.

As Regeneus works towards increasing its global footprint, it is also exploring value accreting M&A opportunities to deliver stronger shareholder returns and value.

-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 osteoarthritis, neuropathic pain, 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 March 22	
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	(274)	(1,413)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	(11)	(32)
(e) staff costs (including Directors)	(320)	(1,252)
(f) administration and corporate costs	(266)	(1,144)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	-	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	829
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(871)	(2,993)
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	1,000	1,000
3.6 Repayment of borrowings	(1,263)	(1,263)
3.7 Transaction costs related to loans and borrowings	(30)	(30)
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
3.10 Net cash from / (used in) financing activities	(293)	(293)

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	1,663	3,793
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(871)	(2,993)

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)	(293)	(293)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	499	499

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	499	1,663
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)	499	1,663

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	198
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 \$198k includes <ul style="list-style-type: none"> - payments of Directors fees, - payments to Mr. Karolis Rosickas consulting CEO role, - rent paid to a company associated with one of the directors and - \$30k loan arrangement fee paid to a company associated with one of the directors
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7. Financing facilities <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>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	4,000	1,000
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	4,000	1,000
7.5 Unused financing facilities available at quarter end		3,000
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.		
<p>Regeneus Ltd entered into a loan facility agreement with Paddington St Finance Pty Ltd on 25 February 2022.</p> <p>The maximum loan value of the facility is the lesser of (i) A\$4 million; or (ii) US\$3 million, with an interest rate of 1% per month and a 3% arrangement fee.</p> <p>The secured loan will be repaid on or before the earlier of: (a) 30 September 2023; and (b) the date on which Regeneus receives the milestone payment of US\$3 million under the agreement Kyocera.</p>		

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)	(871)
8.2 Cash and cash equivalents at quarter end (item 4.6)	499
8.3 Unused finance facilities available at quarter end (item 7.5)	3,000
8.4 Total available funding (item 8.2 + item 8.3)	3,499
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.0
<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 April 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.