ASX Announcement
29 October 2021

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

Highlights

- Progenza™ collaboration with Kyocera continues to successfully progress, with initial clinical development and manufacturing preparations in place
- New research collaboration with Raymond Purves Bone and Joint Research Laboratories at the Kolling Institute of Medical Research, Australia will support Progenza™ clinical programs in Japan and US
- Sygenus development partnership with Australian Department of Defence for combat casualty care continues with research conducted by Adelaide University and first in human study anticipated early 2022
- Cash balance of A$2.42M at 30 September 2021, with continued focus on operating costs
- Regeneus continues to pursue additional funding to initiate Progenza™ US Phase 2 study and strategic partnerships and licensing opportunities outside 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 30 September 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™

Continued momentum with Kyocera

The Company's partnership with Kyocera continues to progress well in preparation for a Phase 2 trial, and towards its application for regulatory approval of Progenza™ for the treatment of knee osteoarthritis (OA) in Japan. Regeneus anticipates receipt of the next milestone payment of US$3.0m in December 2022, under its collaboration and licence agreement with Kyocera.

Research collaboration at Kolling Institute to support phase 2 trial

In the quarter, Regeneus secured a research collaboration with the Raymond Purves Bone and Joint Research Laboratories at the Kolling Institute of Medical Research at Royal North Shore Hospital, Australia.

Under the collaboration, Regeneus and the Kolling Institute will undertake additional non-clinical and manufacturing process research the Company anticipates it will need prior to commencing its Phase 2 clinical trial in Japan in 2022.

The research which will be led by Professor Christopher Little, will support the Progenza™ clinical program, further exploring the disease modifying effects of Progenza™ and evaluating Progenza™'s effect in modulating the inflammatory and immune responses in a pre-clinical model of post-traumatic osteoarthritis.

Early engagement with the Japanese regulator continues, and the research project has commenced.

Dr Cindy C Shu joins Regeneus research following REDI fellowship grant

The Company also welcomed Dr Cindy C Shu from the Kolling Institute and University of Sydney as research fellow, following receipt of the MTPConnect REDI Fellowship Grant[i].

Dr Shu brings expertise in osteoarthritis pathophysiology, animal models and immune cell analysis and she will work with Regeneus to progress its work on Progenza™, and further develop skills in the key commercial aspects of therapeutic development that the Company is undertaking.

MTPConnect deploys the REDI (Researcher Exchange and Development within Industry) program, supported by the Medical Research Future Fund, to provide financial support of up to A$250k per fellow, per year to medical, technology or pharmaceutical companies (MTP) to bring the best talent in-house to work on priority medical research projects.

Ongoing research to support US FDA pre-IND and GMP preparations

In the US, Regeneus continues its US FDA pre-IND consultation preparation, working with regulatory consultants and global clinical research organisation IQVIA, with feedback from the FDA anticipated in late Q4 CY2021.

Non-clinical work required for the US market will be supported by the research collaboration with the Kolling Institute and the Company is now progressing on US GMP final product preparations with its manufacturing partner.

Regeneus anticipates the launch of its US Progenza™ OA Phase 2 trial Q2 CY2022 subject to receipt of Investigational New Drug (IND) approval from the FDA. The Company is actively pursuing many avenues of available funding to progress Progenza™ into the Phase 2 trial in the US, which includes non-dilutive funding opportunities, future licensing and commercialisation partnerships.

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

Sygenus, Regeneus' stem cell bioactive secretome technology, development program for combat casualty care is progressing well with research being conducted by Professor Mark Hutchinson's group at Adelaide University.

The Company previously announced[ii] its partnership with the Australian Department of Defence to develop Sygenus for combat casualty care and the 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, anticipated in early 2022.

Financial update

The Company's cash balance at 30 September 2021 was A$2.42M. Net operating cash outflow for the quarter was A$1.36M which is attributed to additional foreseen one-off R&D and manufacturing costs as well as staffing and corporate costs. The Company continues to maintain its strict focus on operating costs.

AGM

Regeneus' AGM will be held on Thursday 18 November at 3.00pm (Sydney/AEDT time) as a virtual meeting. Full details have been shared with ASX and shareholders.[iii]

Outlook

Regeneus CEO Karolis Rosickas said, "I'm pleased to provide this update at the close of the quarter, following our investor webinar earlier this week outlining our progress to date. Our partnership with Kyocera continues to move towards Phase 2 studies with Progenza™ for knee osteoarthritis, and we are in preparation for our FDA pre-IND consultation meeting towards the end of the year.

Our research collaboration with Kolling Institute initiated this quarter will support non-clinical work needed for our Progenza™ programs in Japan and the US to move forward. I'm also delighted to welcome Dr Shu to Regeneus, her expertise is highly applicable to our current focus and the REDI Fellowship will be invaluable.

Investors will be aware that we actively pursuing additional funding to initiate our US Phase 2 Progenza™ study and are exploring strategic partnerships and licensing opportunities for Progenza™ outside Japan. I look forward to being able to update shareholders in due course as we continue to evaluate all available options.

-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] REDI Fellowships Awarded to Researchers in NSW to Boost Medical Research Commercialisation Capability, MTP Connect, 20 August 2021: https://www.mtpconnect.org.au/Story?Action=View&Story_id=400

[ii] ASX announcement 29 April 2021, Regeneus partners with Defence to treat combat casualties

iii ASX announcements 15 October 2021 Notice of AGM, Virtual AGM Online Guide.

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 September 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	20	20
1.2	Payments for		
	(a) research and development	(723)	(723)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(11)	(11)
	(e) staff costs (including Directors)	(460)	(460)
	(f) administration and corporate costs	(189)	(189)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,363)**	**(1,363)**

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)	(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)**	**(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	-	-
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**	**-**	**-**

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	3,793	3,793
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,363)	(1,363)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	(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**	**2,422**	**2,422**

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	2,422	3,793
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)**	**2,422**	**3,793**

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	159
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 $159k includes 3 months payments of Directors fees, payments to Mr. Karolis Rosickas consulting CEO role and rent paid to a company associated with one of the directors.

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)	(1,363)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	2,422
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	2,422
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	1.78

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: No. Current quarter net operating cash flows included one-off payment of A$107k related to the research collaboration with Kolling Institute and Progenza manufacturing costs of A$236k. The underlying net operating cash flows for the company are expected to be A$250k-300k per month going forward.

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: As a clinical stage biotechnology company, Regeneus Ltd continues to assess various funding options including non-dilutive revenue financing, future licensing deals, and other options. The company has confidence in its ability to raise capital in the near term.

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: Yes. The company has sufficient cash balance to cover its underlying cash flow needs.

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: .. 29 October 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.