

**Regeneus Ltd**  
**ABN 13 127 035 358**

ASX Half-Year Report for 6 months to 31<sup>st</sup> December 2021

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 30<sup>th</sup> June 2021 and any public announcements made during the reporting period, in accordance with the continuous disclosure requirements of the Australian Securities Exchange Listing Rules and the Corporations Act 2001.

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Results for announcement to the market

Half-Year Report

## Appendix 4D

Half-Year Report for the 6 months to 31st December 2021

Regeneus Ltd – ABN 13 127 035 358

### Reporting period

Report for the half-year ended 31st December 2021

Corresponding period is for the half-year ended 31st December 2020

### Results for announcement to the market

	Up/Down	% change		\$'000's
Revenue from ordinary activities	Down	-100%	to	20
Profit/(Loss) from ordinary activities after tax attributable to members	Down	-161%	to	(2,688)
Net Profit/(Loss) from ordinary activities attributable to the member	Down	-161%	to	(2,688)
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 2021 \$0.008 cents

31st December 2020 \$0.015 cents

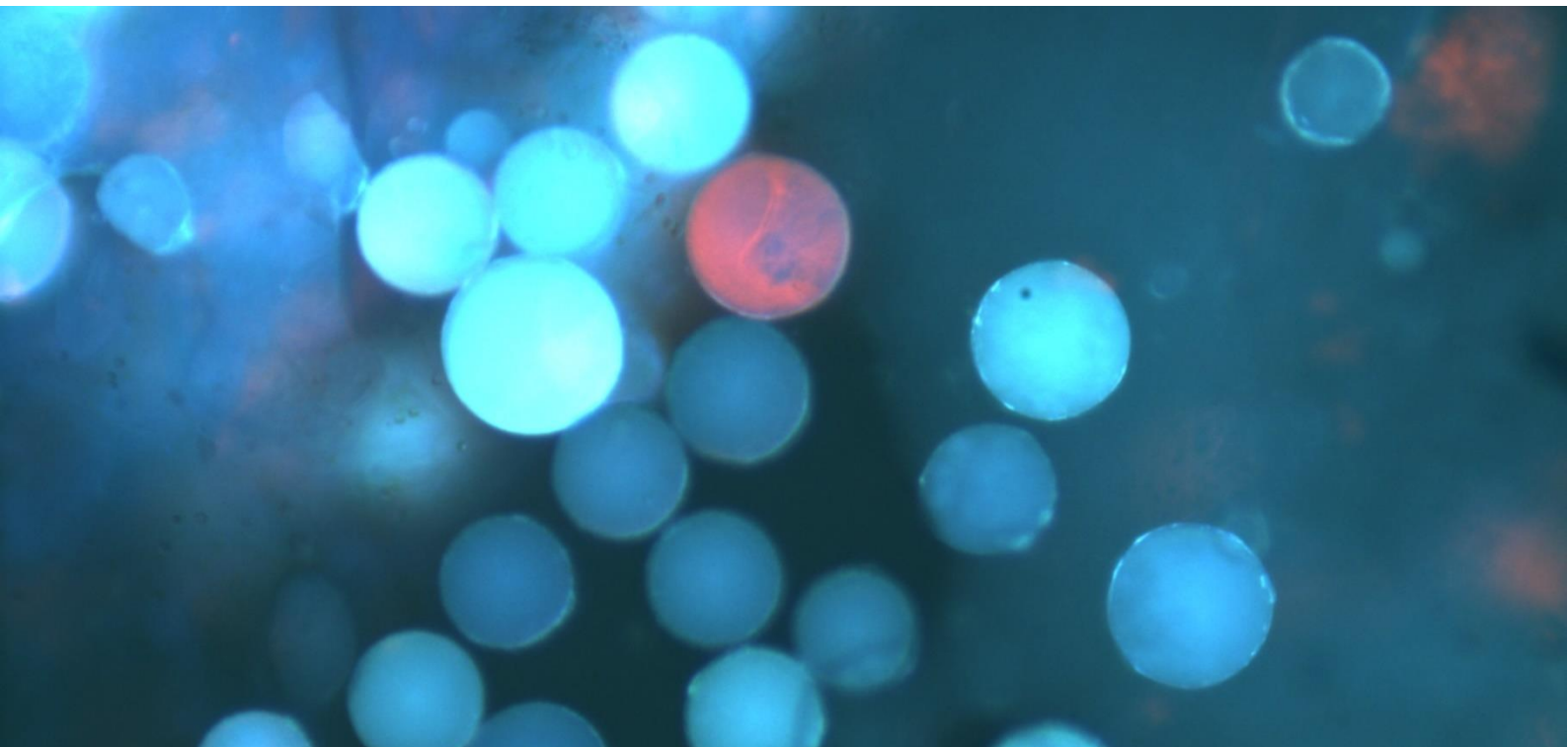
### Independent review of the financial information

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



# Half-Year Report

## 31 December 2021



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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 2021, 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, member of the Remuneration and Nominations Committee
Professor Graham Vesey	CSO and Executive Director
Dr John Chiplin	Non-executive Director, Chair of the Remuneration and Nominations Committee, member of the Audit and Risk Committee

## 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.
- The Company's strategy focuses on bringing its lead stem cell technology platform Progenza™ to commercialisation, through its partnership with Kyocera Corporation (Kyocera) to treat knee OA in Japan. Regeneus progressed positively with this strategy in the first half of FY2022, with initial clinical development and manufacturing preparations continuing, in order to progress to Phase 2 and move toward application for regulatory approval.
- The Company will continue to explore co-development and licensing options for Progenza™ for knee osteoarthritis in other territories and for neuropathic pain globally.
- The Company's second stem cell technology platform, Sygenus, is also a priority, and Regeneus continues to progress the development partnership entered into with the Australian Department of Defence for combat casualty care with research conducted by the University of Adelaide, with the first in human study anticipated in 2022.
- 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.
- Research collaboration continues with Raymond Purves Bone and Joint Research Laboratories at the Kolling Institute of Medical Research, Australia. This study will support additional non-clinical work that is required prior to commencing Phase 2 clinical trials in Japan and other geographies.
- Feedback was received from the FDA Office of Tissues and Advanced Therapies, advancing the Company's preparation for the IND Application submission.
- The Company and New Life Sciences Capital, LLC (New Life Sciences) mutually agreed to terminate the Subscription Agreement entered into in May 2021 and which involved a three stage placement of shares in the Company.
- A Research & Development tax incentive of approximately \$830,000 was received from the Australian Government's Research & Development tax incentive program for activities conducted during FY2021.

### Executing on strategy under licence and collaboration agreement with Kyocera

- Regeneus moved forward over the first half of FY2022 in collaboration with Kyocera on the development of Progenza™ in Japan, with continued preparatory work to progress to Phase 2 and move toward application for regulatory approval of Progenza™ for the treatment of knee osteoarthritis in Japan.
- In September 2021, a variation agreement to the licence and collaboration agreement was entered into and the Company and Kyocera continue collaborating on commencing manufacturing of Progenza in Japan and launching a pivotal Phase 2 trial. The variation agreement reduces Regeneus's future financial commitment under the licence and collaboration agreement and provides more clarity on specific responsibilities of both the Company and Kyocera under the development program.
- Further to the execution of the variation agreement, the Company anticipates receipt of the next milestone payment of US\$3 million in Q2 CY2023 under the licence and collaboration agreement with Kyocera.
- Kyocera continues to fund manufacturing, development and commercialisation costs for Progenza™ OA in Japan under the licence and collaboration agreement.
- The agreement provides a clear commercialisation pathway for Progenza™ into a significant market. The global market for injectable treatments for knee osteoarthritis is US\$6.1 billion with the Japanese market alone worth US\$1.5 billion.

# 01 Directors' Report

## US strategy and IND Filing

- Regeneus continues working with regulatory consultants and global clinical research organization IQVIA to assist the Company with its US FDA pre-IND consultation and the planned IND application.
- In November 2021, Regeneus had a pre-IND consultation (Type B meeting) with the FDA Office of Tissues and Advanced Therapies with the objective of filing an Investigational New Drug (IND) application and initiate a Progenza OA Phase 2 clinical trial in the US.
- The Company received informative feedback from the FDA which will enable it to move forward with the preparation for the IND application submission.
- Regeneus is in discussions with potential licensing partners to develop and commercialise Progenza in the United States.

## Department of Defence

- Regeneus entered into a partnership in Q4 FY2021 with the Australian Department of Defence to develop Sygenus, Regeneus' stem cell bioactive secretome technology, for combat casualty care, with funding of A\$300,000 being provided to the Company to be used to optimise the Sygenus formulation for combat casualties and conduct a first in human study on pain.
- This development program is progressing well and the Company concluded the first animal study in Sygenus development, conducted by Dr Mark Hutchinson at the University of Adelaide.
- Regeneus and the Department of Defence are engaging in further discussions regarding this partnership as the first preliminary study at the University of Adelaide nears completion.

## Research Collaboration with Kolling Institute

- During the half year, the Company secured 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. This study supports additional non-clinical work required prior to commencing Phase 2 clinical trials in Japan and in preparation for a US Phase 2 study.
- Under the collaboration, Regeneus and the Kolling Institute is undertaking an additional non-clinical study. The Company anticipates it will be needed prior to commencing its Phase 2 clinical trial in Japan.

## Institutional Placement Agreement terminated

- On 7 May 2021, the Company entered into an institutional placement agreement with New Life Sciences to raise up to AU\$4.5M of funding. New Life Sciences made an initial investment of AU\$1.5M on 12 May 2021 and the Company granted New Life Sciences the right to subscribe for ordinary shares in the Company with an aggregate value of AU\$1.59M in respect of this first subscription.
- At the commencement of the first placement, 1,353,982 and 1,900,000 shares in Regeneus were issued to New Life Sciences. The 1,353,982 shares were issued for a value of AU\$0.1m in lieu of a commencement fee. The 1,900,000 shares issued were in relation to the initial placement shares. In addition, 3,800,000 options over shares in Regeneus were issued immediately before the first placement as part of the commencement transactions, which can be exercised at any time over a period of 36 months from the date of issue.
- On 13 October 2021 New Life Sciences exercised its first subscription rights in relation to AU\$0.2M of its initial investment of AU\$1.5m and 2,898,551 ordinary shares in Regeneus were redeemed by New Life Sciences at \$0.069 per share on 14 October 2021. The Company's share price on 14 October 2021 was \$0.075 per share.
- In December 2021, the Company's Board of Directors, together with New Life Sciences mutually agreed to terminate the Subscription Agreement. As such, no further investments are to be made by, or shares issued to, New Life Sciences. Under the termination arrangements, Regeneus repaid AU\$1.26M to New Life Sciences in respect of the balance of the prepayment amount received by Regeneus on 12 May 2021, after netting the 1.9 million shares issued to New Life Sciences on 7 May 2021 against Regeneus's obligations, at a deemed issue price of \$0.067 cents per share.
- The AU\$1.26M was repaid to New Life Sciences by the Company on 4 January 2022.

## Other clinical developments

- A new patent, focusing on product composition, was allowed in Japan protecting the Company's Progenza™ product until September 2036.

## Other developments

- During the half year, and as part of the Company's US strategy and focus on prioritizing securing a strategic partner in the US, the Company announced the appointment of Scott Bruder MD, PhD as a Board Advisor. Dr Bruder is a leading US based physician-scientist executive in the regenerative medicine and orthopedics industry.
- The Company has also entered into a strategic partnering agreement with Bruder Consulting & Venture Group during the period.

# 01 Directors' Report

## 3. Financial results

### Operating results

The Group's operating result for the 6-month period to 31 December 2021 (H1 FY2022) was a loss of AU\$2.69M, compared to results of profit of AU\$4.4m for the previous corresponding period (H1 FY2021).

### Revenue and gross margin from continuing operations

Revenue for the 6-month period to 31 December 2021 was AU\$20k. This is in relation to the recent partnership with the Australian Department of Defence, whereby the group received one milestone payment.

### 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 2021 is AU\$0.4m (31 December 2020: AU\$0.2m).

### Events subsequent to the end of the reporting date

Subsequent to 31 December 2021 the Company has secured a cashflow facility from Paddington St Finance Pty Ltd, a related party. The facility forward funds, via a loan, the next milestone payment of US\$3 million to be received by Regeneus under the licence and collaboration agreement with Kyocera, expected to be received in Q2 CY2023. The loan will be secured over the milestone payment receipt and as a first ranking charge over the Group's property.

On 4 January 2022 AU\$1.26M was repaid to New Life Sciences as part of the termination of the New Life Sciences Subscription Agreement referred to above.

There has not arisen in the interval between 31 December 2021 and the date of this report, any other event that would have had any material effect on the Financial Statements at 31 December 2021.

### Expenses from continuing operations

#### Research and Development

Expenditure on research in the half-year period to 31 December 2021 was AU\$1.4m compared to 31 December 2020 of AU\$0.5m.

Research expenditure includes costs associated with product development, GMP manufacture as well as clinical trials. It is anticipated that R&D expenditure will remain well below historic levels as Kyocera will be funding the Phase II trial.

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 AU\$1.5M in half year FY2022 compared to AU\$2.2M in the previous corresponding period. This is attributed to 'non-cash' cost of options of AU\$0.6M and the reduction of administration and independent contractor costs.

#### Occupancy

Occupancy expenditure at AU\$40k in half year FY2022 (31 December 2020: \$45k) The occupancy cost is minimal because Regeneus exited its corporate premises at the end of September 2019, but continues to lease laboratory space in Belrose, NSW.

#### Cash flows

The net outflow for the period was AU\$2.1m compared to the prior corresponding period inflow 31 December 2020: AU\$3.1M.

	31 Dec 21 \$	31 Dec 20 \$	Movement \$
Cash flows (used in) / from operating activities	(2,120,944)	4,221,102	(6,342,046)
Cash flows (used in) investing activities	(8,466)	(7,784)	(682)
Cash flows (used in) financing activities	-	(1,100,000)	1,100,000
<b>Net cash flows</b>	<b>(2,129,410)</b>	<b>3,113,318</b>	<b>(5,242,728)</b>

# 01 Directors' Report

## Operating activities

Cash used in operating activities in H1 FY 2022 is AU\$2.1M, a significant difference on the cash received from operating activities in H1 FY2021 of AU\$4.2M. This can be attributed to the Company's receipt of funding from Kyocera in H1 FY2021 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. The Company's underlying total operating expenses now stand at AU\$250K 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.

## Financing activities

Nil cash movement in financing activities in H1 FY 2022 compare to cash used in financing activities in H1 FY2021, the one-off cost of AU\$1.1M, paid to Leo Lee as the final principal repayment for his loan to the Company which was cancelled in light of the licence and collaboration agreement with Kyocera and subsequent funding.

## Significant changes in state of affairs

There were no significant changes in the Group's state of affairs during the half year FY22.

## 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

25 February 2022





Level 17, 383 Kent Street  
Sydney NSW 2000

Correspondence to:  
Locked Bag Q800  
QVB Post Office  
Sydney NSW 1230

T +61 2 8297 2400  
F +61 2 9299 4445  
E [info.nsw@au.gt.com](mailto:info.nsw@au.gt.com)  
W [www.granthornton.com.au](http://www.granthornton.com.au)

### Auditor's Independence Declaration

To the Directors of Regeneus Ltd

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Regeneus Ltd for the half-year ended 31 December 2021, I declare that, to the best of my knowledge and belief, there have been:

- a no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- b no contraventions of any applicable code of professional conduct in relation to the review.

A handwritten signature in cursive script, appearing to read "Grant Thornton".

Grant Thornton Audit Pty Ltd  
Chartered Accountants

A handwritten signature in cursive script, appearing to read "N J Bradley".

N J Bradley  
Partner – Audit & Assurance

Sydney, 25 February 2022



## 03 Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the half-year ended 31 December	Note	31 Dec 21 \$	31 Dec 20 \$
Revenue	7	20,005	7,067,037
Cost of sales		-	-
<b>Gross profit</b>		<b>20,005</b>	<b>7,067,037</b>
Other income	7	367,119	271,327
Research and development expenses		(1,401,500)	(510,048)
Occupancy expenses		(40,151)	(46,681)
Corporate expenses		(1,552,299)	(2,233,191)
Finance costs		(1,471)	(45,543)
Loss on movement in fair value	13	(17,391)	-
Loss on extinguishment of financial liability	13	(62,398)	-
Realised foreign exchange loss		-	(82,930)
Gain on settlement		-	266
<b>(Loss)/profit before income tax</b>		<b>(2,688,086)</b>	<b>4,420,237</b>
Income tax expense	8	-	-
<b>(Loss)/profit for the period</b>		<b>(2,688,086)</b>	<b>4,420,237</b>
Other comprehensive income		-	-
<b>Total comprehensive loss)/profit for the period</b>		<b>(2,688,086)</b>	<b>4,420,237</b>
<b>Earnings per share</b>			
Basic (loss)/earnings per share from continuing operations	9	(0.009)	0.015
Diluted (loss)/earnings per share from continuing operations	9	(0.009)	0.015

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 21 \$	30 Jun 21 \$
<b>Current assets</b>			
Cash and cash equivalents		1,663,285	3,792,695
R&D tax incentive receivable		289,137	751,428
Other current assets		130,966	112,152
Other financial assets	12	570,227	2,070,227
<b>Total current assets</b>		<b>2,653,615</b>	<b>6,726,502</b>
<b>Non-current assets</b>			
Other financial assets	14	1,750,000	1,750,000
Property, plant and equipment		12,472	20,849
Right of use assets under lease		10,305	12,992
<b>Total non-current assets</b>		<b>1,772,777</b>	<b>1,783,841</b>
<b>Total assets</b>		<b>4,426,392</b>	<b>8,510,343</b>
<b>Current liabilities</b>			
Trade and other payables		565,108	1,108,116
Provisions		154,552	183,379
Lease liabilities		5,475	5,296
Other financial liability	13	1,262,700	-
<b>Total current liabilities</b>		<b>1,987,835</b>	<b>1,296,791</b>
<b>Non-current liabilities</b>			
Lease liabilities		5,809	8,547
Provisions		41,778	16,738
Derivative financial instrument	13	-	3,042,802
<b>Total non-current liabilities</b>		<b>47,587</b>	<b>3,068,087</b>
<b>Total liabilities</b>		<b>2,035,422</b>	<b>4,364,878</b>
<b>Net assets</b>		<b>2,390,970</b>	<b>4,145,465</b>
<b>Equity</b>			
Issued capital		38,618,761	38,258,870
Other contributed equity		-	-
Accumulated losses		(37,330,511)	(34,648,789)
Reserves		1,102,720	535,384
<b>Total equity</b>		<b>2,390,970</b>	<b>4,145,465</b>

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 \$	Other contributed equity \$	Share option reserve \$	Accumulated losses \$	Total equity \$
Balance at 1 July 2020 (Restated)	36,358,675	1,797,017	431,521	(37,493,175)	1,094,038
Profit for the period	-	-	-	4,420,237	4,420,237
Employee share-based payment options issued	-	-	203,339	-	203,339
Employee share-based payment options forfeited	-	-	(232,490)	-	(232,490)
Transfer from reserves to retained earnings for options lapsed	-	-	(85,325)	85,325	-
Other Contributed Equity adjustment after issuance to AGC Inc (Japan)	-	(266)	-	-	(266)
Shares Issued	1,796,751	(1,796,751)	-	-	-
Issue of share capital net of transaction costs	-	-	-	-	-
Balance at 31 December 2020	38,155,426	-	317,045	(32,987,612)	5,484,858
Balance at 1 July 2021	38,258,870	-	535,384	(34,648,789)	4,145,465
Profit 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

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 21 \$	31 Dec 20 \$
<b>Operating activities</b>		
Receipts from customers	20,005	7,659,167
Payments to suppliers and employees	(2,970,360)	(3,730,685)
Interest received		12
R&D tax incentive refund	829,411	676,590
R&D tax incentive repayment	-	(147,341)
Other income and COVID-19 Cash Flow Boost	-	37,500
Finance costs	-	(274,141)
<b>Net cash (used in) / from operating activities</b>	<b>(2,120,944)</b>	<b>4,221,102</b>
<b>Investing activities</b>		
Purchase of property, plant and equipment	(8,466)	(7,784)
Receipts from sale of property, plant and equipment	-	-
<b>Net cash (used in) / from investing activities</b>	<b>(8,466)</b>	<b>(7,784)</b>
<b>Financing activities</b>		
Receipts from loans to shareholders	-	-
Proceeds from related party loan	-	-
Repayments of related party loans	-	(1,100,000)
Proceeds from issue of shares	-	-
<b>Net cash (used in) / provided by financing activities</b>	<b>-</b>	<b>(1,100,000)</b>
<b>Net change in cash and cash equivalents held</b>	<b>(2,129,410)</b>	<b>3,113,318</b>
Cash and cash equivalents at beginning of period	3,792,695	981,845
<b>Cash and cash equivalents at end of period</b>	<b>1,663,285</b>	<b>4,095,163</b>

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 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 2021 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 2021 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 24 February 2022.

## 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 2021, the Group made a loss of AU\$2.69m (2020: AU\$4.4m profit), net cash outflows from operating activities of AU\$2.1m (2020: AU\$4.2m inflow) and the net current asset of AU\$0.67m (2020: net current assets of AU\$4.25m).

After the reporting date, the Company has secured a cashflow facility from Paddington St Finance Pty Ltd, a related party. The facility forward funds, via a loan, the next milestone payment of US\$3 million to be received by Regeneus under the licence and collaboration agreement with Kyocera, expected to be received in Q2 CY2023. The loan will provide Regeneus with the ability to drawdown up to AUD\$4 million and will be secured over the milestone payment receipt and as a first ranking charge over the Group's property.

The Directors consider the availability of this cashflow facility, together with the continuation of cost reduction strategies will enable the Company to continue the normal course of business.

## 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 2021.

## 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 2021 except as set out below:

# 04 Notes to the Consolidated Financial Statements

## Issuance of Shares

The Group entered into a Subscription Agreement with institutional investor, New Life Sciences, LLC, in May 2021 to secure up to \$4.5 million in a three-stage placement of the Group's ordinary shares.

A Settlement notice was received on 13 October 2021 and 2,898,511 shares were redeemed by the investor at \$0.069 per share on 14 October 2021. The placement price was based on the average of five daily VWAPs per share during the 20 consecutive Actual Trading Days immediately prior to the settlement notice date, rounded down to five decimal places at a reference percentage of 95% and the rounding number is 1/10th of a cent.

In December 2021, the Company's Board of Directors, together with New Life Sciences mutually agreed to terminate the Subscription Agreement. As such, no further investments are to be made by, or shares issued to, New Life Sciences. Under the termination arrangements, Regeneus repaid \$1.26m to New Life Sciences in respect of the balance of the prepayment amount received by Regeneus on 12 May 2021, after netting the 1.9 m shares issued to New Life Sciences on 7 May 2021 against Regeneus's obligations, at a deemed issue price of \$0.067 cents per share.

## 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 21 \$	31 Dec 20 \$
<b>Operating activities</b>		
Interest received	-	12
Licence fee revenue	-	7,043,025
Other fee revenue	20,005	24,000
<b>Total revenue</b>	<b>20,005</b>	<b>7,067,037</b>
<b>Other income</b>		
R&D tax incentive	367,119	233,827
Federal Government initiatives and grants	-	37,500
<b>Other income</b>	<b>367,119</b>	<b>271,327</b>

In September 2021, a variation agreement to the licence and collaboration agreement with Kyocera was entered into. The variation agreement sets out specific responsibilities of both the Company and Kyocera under the development program, including establishing the requirement for the Company to provide additional data to Kyocera. There was no impact to revenue recognised to date in relation to the contract.

### 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% (2020: 43.5%) of eligible research and development expenditures.

# 04 Notes to the Consolidated Financial Statements

## 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 2021 is AU\$2,688,086 which would be added to the unused tax losses as at 30 June 2021 of AU\$10,185,387 (30 June 2020 Restated: AU\$12,100,231) which have not previously been brought to account. A full income tax expense calculation for the financial year will be completed in the annual accounts.

	31 Dec 21 \$
Accounting loss before tax	(2,688,086)
Tax rate	25%
Prima facie tax payable on profit before income tax	(672,021)
Tax losses not brought to account	672,021
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 2021 and 31 December 2020

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 21 \$	31 Dec 20 \$
Basic earnings per share from continuing operations	(0.009)	0.015
The weighted average number of ordinary shares used as the denominator on calculating the EPS	304,782,850	291,617,985
Diluted earnings per share		
Diluted earnings per share from continuing operations	(0.009)	0.015
The weighted average number of ordinary shares used as the denominator on calculating the DEPS	304,782,850	291,617,985

At 31 December 2021 share options are not included in the diluted EPS calculation because they are anti-dilutive. (2020: 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.

Share Capital	Shares		\$	
	31 Dec 21	30 June 21	31 Dec 21	30 June 21
Beginning of the period	303,538,363	277,824,988	38,258,870	36,358,675
Shares issued and fully paid	2,898,551	25,713,375	359,891	1,900,195
Closing balance	306,436,914	303,538,363	38,618,761	38,258,870

The Company has 34,059,270 options on issue to acquire ordinary shares in the Company. These options are unlisted, restricted and summarised as follows:

Share options	31 Dec 21 Number	30 Jun 21 Number
Employee share option plan	26,979,770	26,129,770
Share option agreement	7,079,500	8,079,500
	<b>34,059,270</b>	<b>34,209,270</b>



## 04 Notes to the Consolidated Financial Statements

During 6 months ending 31 December 2021, 2,898,551 shares were issued, no options were exercised.

The Group entered into a Subscription Agreement with institutional investor, New Life Sciences, LLC, in May 2021 to secure up to \$4.5 million in a three-stage placement of the Group's ordinary shares. A Settlement notice was received on 13 October 2021 and 2,898,511 shares were redeemed by the investor at \$0.069 per share on 14 October 2021. The share price of the Company on 14 October 2021 was \$0.075.

Under the termination arrangements, Regeneus repaid \$1.26m to New Life Sciences in respect of the balance of the prepayment amount received by Regeneus on 12 May 2021, after netting the 1.9 m shares issued to New Life Sciences on 7 May 2021 against Regeneus's obligations, at a deemed issue price of \$0.067 cents per share. This is reflected in the share capital at the company share price on 21 December 2021 at \$0.075 per share. The value of this initial placement and the shares settled on 14 October 2021 increase the share capital by AU\$359,891.

### 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 AU\$573,700 relating to employee share options (Dec 2020: AU\$29,150).

Share options granted under the option plans	31 Dec 21		30 Jun 21	
	Number	Weighted avg exercise price \$	Number	Weighted avg exercise price \$
Options outstanding at beginning of period	30,409,270	0.10	17,001,674	0.18
Granted	-	-	31,010,270	0.10
Forfeited / lapsed	(150,000)	0.10	(17,602,674)	0.16
Outstanding at end of period	30,259,270	0.10	30,409,270	0.11
Exercisable at end of period	7,653,090	0.12	1,500,000	0.18

Share options that have been forfeited relate to the failure to meet service conditions, whereby employment ceased within the 12 months of the issuance of the options. Share options that have lapsed relate to the post redundancy agreement, whereby 12 months after redundancy options are lapsed if not exercised.

# 04 Notes to the Consolidated Financial Statements

## 12. Related party transactions / Other financial assets

### Shareholder loans

The shareholder loan is a full recourse, interest-free loan initially for 4 years maturing September 2017. The Directors have extended the maturity of the loans to the 15 June 2019 and the loans are technically in default.

While the loans are 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 is subject to market change. Accordingly, an expected credit loss allowance has been made.

	31 Dec 21 \$	30 Jun 21 \$
Shareholder Loan	870,227	870,227
Expected credit loss allowance	(300,000)	(300,000)
Shareholder loan	570,227	570,227

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

	31 Dec 21 \$	30 Jun 21 \$
Related party loan receivable		
Graham Vesey	150,552	150,552
Total related parties loans receivable	150,552	150,552

Regeneus signed a licence agreement with BioPoint Pty Ltd a company of which Graham Vesey is a director and significant shareholder. This licence agreement was agreed upon in September 2020 and is valued at \$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.

After the reporting date, the Company has secured a cashflow facility from Paddington St Finance Pty Ltd, a related party. The facility forward funds, via a loan, the next milestone payment of US\$3 million to be received by Regeneus under the licence and collaboration agreement with Kyocera, expected to be received in Q2 CY2023. The loan will provide Regeneus with the ability to drawdown up to AUD\$4 million and will be secured over the milestone payment receipt and as a first ranking charge over the Group's property.

### Other financial assets

	31-Dec-21 \$	30-Jun-21 \$
Shareholder Loan	870,227	870,227
Institutional Placement (New Life Science)	-	1,500,000
Expected credit loss allowance	(300,000)	(300,000)
Total current other financial assets	570,227	2,070,227

## 13. Derivative financial instrument

The Group entered into a Subscription Agreement with institutional investor, New Life Sciences, LLC, in May 2021 to secure up to \$4.5 million in a three-stage placement of the Group's ordinary shares. An initial placement of \$1.5 million (with a subscription price of \$1.59 million) was received at that time. The investor was to invest \$1.5 million in a second placement (also with a subscription price of \$1.59 million). At the execution of the Subscription Agreement, the Group issued 1,900,000 shares as the initial placement and no value was applied to these shares.

The financial instrument was valued based on the definition of Fair Value under IFRS 13 'Fair Value Measurement' using a Monte Carlo Simulation option pricing model (MCSOPM) which takes into account the contractual terms and assumptions regarding the expected exercise as at 30 June 2021. The instrument was measured at fair value through the profit or loss.

A Settlement notice was received on 13 October 2021 and 2,898,511 shares were issued to the investor at \$0.069 per share on 14 October 2021. The placement price was based on the average of five daily VWAPs per share during the 20 consecutive Actual Trading Days immediately prior to the settlement notice date, rounded down to five decimal places at a reference percentage of 95% and the rounding number is 1/10th of a cent.

## 04 Notes to the Consolidated Financial Statements

A Termination Deed was signed on 21 December 2021 and the initial placement of 1,900,000 shares were priced at \$0.067. The placement price is based on the average of five daily VWAPs per share during the 20 consecutive Actual Trading Days immediately prior to the termination date, rounded down to five decimal places at a reference percentage of 95% and the rounding number is 1/10th of a cent.

The mutually agreed cash repayment amount of the loan amounted to \$1,262,700 and was payable on 4 January 2022. This amount has been recognised as an other financial liability measured at amortised cost.

The market price for the shares issued on 14 October 2021 was at \$0.075 per share. The difference between the investor's valuation and the market price of \$17,391 is recognised as loss movement in fair value. The loss in extinguishment comprises of the market value of the initial placement shares, reversal of the finance cost for the second subscription and the remaining movement in fair value amounted to \$62,398 in total.

	Liability \$
First Subscription	(1,590,000)
Second Subscription	(1,590,000)
Fair value adjustment	137,198
<b>Derivative Financial Instrument at 30 June 2021</b>	<b>(3,042,802)</b>
Shares issued 14 October 2021	200,000
Reversal of Second Subscription	1,590,000
Termination adjustment	(9,898)
<b>Balance at 31 Dec 2021</b>	<b>(1,262,700)</b>

### 14. Other financial assets

The group's equity investment in Sangui Bio Pty Ltd is measured at fair value are valued based on Unobservable inputs for the asset or liability". The share price of the most recent dilutive capital raise event in June 2021 has been used half year FY2022.

	Price Per Share	Amount of shares	Total Valuation
Sangui Bio Pty Ltd Investment	\$2.50	700,000	1,750,000

### 15. Dividends

No dividends were paid during the period (2020: \$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 AU\$50,000.

Other than the above, the Group had no contingent liabilities as at 31 December 2021 (31 December 2020: Nil).

### 17. Events after the reporting date

Subsequent to 31 December 2021 the Company has secured a cashflow facility from Paddington St Finance Pty Ltd, a related party. The facility forward funds, via a loan, the next milestone payment of US\$3 million to be received by Regeneus under the licence and collaboration agreement with Kyocera, expected to be received in Q2 CY2023. The loan will be secured over the milestone payment receipt and as a first ranking charge over the Group's property.

On 4 January 2022 AU\$1.26M was repaid to New Life Sciences as part of the termination of the New Life Sciences Subscription Agreement referred to in the Directors Report.

There has not arisen in the interval between 31 December 2021 and the date of this report, any other event that would have had any material effect on the Financial Statements at 31 December 2021.

# 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 2021 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 25 February 2022.



Level 17, 383 Kent Street  
Sydney NSW 2000

Correspondence to:  
Locked Bag Q800  
QVB Post Office  
Sydney NSW 1230

T +61 2 8297 2400  
F +61 2 9299 4445  
E [info.nsw@au.gt.com](mailto:info.nsw@au.gt.com)  
W [www.grantthornton.com.au](http://www.grantthornton.com.au)

## Independent Auditor's Review Report

To the Members of Regeneus Ltd

### Report on the review of the half-year financial report

#### Conclusion

We have reviewed the accompanying half-year financial report of Regeneus Ltd (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2021, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half year ended on that date, a description of accounting policies, other selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Regeneus Ltd does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the Regeneus Ltd's financial position as at 31 December 2021 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 Conclusion

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 Company 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.

#### Directors' responsibility for the half-year financial report

The Directors of the Company 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

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, 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 Group's financial position as at 31 December 2021 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.

A handwritten signature in grey ink, appearing to read "Grant Thornton".

Grant Thornton Audit Pty Ltd  
Chartered Accountants

A handwritten signature in grey ink, appearing to read "N J Bradley".

N J Bradley  
Partner – Audit & Assurance  
Sydney, 25 February 2022

## 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)  
Dr. John Chiplin (Non-executive Director)

## Chief Executive Officer

Karolis Rosickas

## Company Secretary

Hang Ling (Helen) Leung

## Website

[regeneus.com.au](http://regeneus.com.au)

## Lawyers

Dentons Australia Pty Ltd  
77 Castlereagh Street  
Sydney NSW 2000

## Auditors

Grant Thornton Audit Pty Ltd  
Level 17, 383 Kent Street  
Sydney NSW 2000

## 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