ASX Announcement
21 July 2022

Quarterly Cashflow Report & Business Update – Period ending 30 June 2022

Highlights

- Search for strategic partners to co-develop Progenza™ continues in the US, South Korea and China
- Kyocera had further consultations with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan regarding regulatory compliance
- Regeneus delivers clinical milestone with completed study at the Kolling Institute with positive results
- CEO Karolis Rosickas cements support with 3.8M share purchase
- RGS remains well capitalised to complete its clinical pipeline with a cash balance of A$95k and an undrawn credit facility of A$3.0M at 30 June 2022

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 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), with positive preclinical study results from the Kolling Institute. Regeneus also progressed the development of Sygenus for pain management and dermatological conditions.

With cash balance of A$95k and an undrawn credit facility of A$3.0M, Regeneus starts FY23 well positioned to continue the development of Progenza™ with a focus on commercialization.

US Strategy update
Regeneus is continuing its search for a strategic partner to co-develop Progenza™ for knee osteoarthritis in the United States and is in conversations with 70 parties. Discussions are ongoing and select companies are conducting detailed due diligence of Progenza™ non-clinical, CMC, and clinical data. The process continues to be led by Regeneus Board Advisor Dr Scott Bruder and his team at Bruder Consulting and Venture Group.

Global search for additional partners for commercialisation of Progenza™
In South Korea, over 30 companies have been contacted with discussions ongoing, and due diligence has commenced with multiple companies. Regeneus has engaged Korea Development Bank (KDB) to run the process. KDB previously advised on successful licensing of Biosplice's lorecivivint OA drug in 2021 in South Korea.

In China, Regeneus has engaged YAFO Capital to run a licensing process for Progenza. 60 companies have been contacted with ongoing due diligence continuing with selected parties. YAFO Capital has previously successfully closed licensing deals for Biosplice's lorecivivint and Flexion's Zilretta small molecule OA drugs in China and has strong access to pharmaceutical and biotechnology companies interested in OA assets.

Partnership with Kyocera Corporation
During the quarter, Kyocera had further consultations with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan regarding Progenza non-clinical and CMC data. Further consultations are planned in calendar year 2022 as the Company moves closer to the commencement of the pivotal Phase 2 trial and the commercialisation of Progenza™ in Japan.

Preclinical studies
In a significant clinical milestone, Regeneus successfully completed its study at the Kolling Institute during the quarter delivering positive results. The purpose of the study was to demonstrate proof-of-concept efficacy of Progenza™ in the destabilization of the medial meniscus (DMM) model in 384 mice. The study explored the disease-modifying effect of different therapeutic formulations and their effect in modulating the inflammatory and immune response in a mouse model of post-traumatic osteoarthritis.

Specific study results include:

- The effect on structural pathology of the Progenza™ formulation was superior to that seen with mouse MSCs or hyaluronic acid, both with regard to effect size and the number of tissue pathologies modified.

  Hyaluronic acid showed no structural pathology improvements in this model. Progenza™, however demonstrated not only pain reduction effects, but also structural pathology changes to support Progenza™ becoming the first Disease-Modifying Osteoarthritis Drug (DMOAD).

- The Progenza™ treatment showed a significant reduction in pain (by Von Frey measurements of tactile allodynia) compared to a cells-only preparation without secretome added and compared to vehicle control and surgery-only groups. This concludes the therapeutic benefit on pain provided by the Progenza™ MSCs plus secretome formulation.

- Additional analysis of various immune cell populations has also shown some significant differences, especially in the anti-inflammatory balance of T cells and Macrophages, which helps to further understand the immunomodulatory mechanisms of action of Progenza™.

The study was a significant part of Additional Data agreed to be provided to Kyocera in the Variation Agreement signed in 2021.

Furthermore, Regeneus completed "An mRNA-SEQ study of the benefit of the MSC secretome" study. The report was submitted to Kyocera and further demonstrates

the benefit of secretions and will be used in discussions with various regulators globally.

In regard to Sygenus, Regeneus is currently conducting a preclinical study in the post operation pain (POP) model with MD Biosciences in Israel. Further, Regeneus is entitled to receive A$93k in milestone payments from the Department of Defence next quarter under the terms of its Collaboration Agreement in respect of this study.

The University of Technology Sydney (UTS) study conducted by Dr. Majid Warkiani has been presented with a manufacturing scale-up opportunity to further reduce cost of goods manufacture of Progenza™. UTS has developed a unique 3D printed system for harvesting stem cells from bioreactors, offering the potential for high quality, wide-scale production of stem cells in Australia at a lower cost.

Strategic transactions

The Company continues to explore various M&A options globally to extract operational, manufacturing and clinical development synergies. Small biotech companies were severely affected by the recent global downturn since the sector peaked in February 2021 and as a result, more companies are now open to exploring strategic options and discussions are ongoing.

Events

To support the Company's business and commercial development strategy Chief Executive Officer Karolis Rosickas attended and presented in a series of events including the BIO Korea in Seoul, the ISCT Annual Meeting in San Francisco, and the BIO Convention in San Diego.

Financial update

Regeneus closed the quarter with a cash balance of A$95k and an undrawn credit facility of A$3.0M. The Company remains in a highly capital efficient position, operating on an ongoing concern basis.

Aggregate payments to related parties of $175k 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
- $40k interest paid to a company associated with one of the directors

Financing

Regeneus remains well capitalised to continue its complete its clinical activity having secured a A$4.0M credit facility against the next milestone payment from Kyocera. Regeneus is fully funded and does not need to raise capital to support ongoing operations.

A$348k in additional proceeds were generated from selling approximately 8.0M shares from shareholders. These shareholders took out loans from the company to exercise their stock options before the Company's IPO in 2013. The Company sold 4.2M shares in the market in April and May. Cementing his support for Regeneus and its growth strategy, Chief Executive Officer, Karolis Rosickas purchased the remaining 3.8M fully paid ordinary shares off market from existing shareholders.

Outlook

Regeneus is focused on bringing Progenza™ to market in Japan through its partnership with Kyocera. Japan represents a significant market opportunity given its accelerated approval pathway for Progenza™.

The Company is currently running active processes to find strategic licensing partners in the US, South Korea and China. Management is actively involved in multiple discussions and due diligence processes.

Regeneus is also engaged in various M&A discussions to leverage operational, manufacturing and clinical development synergies with other biotechnology companies.

-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

Investor and Media Contact
Hannah Howlett, WE Communications
T: 04 5064 8064
E: hhowlett@we-worldwide.com

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 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	(136)	(1,476)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(7)	(39)
	(e) staff costs (including Directors)	(242)	(1,550)
	(f) administration and corporate costs	(173)	(1,334)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(40)	(41)
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**	**(598)**	**(3,591)**

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	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (.....months) $A'000
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 (Loan repayment from shareholders)	194	194
2.6	**Net cash from / (used in) investing activities**	**194**	**(186)**

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
3.6	Repayment of borrowings	-	(1,263)
3.7	Transaction costs related to loans and borrowings	-	(30)
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**(293)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	499	3,793
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(598)	(3,591)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	194	186

Consolidated statement of cash flows		Current quarter $A'000	Year to date (.....months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(293)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**95**	**95**

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	95	499
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)**	**95**	**499**

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	175
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 $175k 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
- $40k interest 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	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.

Regeneus Ltd entered into a loan facility agreement with Paddington St Finance Pty Ltd on 25 February 2022.

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.

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.

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)	(598)
8.2	Cash and cash equivalents at quarter end (item 4.6)	95
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)	3,095
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.2

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: .....21 July 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.