

Regeneus Ltd
ABN 13 127 035 358

ASX Half-Year Report for 6 months to 31st December 2022

Provided to the ASX under Rule 4.2.A.3

This report is to be read in conjunction with the Annual Report for the year ended 30th June 2021 and any public announcements made during the reporting period, in accordance with the continuous disclosure requirements of the Australian Stock Exchange Listing Rules and the Corporations Act 2011.

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Half-Year Report for the 6 months to 31st December 2022

Regeneus Ltd – ABN 13 127 035 358

Reporting period

Report for the half-year ended 31st December 2022

Corresponding period is for the half-year ended 31st December 2021

Results for announcement to the market

	Up/Down	% change		\$'000's
Revenue from ordinary activities	Up	41%	to	28
Profit/(Loss) from ordinary activities after tax attributable to members	Down	-9%	to	(2,436)
Net Profit/(Loss) from ordinary activities attributable to the member	Down	-9%	to	(2,436)
It is not proposed to pay any dividend				
Full details are in the attached accounts.				

Net Tangible assets per security

The net tangible assets (liabilities) per security

31st December 2022 (\$0.003) cents

31st December 2021 \$0.008 cents

Independent review of the financial information

The independent auditor review is attached to the half-year financial statements.



Half-Year Report

31 December 2022

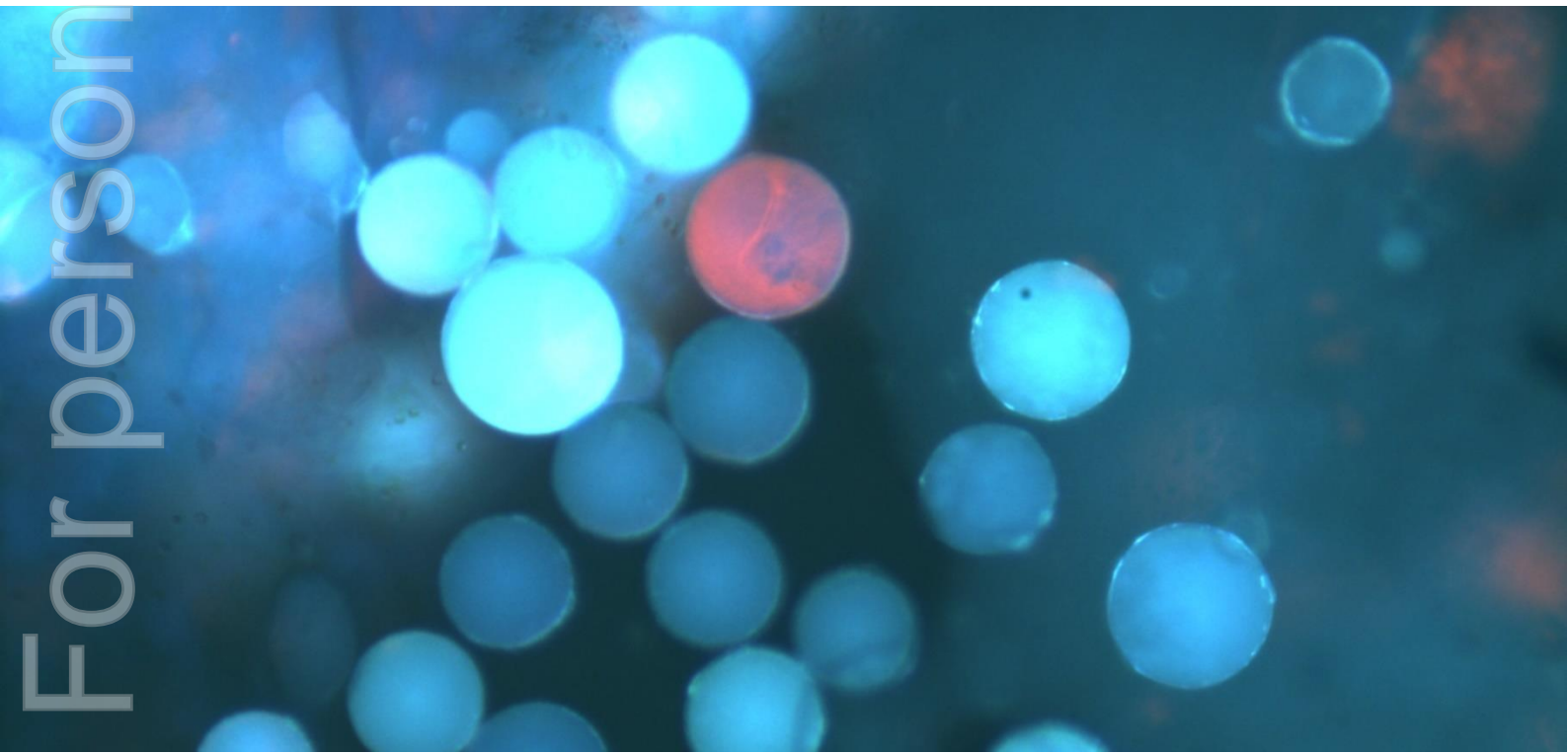


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01 Directors' Report

Your Directors present their half-year report for Regeneus Ltd (**Regeneus** or the **Company**) and its controlled entities (the **Group**) for the half-year ended 31 December 2022, in order to comply with the provisions of the Corporations Act 2001. The Directors' report the following information.

1. Directors

The following persons were Directors of Regeneus during the whole of the half-year and up to the date of this report, unless otherwise stated.

Name	Position
Barry Sechos	Non-executive Chairman, member of the Remuneration and Nominations Committee, Chair of the Audit and Risk Committee
Leo Lee	Non-Executive Director, Chair of the Remuneration and Nominations Committee, member of the Audit and Risk Committee
Professor Graham Vesey	CSO and Executive Director

2. Review of operations

Overview and strategy

- Regeneus is an ASX-listed clinical stage regenerative medicine company using stem cell technologies to develop a portfolio of novel cell-based therapies focused on neuropathic pain, including osteoarthritis and various skin conditions. The Company has two platform technologies, Progenza™ and Sygenus.
- In August 2020 Regeneus entered into an exclusive licence and collaboration agreement (**Licence Agreement**) with Japanese manufacturer Kyocera Corporation (**Kyocera**) for the commercialisation of Progenza™ to treat knee osteoarthritis in Japan.
- On 27 January 2023 Regeneus received a notice of termination (**Notice**) from Kyocera under the Licence Agreement. The Notice purports to terminate the Agreement for Kyocera's failure to meet its Development Target relating to establishment of first Standard Operating Procedures for the manufacture of Progenza™ for the clinical trial to be held in Japan by the required date – being 30 September 2022. Regeneus maintains a position that Kyocera did not exercise commercially reasonable efforts as defined in the Collaboration Agreement and, therefore, that Kyocera does not have any right to terminate the Agreement. The parties are currently undertaking dispute resolution procedures in accordance with the terms of the Licence Agreement.
- As a result of the purported termination of the Licence Agreement, Kyocera has indicated that no further milestone payments will be made under the Licence Agreement.
- The Company has initiated discussions with other potential partners for licensing the Progenza™ knee osteoarthritis product in Japan.
- The Company is searching for strategic partners to co-develop Progenza™ for knee osteoarthritis around the globe. Strategic partnering processes in the United States, China, and South Korea are ongoing.
- The Company continues exploring various M&A options globally to extract operational, manufacturing and clinical development synergies.
- Regeneus continues to progress the development partnership entered into with the Australian Department of Defence for combat casualty care with research conducted in collaboration with the University of Adelaide.
- Regeneus will continue to explore co-development and licensing options for Sygenus to treat burns and wounds, neuropathic pain, inflammatory skin conditions, and rare/orphan skin diseases globally.
- A Research & Development tax incentive of approximately \$1.1 million was received from the Australian Government's Research & Development tax incentive program for activities conducted during FY2022.
- In February 2022 the Company secured a cashflow facility (the **PSF Facility**) from Paddington St Finance Pty Ltd, a related party. As at 31 December 2022 a total of \$2 million was drawn, and remains owing, under the PSF Facility. Interest under the PSF Facility has been paid through to 31 December 2022.
- Regeneus has reached agreement to settle the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of \$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio Pty Ltd (**Sangui Bio**) by 31 August 2023. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.

Disposal of non-core assets

- Regeneus is exploring opportunities to dispose of non-core assets to improve the Company's liquidity position. For example, Regeneus has accumulated Good Manufacturing Practices (GMP) grade and non-GMP grade donor material in excess of its current, and anticipated future, needs. The Company is in discussions with external parties to sell the donor material (stromal vascular fraction or isolated mesenchymal stem cells). The sale of select donor material, if achieved, is expected to improve the Company's liquidity position.

01 Directors' Report

3. Financial results

Operating results

The Group's operating result for the 6-month period to 31 December 2022 (H1 FY2023) was a loss of \$2.44m, compared to results of loss of \$2.69m for the previous corresponding period (H1 FY2022).

Revenue and gross margin from continuing operations

Revenue for the 6-month period to 31 December 2022 was \$28k. This is in relation to collaboration with Kyocera on commencing manufacturing of Progenza in Japan.

Other income

The Group's research and development activities are eligible expenditure under the Australian Government tax incentive.

The R&D tax incentive recognised in the Consolidated Statement of Profit or Loss for the period to 31 December 2022 is \$0.8m (31 December 2021: \$0.4m).

Events subsequent to the end of the reporting date

On 27 January 2023 Regeneus received a notice of termination (**Notice**) from Kyocera under the Licence Agreement. The Notice purports to terminate the Agreement for Kyocera's failure to meet its Development Target relating to establishment of first Standard Operating Procedures for the manufacture of Progenza for the clinical trial to be held in Japan by the required date – being 30 September 2022. The Company does not accept that Kyocera has any right to terminate the Agreement and the dispute resolution procedures under the Agreement have commenced. Regeneus is considering its legal position.

As a result of the purported termination of the Licence Agreement, Kyocera has indicated that no further milestone or other payments will be made under the Licence Agreement.

Regeneus has reached agreement to settle the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of \$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio by 31 August 2023. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.

There has not arisen in the interval between 31 December 2022 and the date of this report, any other event that would have had any material effect on the Financial Statements at 31 December 2022.

Expenses from continuing operations

Research and Development

Expenditure on research in the half-year period to 31 December 2022 was \$399k compared to 31 December 2021 of \$1.4m.

The current accounting policy, and to comply with the accounting standards, is that all costs incurred for research are fully expensed. This policy is being continually reviewed as products move toward licensing and commercialisation.

Corporate

Corporate expenses at approximately \$0.9m in half year FY2023 compared to \$1.6M in the previous corresponding period. This is attributed to 'non-cash' cost of options of \$0.3M and the reduction of administration and overhead costs.

Occupancy

Occupancy expenditure at \$8k in half year FY2023 (31 December 2021: \$40k) The occupancy cost is minimal because Regeneus reduced the size of laboratory space leased in Belrose, NSW.

Cash flows

The net inflow for the period was \$0.9m compared to the prior corresponding period outflow 31 December 2021: \$2.1M.

	31 Dec 22 \$	31 Dec 21 \$	Movement \$
Cash flows (used in) / from operating activities	(43,064)	(2,117,722)	2,074,658
Cash flows (used in) investing activities	7,725	(8,466)	16,191
Cash flows provided by financing activities	966,778	(3,222)	970,000
Net cash flows	931,439	(2,129,410)	3,060,849

01 Directors' Report

Operating activities

Cash used in operating activities in H1 FY 2023 is \$43k, a significant difference on the cash spent in operating activities in H1 FY2022 of \$2.1M. This can be attributed to the Company's receipt of approval of overseas findings application for R&D tax incentive scheme and represents the ongoing benefit of the Company's initiatives to reduce operating costs in line with its revised strategic direction, as announced on 13 August 2019. As at December 2022, the Company's underlying total operating expenses stood at \$150K per month after efficiencies were realised in aligning operations with the Company's priority to commercialise Progenza™, and the implementation of a revised executive remuneration structure that enabled more efficient deployment of cash and ensured strong alignment of senior executives to long-term value creation of shareholders. Management and the Board are now implementing additional restructuring measures and other initiatives to further reduce the Company's monthly operating expenses and extend its runway to further explore a strategic transaction in 2023.

Financing activities

\$967k cash movement in financing activities in H1 FY 2023, relates to a cashflow facility (**PSF Facility**) from Paddington St Finance Pty Ltd, a related party. The Company has reached agreement to settle the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio and payment of \$400,000 in cash. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.

Significant changes in state of affairs

On 27 January 2023 Regeneus received a notice of termination from Kyocera under the Licence Agreement. The Notice purports to terminate the Agreement for Kyocera's failure to meet its Development Target relating to establishment of first Standard Operating Procedures for the manufacture of Progenza™ for the clinical trial to be held in Japan by the required date – being 30 September 2022. Regeneus maintains a position that Kyocera did not exercise commercially reasonable efforts as defined in the Collaboration Agreement and, therefore, that Kyocera does not have any right to terminate the Agreement. The parties are currently undertaking dispute resolution procedures in accordance with the terms of the Licence Agreement.

The Company is not, at this time, incurring material legal expenses and will weigh further legal actions based on the outcome of the dispute resolution process and the expected probability of a successful outcome.

Regeneus has reached agreement to settle the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of \$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio by 31 August 2023. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.

There were no further significant changes in the Group's state of affairs during the half year FY23.

Auditor's Independence Declaration

A copy of the auditor's independence declaration, as required under Section 307C of the Corporations Act 2001, is included on page 6 of this report.

Rounding

The amounts shown in this Financial Report, including the Directors' report, have been rounded off, except where otherwise stated, to the nearest dollar as the Company is in a class specified in ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191 dated 24 March 2016.

Signed in accordance with a resolution of the Board of Directors:



Barry Sechos

Non-executive Chairman

28 February 2023

02 Auditor's Independence Declaration



PO Box 1908
West Perth WA 6872
Australia

Level 2, 40 Kings Park Road
West Perth WA 6005
Australia

Tel: +61 8 9481 3188
Fax: +61 8 9321 1204

ABN: 84 144 581 519
www.stantons.com.au

28 February 2023

Board of Directors
Regeneus Limited
2 Paddington Street
Paddington
Sydney NSW 2000

Dear Sirs

RE: REGENEUS LIMITED

In accordance with section 307C of the *Corporations Act 2001*, I am pleased to provide the following declaration of independence to the directors of Regeneus Limited.

As Audit Director for the review of the financial statements of Regeneus Limited for the half-year ended 31 December 2022, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (i) the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (ii) any applicable code of professional conduct in relation to the review.

Yours faithfully

STANTONS INTERNATIONAL AUDIT AND CONSULTING PTY LTD
(An Authorised Audit Company)

Samir Tirodkar
Director

Liability limited by a scheme approved under Professional Standards Legislation



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03 Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the half-year ended 31 December	Note	31 Dec 22 \$	31 Dec 21 \$
Revenue	7	28,224	20,005
Cost of sales		-	-
Gross profit		28,224	20,005
Other income	7	836,125	367,119
Research and development expenses		(398,985)	(1,401,500)
Occupancy expenses		(7,953)	(40,151)
Corporate expenses		(944,785)	(1,552,299)
Finance costs		(129,121)	(1,471)
Loss on movement in fair value		-	(17,391)
Loss on extinguishment of financial liability		-	(62,398)
Loss on written off investments	14	(1,750,000)	-
Impairment on Shareholders loan	13	(69,273)	-
(Loss)/profit before income tax		(2,435,769)	(2,688,086)
Income tax expense	8	-	-
(Loss)/profit for the period		(2,435,769)	(2,688,086)
Other comprehensive income			-
Total comprehensive loss)/profit for the period		(2,435,769)	(2,688,086)
Earnings per share			
Basic (loss)/earnings per share from continuing operations	9	(0.008)	(0.009)
Diluted (loss)/earnings per share from continuing operations	9	(0.008)	(0.009)

Note: This statement should be read in conjunction with the accompanying notes.

03 Consolidated Statement of Financial Position

As at 31 December	Note	31 Dec 22 \$	30 Jun 22 \$
Current assets			
Cash and cash equivalents		1,026,561	95,122
Trade and other receivables		-	110,797
R&D tax incentive receivable		232,845	447,023
Other current assets		86,844	65,236
Other financial assets	13	-	69,273
Total current assets		1,346,250	787,451
Non-current assets			
Other financial assets (Investment)	14	-	1,750,000
Property, plant and equipment		7,294	9,730
Right of use assets under lease		4,930	7,617
Total non-current assets		12,224	1,767,347
Total assets		1,358,474	2,554,798
Current liabilities			
Trade and other payables		251,267	309,942
Provisions		164,319	160,780
Borrowings		2,000,000	1,000,000
Lease liabilities		5,439	5,858
Total current liabilities		2,421,025	1,476,580
Non-current liabilities			
Lease liabilities		-	2,510
Provisions		971	917
Total non-current liabilities		971	3,427
Total liabilities		2,421,996	1,480,007
Net assets		(1,063,522)	1,074,791
Equity			
Issued capital	10	38,618,762	38,618,762
Accumulated losses		(41,387,079)	(38,951,310)
Reserves		1,704,795	1,407,339
Total equity		(1,063,522)	1,074,791

Note: This statement should be read in conjunction with the notes to the financial statements

03 Consolidated Statement of Changes in Equity

For the half-year ended 31 December	Share capital \$	Share option reserve \$	Accumulated losses \$	Total equity \$
Balance at 1 July 2021	38,258,870	535,384	(34,648,789)	4,145,465
Loss for the period	-	-	(2,688,086)	(2,688,086)
Employee share-based payment options issued	-	573,700	-	573,700
Employee share-based payment options forfeited	-	-	-	-
Transfer from reserves to retained earnings for options lapsed	-	(6,364)	6,364	-
Equity issued to New Life Sciences LLC (US)	359,891	-	-	359,891
Issue of share capital net of transaction costs	-	-	-	-
Balance at 31 December 2021	38,618,761	1,102,720	(37,330,511)	2,390,970
Balance at 1 July 2022	38,618,762	1,407,339	(38,951,310)	1,074,791
Loss for the period	-	-	(2,435,769)	(2,435,769)
Employee share-based payment options issued	-	297,456	-	297,456
Employee share-based payment options forfeited	-	-	-	-
Transfer from reserves to retained earnings for options lapsed	-	-	-	-
Issue of share capital net of transaction costs	-	-	-	-
Balance at 31 December 2022	38,618,762	1,704,794	(41,387,079)	(1,063,522)

Note: This statement should be read in conjunction with the notes to the financial statements.

03 Consolidated Statement of Cash Flows

For the half-year ended 31 December	31 Dec 22 \$	31 Dec 21 \$
Operating activities		
Receipts from customers	28,207	20,005
Payments to suppliers and employees	(1,171,885)	(2,967,138)
Interest received	15	-
R&D tax incentive refund	1,050,303	829,411
Grant receipts	93,000	-
Finance costs	(42,704)	-
Net cash (used in) / from operating activities	(43,064)	(2,117,722)
Investing activities		
Purchase of property, plant and equipment	-	(8,466)
Receipts from sale of property, plant and equipment	7,725	-
Net cash (used in) / from investing activities	7,725	(8,466)
Financing activities		
Receipts from loans to shareholders	-	-
Payments for lease liabilities	(3,222)	(3,222)
Proceeds from related party loan	970,000	-
Repayments of related party loans	-	-
Proceeds from issue of shares	-	-
Transaction costs related to borrowings	-	-
Net cash (used in) / provided by financing activities	966,778	(3,222)
Net change in cash and cash equivalents held	931,439	(2,129,410)
Cash and cash equivalents at beginning of period	95,122	3,792,695
Cash and cash equivalents at end of period	1,026,561	1,663,285

Note: This statement should be read in conjunction with the notes to the financial statements.

04 Notes to the Consolidated Financial Statements

1. Nature of operations

Regeneus is a Sydney based Australian Securities Exchange (ASX) listed clinical stage regenerative medicine company that develops innovative cell-based therapies to address significant unmet medical needs in the human health markets with a focus on osteoarthritis and other musculoskeletal disorders, neuropathic pain and dermatology.

Regenerative medicine is a rapidly growing multidisciplinary specialty that is focused on the repair or regeneration of cells, tissues and organs. The primary goal is to enhance the body's natural ability to replace tissue damaged or destroyed by injury or disease.

Where commercial opportunities are identified, the Group seeks to licence appropriate parties.

2. General information and basis of preparation

The half-year consolidated financial statements of the Group are for the six months ended 31 December 2022 and are presented in Australian dollars (\$), which is the functional currency of the parent company.

These general purpose half-year financial statements have been prepared in accordance with the requirements of the Corporations Act 2001 and AASB 134 Interim Financial Reporting. They do not include all of the information required in annual financial statements in accordance with Australian Accounting Standards and should be read in conjunction with the consolidated financial statements of the Group for the year ended 30 June 2022 and any public announcements made by the Group during the half-year in accordance with continuous disclosure requirements arising under the Australian Securities Exchange Listing Rules and the Corporations Act 2001.

The half-year financial statements have been approved and authorised for issue by the Board of Directors on 28 February 2023.

3. Going concern basis of accounting

The Directors have prepared the financial statements on a going concern basis which contemplates continuity of normal activities and realisation of assets and settlement of liabilities in the normal course of business. In making their going concern assessment the Directors have considered the following:

For the half-year ended 31 December 2022, the Group made a loss of \$2.44m (2021: \$2.67), net cash outflows from operating activities of \$43k (2021: \$2.12m) and the net current asset of \$1.07m (2021: net current assets of \$0.67m).

The Company has undertaken further restructuring measures in 2023 to reduce monthly operating expenses and extend its runway to further explore a strategic transaction in 2023.

The Group is exploring opportunities to dispose of non-core assets to improve its liquidity position. Regeneus has accumulated Good Manufacturing Practices (GMP) grade and non-GMP grade donor material in excess of its current, and anticipated future, needs. The Company is in discussions with external parties to sell the donor material (stromal vascular fraction or isolated mesenchymal stem cells). The sale of select donor material, if achieved, is expected to improve the Group's liquidity position.

The potential sale of non-core assets will further extend the cash runway of the Group.

Regeneus also expects an R&D Tax Incentive rebate after the 30 June 2023 Financial Year closes.

Regeneus has reached agreement to settle the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of \$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio by 31 August 2023. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.

The Company continues exploring various M&A options globally to extract operational, manufacturing, and clinical development synergies. The Company is in merger discussions with US and Japanese biotechnology companies. In the coming months, consummating a strategic transaction remains a priority for the Regeneus Board and the management team.

The continuing ability of the Group to continue as a going concern and to undertake further activities is dependent on the successful sale of non-core assets as currently contemplated and the negotiation, entry and execution of an M&A or merger transaction.

There is however material uncertainty related to events or conditions that may cast doubt on the Group's ability to continue as a going concern and, therefore, it may be unable to realise its assets and discharge its liabilities in the normal course of business and at the amounts stated in this Financial Report.

04 Notes to the Consolidated Financial Statements

At the date of this report, the Directors are of the opinion that there are reasonable grounds to expect that the Group will be able to continue as a going concern. In arriving at this conclusion, the Directors considered the following:

- The settlement of the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, which has been agreed between the parties, in exchange for the payment of \$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio by 31 August 2023.
- The Company does not have any additional significant debt liabilities.
- The Company is in advanced discussions with external parties to sell certain non-core assets, including the donor material referred to above. The sale of select donor material is expected to improve the Company's liquidity position.
- The Company is in merger discussions with US and Japanese biotechnology companies and the consummation of a strategic transaction remains a priority for the Regeneus Board and the management team.

At this time, the Directors are of the opinion that no asset is likely to be realised for an amount less than the amount at which it is recorded in the Financial Report as at 31 December 2022. Accordingly, no adjustments have been made to the Financial Report relating to the recoverability and the classification of liabilities that might be necessary should the Group not continue as a going concern.

4. Significant accounting policies

The half-year financial statements have been prepared in accordance with the same accounting policies adopted in the Group's last annual financial statements for the year ended 30 June 2022.

5. Estimates

When preparing the half-year financial statements, management undertakes a number of judgements, estimates and assumptions about recognition and measurement of assets, liabilities, income and expenses. The actual results may differ from the judgements, estimates and assumptions made by management, and will seldom equal the estimated results.

The judgements, estimates and assumptions applied in the half-year financial statements, including the key sources of estimation uncertainty were the same as those applied in the Group's last annual financial statements for the year ended 30 June 2022, except for the impairments discussed in notes 13 and 14.

6. Segment reporting

Operating segments are presented using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Operating Decision Makers (CODM). The CODM is responsible for the allocation of resources to operating segments and assessing their performance.

The Group's operating segment is based on the internal reports that are reviewed and used by the Board of Directors (being the CODM) in assessing performance and in determining the allocation of resources. Reports provided to the CODM reference the Group operating in one segment, being the development of innovative cell-based therapies to address significant unmet medical needs in the human health markets. Initial focus is osteoarthritis and other musculoskeletal disorders, neuropathic pain and dermatology. The information reported to the CODM, on a monthly basis, is profit or loss before tax, assets and liabilities and cash flow.

7. Revenue and other income

The Groups revenue and other income include the following:

	31 Dec 22 \$	31 Dec 21 \$
Operating activities		
Interest received	17	-
Licence fee revenue	28,207	-
Other fee revenue	-	20,005
Total revenue	28,224	20,005
Other income		
R&D tax incentive	836,125	367,119
Federal Government initiatives and grants	-	-
Other income	836,125	367,119

04 Notes to the Consolidated Financial Statements

On 27 January 2023 Regeneus received a notice of termination (Notice) from Kyocera under the Licence Agreement. The Notice purports to terminate the Agreement for Kyocera's failure to meet its Development Target relating to establishment of first Standard Operating Procedures for the manufacture of Progenza for the clinical trial to be held in Japan by the required date – being 30 September 2022.

As a result of the purported termination of the Licence Agreement, Kyocera have indicated that no further milestone or other payments will be made under the Licence Agreement.

R&D tax incentive

The Group's research and development activities are eligible expenditure under the Australian Government tax incentive program. Under this program the government provides a cash refund for 43.5% (2021: 43.5%) of eligible research and development expenditures.

8. Income tax expense

No income tax expense or liability has been recognised in the half-year accounts. The Group's accounting loss as at 31 December 2022 is \$2,435,768.58 which would be added to the unused tax losses as at 30 June 2022 of \$13,351,320 (30 June 2021: \$10,185,387) which have not previously been brought to account. The losses mentioned includes capital loss of \$ 840,895. A full income tax expense calculation for the financial year will be completed in the annual accounts.

	31 Dec 22 \$
Accounting loss before tax	(2,435,769)
Tax rate	25%
Prima facie tax payable on profit before income tax	(608,942.15)
Tax losses not brought to account	608,942.15
Income tax expense	-

9. Earnings per share

Both the basic and diluted earnings per share have been calculated using the loss attributable to shareholders of the parent company (Regeneus Ltd) as the numerator, i.e., no adjustments to losses were necessary during the six-month period to 31 December 2022 and 31 December 2021

The weighted average number of shares for the purposes of the calculation of diluted earnings per share can be reconciled to the weighted average number of ordinary shares used in the calculation of basic earnings per share as follows:

	31 Dec 22 \$	31 Dec 21 \$
Basic earnings per share from continuing operations	(0.008)	(0.009)
The weighted average number of ordinary shares used as the denominator on calculating the EPS	306,436,914	304,782,850
Diluted earnings per share		
Diluted earnings per share from continuing operations	(0.008)	(0.009)
The weighted average number of ordinary shares used as the denominator on calculating the DEPS	306,436,914	304,782,850

At 31 December 2022 share options are not included in the diluted EPS calculation because they are anti-dilutive. (2021: nil)

10. Share Capital

The share capital of Regeneus Ltd consists only of fully paid ordinary shares; the shares do not have a par value. All shares are equally eligible to receive dividends and the repayment of capital and represent one vote at the shareholders' meeting of Regeneus Ltd.

	Shares		\$	
Share Capital	31 Dec 22	30 June 22	31 Dec 22	30 June 22
Beginning of the period	306,436,914	303,538,363	38,618,762	38,258,870
Shares issued and fully paid	-	2,898,551	-	359,892
Closing balance	306,436,914	306,436,914	38,618,762	38,618,762

04 Notes to the Consolidated Financial Statements

The Company has 33,324,143 options on issue to acquire ordinary shares in the Company. These options are unlisted, restricted and summarised as follows:

Share options	31 Dec 22 Number	30 Jun 22 Number
Employee share option plan	28,274,143	28,274,143
Share option agreement	5,050,000	5,050,000
	33,324,143	33,324,143

During 6 months ending 31 December 2022, no shares were issued, no options were issued/exercised.

11. Share-based payments

The grant date fair value of options granted to employees is recognised as an employee benefit expense, with a corresponding increase in equity within the shares options reserve. The amount recognised is adjusted to reflect the actual number of the share options vested.

All share-based remuneration will be settled in equity. The Group has no legal or constructive obligation to repurchase or settle the options.

The fair value of share options calculated using the Black-Scholes pricing model.

For the options outstanding at period end, the following inputs were used:

Grant date	31 Jan 19	1 Sep 19	1 July 20	14 Oct 20	14 Oct 20	24 May 21	24 May 21	24 May 21
Share price at date of grant	\$0.155	\$0.070	\$0.070	\$0.160	\$0.160	\$0.095	\$0.095	\$0.095
Volatility	65%	85%	75%	65%	65%	90%	90%	90%
Option life	5 years	5 years	5 years	5 years	5 years	5 years	5 years	5 years
Dividend yield	0%	0%	0%	0%	0%	0%	0%	0%
Risk free investment rate	1.900%	0.680%	0.40%	0.32%	0.32%	0.500%	0.500%	0.500%
Fair value at grant date	\$0.0767	\$0.0424	\$0.0370	\$0.1002	\$0.0908	\$0.067	\$0.067	\$0.067
Exercise price at date of grant	\$0.20	\$0.10	\$0.10	\$0.1075	\$0.14	\$0.10	\$0.10	\$0.10

Employee benefits expenses in the profit or loss includes a debit of \$297,456 relating to employee share options (Dec 2021: \$573,700).

Share options granted under the option plans	31 Dec 22		30 Jun 22	
	Number	Weighted avg exercise price \$	Number	Weighted avg exercise price \$
Options outstanding at beginning of period	29,524,143	0.11	30,409,270	0.11
Granted	-	-	-	-
Forfeited / lapsed	-	-	(885,127)	0.11
Outstanding at end of period	29,524,143	0.11	29,524,143	0.11
Exercisable at end of period	13,677,206	0.11	7,630,270	0.12

04 Notes to the Consolidated Financial Statements

12. Related party transactions

Borrowings

On 25 February 2022, the Group signed a loan facility agreement (**PSF Facility**) with Paddington St Finance Pty Ltd, a related party. The maximum loan value of the facility is the lesser of (i) AUD\$4 million; and (ii) USD\$3 million. The loan forward funds the receipt of the next milestone payment of US\$3million receivable under the licence and collaboration agreement with Kyocera. For the \$1m loan withdrew in the 6-month ending 31 Dec 2022, \$30,000 arrangement fee was paid to PSF.

As at 31 December 2022 a total of \$2 million was drawn, and remains owing, under the PSF Facility. Interest under the PSF Facility has been paid through to 31 December 2022. In February 2023, Regeneus reached agreement to settle the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of \$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio by 31 August 2023. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.

Related party loan payable	31 Dec 22 \$	30 Jun 22 \$
Paddington St Finance Pty Ltd		
Balance at beginning of the year	1,000,000	-
Loan received	1,000,000	1,000,000
Loan repaid	-	-
Total related parties loans payable	2,000,000	1,000,000

In April 2022, Regeneus signed a new licence agreement with BioPoint Pty Ltd a company of which Graham Vesey is a director and significant shareholder. This licence was valued at \$1,500 per month, reduced from \$3,000 per month. This licence agreement provides Regeneus with laboratory space and facilities in order to develop and manufacture a stem cell secretion product (Sygenus) and supply the product to the cosmetic market. The licence also provides Regeneus with the opportunity to research and manufacture a stem cell product, Progenza.

13. Other financial assets

Shareholder loans

The shareholder loans are interest-free loans initially for 4 years maturing September 2017. The Directors extended the maturity of the loans to the 15 June 2019 and the loans are technically in default. While the loan is full recourse, in accordance with AASB 9 the ECL (expected credit loss) model credit risk has increased as the amounts are in default and the share price has reduced. Accordingly, an expected credit loss allowance has been made.

In May 2022, a letter was sent to each shareholder to whom the Company had provided a loan, advising them the full amount of the loan was due and payable on 30 June 2022. Participants were given the option to either repay the loan in full or transfer their RGS shares that were subject of the loans to Regeneus, who would then sell the shares on market, and apply the proceeds of such sale in repayment of the loans owing. On completion of this sales process undertaken by the Company, a total of 7.563 million RGS shares were sold, with total net proceeds of \$369,000 being received by the Company and applied in repayment of loans owing. The balance of the Shareholder loans owing after completion of this sales process has been written off by the Company, other than the loan extended to Graham Vesey, Executive Director of Regeneus.

Included within the loans to shareholders in other current assets, are balances owing by the Directors as follows:

Related party loan receivable	31 Dec 22 \$	30 Jun 22 \$
Graham Vesey	98,962	98,962
Total related parties loans receivable	98,962	98,962

	31-Dec-22 \$	30-Jun-22 \$
Shareholder Loan	98,962	98,962
Expected credit loss allowance	(29,689)	(29,689)
Impairment on Shareholder loan	(69,273)	-
Shareholder loan	-	69,273

The extended shareholder loan to Graham Vesey was impaired.

04 Notes to the Consolidated Financial Statements

14. Other financial assets (Investment)

	Price Per Share	Amount of shares	Total Valuation
Sangui Bio Pty Ltd Investment	\$2.50	700,000	nil

Since June 2021, there have been no activities or events that enable Regeneus to determine the fair value of the investment. After reviewing Sangui Bio's investment memorandum and financial statements, as the group have not been able to obtain sufficient appropriate evidence support the value of the investment, the group has decided to impair the carrying value of the investment to nil.

15. Dividends

No dividends were paid during the period (2021: \$nil).

16. Contingent liabilities

A claim has been received for reimbursement of additional expenditure from a group that undertook an animal trial for the Group in 2015 through to 2018. Management believe it is an ambit claim with little merit and will pursue avenues to minimise this claim and may potentially seek reimbursement of the costs of the failed trial paid to date. It is anticipated the net claim including costs would not exceed \$50,000.

Other than the above, the Group had no contingent liabilities as at 31 December 2022 (31 December 2021: Nil).

17. Events after the reporting date

On 27 January 2023 Regeneus received a notice of termination (**Notice**) from Kyocera under the Licence Agreement. The Notice purports to terminate the Agreement for Kyocera's failure to meet its Development Target relating to establishment of first Standard Operating Procedures for the manufacture of Progenza for the clinical trial to be held in Japan by the required date – being 30 September 2022. The Company does not accept that Kyocera has any right to terminate the Agreement and the dispute resolution procedures under the Agreement have commenced. Regeneus is considering its legal position.

As a result of the purported termination of the Licence Agreement, Kyocera has indicated that no further milestone or other payments will be made under the Licence Agreement.

Regeneus has reached agreement to settle the \$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of \$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio by 31 August 2023. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.

There has not arisen in the interval between 31 December 2022 and the date of this report, any other event that would have had any material effect on the Financial Statements at 31 December 2022.

05 Director's Declaration

Directors' declaration

1. In the opinion of the Directors of Regeneus Ltd:

- a. the consolidated financial statements and notes of Regeneus Ltd are in accordance with the Corporations Act 2001, including:
 - i) giving a true and fair view of its financial position as at 31 December 2022 and of its performance for the half-year ended on that date; and
 - ii) complying with Accounting Standard AASB 134 Interim Financial Reporting; and
- b. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Board of Directors:



Non-executive Chairman

Barry Sechos

Dated 28 February 2023



PO Box 1908
West Perth WA 6872
Australia

Level 2, 40 Kings Park Road
West Perth WA 6005
Australia

Tel: +61 8 9481 3188
Fax: +61 8 9321 1204

ABN: 84 144 581 519
www.stantons.com.au

INDEPENDENT AUDITOR'S REVIEW REPORT TO THE MEMBERS OF REGENEUS LIMITED

Report on the Half-Year Financial Report

Qualified Opinion

We have reviewed the half-year financial report of Regeneus Limited, which comprises the consolidated statement of financial position as at 31 December 2022, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the half-year ended on that date, condensed notes to the consolidated financial statements comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, except for the effects of the matter in the Basis for Qualified Opinion section of our report we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Regeneus Limited does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of Regeneus Limited's financial position as at 31 December 2022 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for Qualified Opinion

The consolidated entity assigned a non-core patent application for an equity interest in Sanguis Bio Pty Limited. The investment's fair value at 30 June 2021 was estimated at \$1.75 million based on a recent capital raise. This investment is included as a non-current financial asset. As this investment is in a private company, Management was unable to estimate the fair value of the investment at 30 June 2022. As a result, the previous auditors were unable to obtain sufficient and appropriate audit evidence to state that the investment had been stated at fair value as at 30 June 2022, which constituted a departure from the Australian Accounting Standards. As at 31 December 2022 the Directors impaired this investment to nil.

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the Auditor's Responsibilities for the Review of the Financial Report section of our report. We are independent of the consolidated entity in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001* has been given to the directors of the Company on 28 February 2023.



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Material Uncertainty Related to Going Concern

We draw attention to Note 3 in the half year financial report, which indicates that the Group incurred a net loss of \$2,435,769 during the period ended 31 December 2022 and the condensed consolidated statement of cash flows reflects net operating cash outflows of \$43,064. Further, the consolidated statement of financial position reflects a working capital deficiency of \$1,074,775 and a net asset deficiency of \$1,063,522.

The ability of the Group to continue as a going concern and meet its planned operating, administration and other commitments is dependent upon the Group meeting the key assumptions in its cashflow budgets as discussed in note 3 and/or raising further working capital, completing the sale of its non-core assets and completing the settlement of its loan financing. In the event that the Group is not successful in meeting the assumptions in the cashflow budgets and/or raising further working capital, completing the sale of its non-core assets, the settlement of its loan financing, the Group may not be able to meet its liabilities as and when they fall due and the realisable value of the Group's current and non-current assets may be significantly less than book values.

Responsibility of the Directors for the Financial Report

The directors of Regeneus Limited are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility for the Review of the Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Company's financial position as at 31 December 2022 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

STANTONS INTERNATIONAL AUDIT AND CONSULTING PTY LTD
(An Authorised Audit Company)

Samir Tirodkar
Director

West Perth, Western Australia
28 February 2023

Registered Office and Principal Place of Business

2 Paddington Street
Paddington, NSW 2021, Australia

Board of Directors

Barry Sechos (Non-executive Chairman)
Leo Lee (Non-executive Director)
Professor Graham Vesey (Executive Director)

Chief Executive Officer

Karolis Rosickas

Company Secretary

Hang Ling (Helen) Leung

Website

regeneus.com.au

Lawyers

Dentons Australia Limited
77 Castlereagh Street
Sydney NSW 2000

Auditors

Stantons International Audit and Consulting Pty Ltd
Level 2, 40 Kings Park Road, West Perth, WA 6005, Australia

Patent Attorneys

Spruson & Ferguson
Level 35, 31 Market Street
Sydney, NSW 2000

Share Registry

Link Market Services Limited
Level 12, 680 George Street
Sydney, NSW 2000

Stock Exchange Listing

Australian Securities Exchange
ASX Code: RGS