ASX Announcement
29 July 2021

Quarterly Cashflow Report & Business Update – Period ending 30 June 2021

Highlights

- Australian Department of Defence to provide A$300k funding to develop Sygenus for combat casualty care with first in human study on pain
- Up to $4.5 million secured in three-stage placement to fund initiation of Progenza™ Osteoarthritis (OA) Phase 2 trial in the US and for general working capital needs.
- Kyocera collaboration on Progenza™ OA in Japan continues to move forward, with initial manufacturing and clinical development preparations.
- Cash balance of A$3.79 million at 30 June 2021 with the Company now operating fully in its new streamlined, optimised structure while maintaining focus on key R&D and market development activities.

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 30 June 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.

Progenza™

Over the quarter, preparatory work has continued in partnership with Kyocera to progress Phase 2 and move towards application for regulatory approval of Progenza™ for the treatment of knee osteoarthritis (OA) in Japan. An agreement in principle is currently being finalised with Kyocera to undertake some additional non-clinical[i] and manufacturing process work needed prior to commencement of Phase 2 clinical trial in Japan. Initial manufacturing work has commenced as well as early engagement with the Japanese regulator, PDMA. Regeneus anticipates receipt of the next milestone payment of US$3.0M under its collaboration and licence agreement with Kyocera in December 2022.

Regeneus announced[i] post quarter end that it had entered into a research collaboration with Professor Christopher Little and the Raymond Purves Bone and Joint Research Laboratories at the Kolling Institute of Medical Research at Royal North Shore Hospital, Australia. The study will support the Progenza™ clinical program, further exploring the disease modifying effects of Progenza™ and assess Progenza™'s effect in modulating the inflammatory and immune responses in a pre-clinical model of post-traumatic osteoarthritis.

In the US, Regeneus has initiated the US FDA pre-IND consultation preparation process, working with regulatory consultants and global clinical research organisation IQVIA, with an anticipated meeting with the FDA in Q4 CY2021. The Company has also entered into a manufacturing agreement for the US GMP final product and has started to conduct the required non-clinical work[i] for the US market.

The US Progenza™ OA Phase 2 trial is anticipated to launch in Q2 CY2022 subject to securing further additional funding. Regeneus is actively exploring options for this additional funding to progress Progenza™ into Phase 2 trials and beyond in the US market. These include public development funding opportunities, future licensing and commercialisation partnerships, and potential future capital raising activity.

Regeneus is committed to pursuing all potential options to develop and commercialise Progenza™ for the US market where there remains large unmet medical need in treating knee osteoarthritis and significant market potential for next generation therapeutics.

Sygenus

During the quarter, Regeneus announced[ii] 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[iii] how the analgesic effect of Sygenus is more potent and longer lasting than morphine which is the current mainstay for acute severe battlefield pain. The funding is part of the Defence Industry Competitive Evaluation Research Agreement (ICERA[iv]) which will fund eligible Australian small to medium sized enterprises with up to A$300,000 per project for up to 18 months.

Institutional Placement

In the quarter the Company secured[v] up to A$4.5 million in a three-stage placement of the Company's ordinary shares to New Life Sciences Capital, LLC, a U.S.-based institutional investor. The placements are made by way of the investor pre-paying each of the three subscription amounts for the shares in a lump sum, each of A$1.5M. The initial placement of A$1.59M shares to raise A$1.5M has been made, with the second and third placements planned to occur in the 6 months (anticipated November 2021)

and 12 months (anticipated May 2022) post announcement. Funds from the Placements will be used to accelerate the work needed to initiate a Progenza™ OA Phase 2 trial in the US and to fund general working capital needs. This includes working with regulatory consultants in preparation for pre-IND consultation with the FDA, initiating GMP final product manufacturing, and preparatory work with Clinical Research Organisations to conduct the Phase 2 trial.

Financial update

The Company's cash balance at 30 June 2021 was A$3.79M. Net operating cash outflow for the quarter was A$0.86M which is attributed to continuing R&D activities, staffing and corporate costs.

Regeneus is now operating in its newly optimised structure, with costs having been streamlined, ensuring key R&D activities and business development is supported to drive successful development of Progenza™ and Sygenus. The Company will continue to 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$225k for the quarter includes three months payments of non-executive Directors fees and payments to Mr. Karolis Rosickas in his role as Consulting CEO and on achievement of a successful capital raise in the period.

Outlook

Regeneus CEO Karolis Rosickas said, "I'm pleased to provide this update to shareholders at the close of this quarter. Our partnership with the Australian Department of Defence to develop Sygenus for treating combat casualties was an exciting development for the Company in the quarter, moving into the next step in development of Sygenus with a first in human study for pain.

Our collaborative partnership with Kyocera also continues to move forward successfully towards commencing Progenza™ OA Phase 2 in Japan. The new funds raised have also given us access to capital to quickly complete the preparatory work needed to initiate a Progenza™ US Phase 2. We are actively pursuing additional funding to initiate a US Phase 2 trial and are in discussions with several large pharmaceutical and orthopaedic companies to explore strategic partnerships and licensing opportunities for Progenza™ outside Japan.

I look forward to sharing progress with shareholders as we explore all the available options and move forward in progressing on 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 announcement 28 July 2021, R&D Collaboration with Kolling Institute
[ii] ASX announcement 29 April 2021, Regeneus partners with Defence to treat combat casualties
[iii] 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
[iv] About ICERA: https://www.dst.defence.gov.au/icera
[v] ASX Announcement 7 May 2021, Regeneus Announces Institutional Placement

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	30th June 21

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	7,659
1.2	Payments for		
	(a) research and development	(306)	(704)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(2)	(6)
	(e) staff costs (including Directors)	(478)	(2,614)
	(f) administration and corporate costs	(77)	(2,208)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(1)	(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**	**(864)**	**2,419**

1.2 (a)	Research and development costs in relation to the production of Progenza and Sygenus technologies

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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)	1,500	1,500
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**	**1,500**	**400**

3.1 Proceeds from issues of equity securities relates to the receipt of the first $1.5m tranche from the recent capital raised announced to the market on the 7th May 2021.

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 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	3,157	982
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(864)	2,419
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)	1,500	400
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**3,793**	**3,793**

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	3,793	3,157
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)**	**3,793**	**3,157**

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	225
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 $225k includes 3 months payments of non-executive Directors fees and payments to Mr. Karolis Rosickas for his bonus in relation to a successful capital raise and his consulting CEO role.

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.

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)	(864)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	3,793
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	3,793
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	4.39

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:

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:

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.

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: .. 29th July 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.