

Regeneus Ltd ABN 13 127 035 358

ASX Half-Year Report for 6 months to 31st December 2020

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 2020 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 2001.

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Results for announcement to the market

Half-Year Report

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Half-Year Report for the 6 months to 31st December 2020

Regeneus Ltd - ABN 13 127 035 358

Reporting period

Report for the half-year ended 31st December 2020 Corresponding period is for the half-year ended 31st December 2019

Results for announcement to the market

	Up / down	% Change		\$'000's
Revenues from ordinary activities	up	905930%	to	7,067
Profit from ordinary activities after tax attributable to members	up	459%	to	4,420
Net Profit from ordinary activities attributable to the members	up	459%	to	4,420

It is not proposed to pay any dividend

Revenue is inclusive of the recent license and collaboration agreement with Kyocera. In the half year ended 31 December 2020 the group received two milestone payments; \$1.4m and \$5.6m.

Full details are in the attached accounts.

Net Tangible assets per security

The net tangible assets (liabilities) per security

31st December 2020 \$0.015 cents 31st December 2019 \$0.001 cents

Independent review of the financial information

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



Half-Year Report 31 December 2020



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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 2020, 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 (Ceased as Executive Director 2 nd November 2020)
Professor Graham Vesey	CSO and Executive Director
Dr Alan Dunton	Non-executive Director (Ceased Directorship 24th February 2021)
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 in Japan, targeting osteoarthritis (OA). Regeneus progressed positively with this strategy in the first half of FY2021, signing an exclusive licence and collaboration agreement with Japanese manufacturer Kyocera Corporation for the commercialisation of Progenza™ to treat knee OA in Japan. Regeneus is targeting Phase II trials for Progenza™ to treat knee OA in Japan, US, and Australia by 2022, and will continue to explore co-development and licensing options for Progenza™ for neuropathic pain. The Company's second stem cell technology platform, Sygenus, is also a priority, with Regeneus exploring co-development and licensing options for Sygenus to treat burns and wounds, neuropathic pain, inflammatory skin conditions, and rare/orphan skin diseases globally.

Executing on strategy as licence and collaboration agreement with Kyocera signed

- A significant milestone was achieved in the half year, with Japanese manufacturer Kyocera and Regeneus signing a licence and collaboration agreement granting Kyocera exclusive rights to develop and commercialise Progenza™ for the treatment of knee OA in Japan.
- Pursuant to the agreement between Kyocera and Regeneus, on 28 August 2020 the company received a payment of AU\$1.4M for the completion of execution of the agreement. The second milestone payment of AU\$5.6M was received on 29 October 2020 following the delivery of the initial Progenza™ OA data package. As the partnership continues, further milestone payments from Kyocera will be triggered.
- Kyocera will fund manufacturing, development and commercialisation costs for Progenza™ OA in Japan under the agreement.
- The agreement provides a clear commercialisation pathway for Progenza™ into a significant market. The global market for osteoarthritis is expected to grow to US\$3.5B by 2026 with the Japanese market alone worth US\$350M.

Other clinical developments

- In terms of other clinical developments, Regeneus expanded its patent portfolio for its second platform technology Sygenus and received a new patent to be granted in the US. This patent expands the application of the platform technology into the US\$53B Aesthetics Therapeutic market and covers treatment of a broad range of non-inflammatory skin conditions with adipose-derived cell secretions.
- In further advancements to Regeneus' patent portfolio, the company secured a Notice of Acceptance for a patent application covering the use of biomarkers to monitor disease progression for stem cell therapy in Australia and a new Sygenus patent granted in Canada for the treatment of acne until 2032.

Other developments

Osteoarthritis market set to be worth \$3.5B by 2026, https://www.globaldata.com/osteoarthritis-7mm-market-set-to-be-worth-3-5B -by-2026

² Grand View Research, Aesthetic Medicine Market Size, Share and Trends Analysis Report, https://www.grandviewresearch.com/industry-analysis/medical-aesthetics-market

01 Directors' Report

During the half year, Leo Lee resigned as CEO of the Company to pursue a new role in a major Japanese
pharmaceutical company. Regeneus appointed experienced executive and healthcare entrepreneur, Karolis Rosickas
as CEO. Karolis Rosickas brings to the Company 15 years' business experience in healthcare, technology and finance,
including co-founding SingCell, a stem cell contract development and manufacturing organisation in Singapore. Leo
Lee remains on the Board of Regeneus as Non-Executive Director.

3. Financial results

Operating results

The Group's operating result for the 6-month period to 31 December 2020 (H1 FY2021) was a profit of AU\$4.4M, compared to results of \$1.2M loss for the previous corresponding period (H1 FY2020).

Revenue and gross margin from continuing operations

Revenue for the 6-month period 31 December 2020 was AU\$7.07M. This is in relation to the recent licence and collaboration agreement with Kyocera, whereby the group received two milestone payments.

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 2020 is AU\$0.2M (31 December 2019: AU\$0.3M).

Events subsequent to the end of the reporting date

Alan Dunton, Non-executive Director resigned on 24 February 2021. Dr Dunton had been granted 1M unlisted options on 1 September 2020. These options lapse immediately as the vesting conditions for the options was not met.

Other than this there has not arisen in the interval between 31 December 2020 and the date of this report, any event that would have had any material effect on the Financial Statements at 31 December 2020.

Expenses from continuing operations

Research and Development

Expenditure on research in the half-year period to 31 December 2020 was AU\$0.5M compared to 31 December 2019 of AU\$0.9M.

Research expenditure includes costs associated with product development as well as clinical trials. Post the successful Phase 1 clinical trial the research expenditure has been maintained at lower levels than prior years. 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\$2.2M in H1 FY2021 compared to AU\$2.0M in the previous corresponding period. This is attributed to 'non-cash' cost of options of AU\$0.2M and the cost of implementing the Company's strategic review, whereby the total monthly operating cost was reduced to AU\$250K.

Occupancy

Occupancy expenditure at AU\$0M (31 December 2019: \$0.2M) is because Regeneus exited the corporate premises at the end of September 2019, although continues to lease a laboratory space in Belrose, NSW.

Finance

Finance costs for the period is AU\$0M (31 December 2019: AU\$0.2M), this is a reflection of the changing debt instruments whereby the loan facility with Leo Lee (\$1.1M) was repaid in full and cancelled following the recent licence and collaboration agreement with Kyocera.

01 Directors' Report

Cash flows

The net inflow for the period was AU\$3.1M compared to the prior corresponding period inflow 31 December 2019: AU\$563K.

Cash flows (used in) / from financing activities Net cash flows	(1,100,000) 3,113,318	2,627,786 562,584	(3,727,786) 2,550,734
Cash flows (used in) / from investing activities	(7,784)	5,430	(13,214)
Cash flows from / (used in) operating activities	4,221,102	(2,070,632)	6,291,734
	31 Dec 20 \$	31 Dec 19 \$	Movement \$

Operating activities

Cash received from operating activities in H1 FY2021 is AU\$4.2M, a significant difference on the cash used in operating activities in H1 FY2020 of AU\$2.1M. This can be attributed to the Company's receipt of funding from Kyocera (including milestone payments of AU\$1.4M and AU\$5.6M) 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 ProgenzaTM, 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

Cash used in financing activities is 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 recent 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 first-half FY21.

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 5 of this report.

Rounding

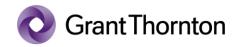
The amounts shown in this Financial Report, including the Directors' report, have been rounded off, except where otherwise stated, to the nearest dollar as the Company is in a class specified in ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191 dated 24 March 2016.

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

Barry Sechos

Non-executive Chairman

26 February 2021



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Auditor's Independence Declaration

To the Directors of Regeneus Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Regeneus Limited for the half-year ended 31 December 2020, I declare that, to the best of my knowledge and belief, there have been:

no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and

no contraventions of any applicable code of professional conduct in relation to the review.

Grant Thornton Audit Pty Ltd
Chartered Accountants

N J Bradley

Partner - Audit & Assurance

Sydney, 26 February 2021

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Consolidated Statement of Profit or Loss and Other Comprehensive Income

Cost of sales - Gross profit 7,067,037 7 Other income 7 271,327 260.6 Research and development expenses (510,048) (851,28 Occupancy expenses (46,681) (238,62 Corporate expenses (2,233,191) (1,973,90 Finance costs (45,543) (179,01 Realised foreign exchange loss (82,930) (87,50 Loss on disposal of fixed assets - (17,62 Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72 Income tax expense 8 - Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share 9 0.015 (0.00	For the half-year ended 31 December	Note	31 Dec 20 \$	31 Dec 1
Gross profit 7,067,037 7 Other income 7 271,327 260.6 Research and development expenses (510,048) (851,28 Occupancy expenses (46,681) (238,64 Corporate expenses (2,233,191) (1,973,90 Finance costs (45,543) (179,01 Realised foreign exchange loss (82,930) (87,50 Loss on disposal of fixed assets - (17,62 Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72 Income tax expense 8 - - Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes. - - -	Revenue	7	7,067,037	78
Other income 7 271,327 260.6 Research and development expenses (510,048) (851,28 Occupancy expenses (46,681) (238,64 Corporate expenses (2,233,191) (1,773,90 Finance costs (45,543) (179,01 Realised foreign exchange loss (82,930) (87,50 Loss on disposal of fixed assets - (17,62 Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72 Income tax expense 8 - Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share - - - Basic earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes. - -	Cost of sales		-	
Research and development expenses (510,048) (851,28 Occupancy expenses (46,681) (238,64 Corporate expenses (2,233,191) (1,973,90 Finance costs (45,543) (179,01 Realised foreign exchange loss (82,930) (87,50 Loss on disposal of fixed assets - (17,62 Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72 Income tax expense 8 - Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00 Diluted earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Gross profit		7,067,037	78
Occupancy expenses (46,681) (238,64 Corporate expenses (2,233,191) (1,973,90 Finance costs (45,543) (179,01 Realised foreign exchange loss (82,930) (87,50 Loss on disposal of fixed assets - (17,62 Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72 Income tax expense 8 - Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00 Diluted earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Other income	7	271,327	260.68
Corporate expenses (2,233,191) (1,973,975) Finance costs (45,543) (179,017) Realised foreign exchange loss (82,930) (87,575) Loss on disposal of fixed assets - (17,627) Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,727) Income tax expense 8 - Profit/(loss) for the period 4,420,237 (1,231,727) Other comprehensive income - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,727) Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.007) Note: This statement should be read in conjunction with the accompanying notes.	Research and development expenses		(510,048)	(851,28
Finance costs (45,543) (179,01 Realised foreign exchange loss (82,930) (87,50 Loss on disposal of fixed assets - (17,62 Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72 lncome tax expense 8 - Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00 Diluted earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Occupancy expenses		(46,681)	(238,644
Realised foreign exchange loss Loss on disposal of fixed assets - (17,62) Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72) Income tax expense 8 - Profit/(loss) for the period Other comprehensive income Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72) Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00) Note: This statement should be read in conjunction with the accompanying notes.	Corporate expenses		(2,233,191)	(1,973,906
Loss on disposal of fixed assets - (17,62) Gain on settlement 5 266 1,854,7 Profit/(loss) before income tax 4,420,237 (1,231,72 Income tax expense 8 - Profit/(loss) for the period Other comprehensive income Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Finance costs		(45,543)	(179,019
Gain on settlement Profit/(loss) before income tax 4,420,237 (1,231,72) Income tax expense Profit/(loss) for the period Other comprehensive income Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72) Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00) Diluted earnings per share from continuing operations 9 0.015 (0.00) Note: This statement should be read in conjunction with the accompanying notes.	Realised foreign exchange loss		(82,930)	(87,50
Profit/(loss) before income tax Income tax expense Profit/(loss) for the period Other comprehensive income Total comprehensive profit/(loss) for the period Earnings per share Basic earnings per share from continuing operations Diluted earnings per share from continuing operations Note: This statement should be read in conjunction with the accompanying notes.	Loss on disposal of fixed assets		-	(17,62
Income tax expense 8 - Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00 Diluted earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Gain on settlement	5	266	1,854,78
Profit/(loss) for the period 4,420,237 (1,231,72 Other comprehensive income - Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72 Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00 Diluted earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Profit/(loss) before income tax		4,420,237	(1,231,72
Other comprehensive income Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72) Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00) Diluted earnings per share from continuing operations 9 0.015 (0.00) Note: This statement should be read in conjunction with the accompanying notes.	Income tax expense	8	-	
Total comprehensive profit/(loss) for the period 4,420,237 (1,231,72) Earnings per share Basic earnings per share from continuing operations 9 0.015 (0.00) Diluted earnings per share from continuing operations 9 0.015 (0.00) Note: This statement should be read in conjunction with the accompanying notes.	Profit/(loss) for the period		4,420,237	(1,231,72
Earnings per share Basic earnings per share from continuing operations Diluted earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Other comprehensive income		-	
Diluted earnings per share from continuing operations 9 0.015 (0.00 Note: This statement should be read in conjunction with the accompanying notes.	Earnings per share			
Note: This statement should be read in conjunction with the accompanying notes.	Basic earnings per share from continuing operations	9	0.015	(0.00
2) 	Diluted earnings per share from continuing operations	9	0.015	(0.00

03 Consolidated Statement of Financial Position

As at 31 December	Note 3	31 Dec 20 \$	30 Jun 20 \$
Current assets			
Cash and cash equivalents	4	1,095,163	981,845
Trade and other receivables		-	1,466,400
R&D tax incentive receivable		133,971	429,394
Other current assets		93,959	36,421
Financial asset at amortised cost	13	570,227	570,227
Total current assets	4	1,893,320	3,484,287
Non-current assets			
Property, plant and equipment		43,948	61,805
Right of use assets under lease		15,680	18,367
Total non-current assets		59,628	80,172
Total assets	2	1,952,948	3,564,459
Current liabilities			
Trade and other payables		452,187	946,268
Provisions		182,723	141,122
Other current liabilities	13	-	1,100,000
Lease liabilities		5,296	5,117
Contract liabilities		-	1,440,000
Total current liabilities		640,206	3,632,507
Non-current liabilities			
Lease liabilities		11,106	13,843
Provisions		41,778	49,071
Total non-current liabilities		52,884	62,914
Total liabilities		693,090	3,695,421
Net assets		1,259,858	(130,962)
Equity			
Issued capital	38	3,155,426	36,358,675
Other contributed equity		-	1,797,017
Accumulated losses	(34	,212,613)	(38,718,175)
Reserves		317,045	431,521
Total equity		1,259,858	(130,962)

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 2019	31,076,819	-	412,065	(37,875,379)	(6,386,495)
	Loss for the period	-	-	-	(1,231,726)	(1,231,726)
	Employee share-based payment option expense	-	-	161,785	-	161,785
	Transfer from reserves to retained earnings for options forfeited	-	-	(161,100)	161,100	
715	Equity confirmed pending issuance to AGC Inc (Japan)	-	1,797,017		-	1,797,017
	Issue of share capital net of transaction costs	5,281,856	-			5,281,856
	Balance at 31 December 2019	36,358,675	1,797,017	412,750	(38,946,005)	(377,563
	Balance at 1 July 2020	36,358,675	1,797,017	431,521	(38,718,175)	(130,962)
	Profit for the period	-	-	-	4,420,237	4,420,23
30	Employee share-based payment options issued	-	-	203,339	-	203,33
	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	(34,212,613)	4,259,858

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

Consolidated Statement of Cash Flows

Operating activities Receipts from customers Payments to suppliers and employees		
Payments to suppliers and employees	7,659,167	
_ · · · · · · · · · · · · · · · · · · ·	(3,730,685)	(3,505,
Interest received	12	
R&D tax incentive refund	676,590	1,491
R&D tax incentive repayment	(147,341)	
Grant received	37,500	
Finance costs	(274,141)	(57,8
Net cash from / (used in) operating activities	4,221,102	(2,070,6
Investing activities		
Purchase of property, plant and equipment	(7,784)	
Receipts from sale of property, plant and equipment	-	5
Net cash (used in) / from investing activities	(7,784)	5
Financing activities		
Receipts from loans to shareholders	-	25
Proceeds from related party loan	-	
Repayments of related party loans	(1,100,000)	(1,280,
Proceeds from issue of shares	-	3,881
Net cash (used in) / provided by financing activities	(1,100,000)	2,627
Net change in cash and cash equivalents held	3,113,318	562
Cash and cash equivalents at beginning of period	981,845	255
Cash and cash equivalents at end of period	4,095,163	818

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 2020 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 2020 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 26 February 2021.

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 2020, the Group generated a profit after income tax of AU\$4.4M (2019: AU\$1.2M loss), net cash inflows from operating activities of AU\$4.2M (2019: AU\$2.1M outflow) and the net current asset balance of AU\$4.25M (2019: net deficit of AU\$148,220).

The Directors additionally assessed the Group's recent licence and collaboration agreement with Kyocera (August 2020), whereby in the half-year ended 31 December 2020 the group received two milestone payments; AU\$1.4M & AU\$5.6M. This agreement gives rise to Regeneus receiving a total US\$19M in upfront, development and regulatory milestones. As such it is expected to provide funding for the Group's current anticipated business activities.

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 2020, in exception to the valuation approach used to calculate the share options.

Previously a variation of the binominal method was used, however in the half-year financial statements ending 31 December 2020 the Black-Scholes method has been used for options during the period.

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 2020 except as set out below:

Issuance of Shares

In December 2016, the Company entered into a Manufacturing Licence Agreement and Shareholders Agreement with AGC Inc of Japan (AGC). As part of these arrangements and in satisfaction of performance obligations the Company received an upfront payment and milestone payment totalling US\$6.5M. The Shareholders Agreement anticipated that AGC and Regeneus would work together to secure a marketing partner for the clinical development and commercialisation of Progenza™ in Japan.

Furthermore, if securing such a partner was not achieved by 31 December 2018 then AGC had the opportunity to use US\$2.5M, paid as upfront and milestone payments, to subscribe for shares in Regeneus and to cancel the arrangements.

In December 2019, the Company and AGC Inc agreed to the termination of their JV Agreements including the exclusive Manufacturing Licence Agreement and Regeneus Japan Shareholder Agreement. As part of the termination the parties agreed to the conversion of the US\$2.5M of upfront and milestone payments already received by Regeneus into equity of the Company at a fixed subscription price of AU\$0.16 per share, representing a 100% premium to the Company's share price at the date of the agreement.

The issuance of shares was dependent upon AGC nominating the timing, which was invoked in this half year period. As such in the financial statements for 31 December 2020 the estimates for 'Other contributed equity' and 'Gain on settlement" were adjusted to reflect the actuals. AGC was issued a total of 22,459,393 ordinary shares compared to the estimate of 22,462,712 thereby an adjustment to 'Other contributed equity" and 'Gain on settlement" of AU\$266 was required which has been recognised in the income statement & statement of financial position for the period.

Loans to Shareholders

The loans made by the Company to certain shareholders are full recourse, interest-free loans for 4 years initially maturing September 2017. Having extended the maturity to 15 June 2018 the Directors considered that it was in all shareholders interest if the loan repayment was extended a further 12 months to 15 June 2019. These loans are currently repayable.

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 overdue and the share price has reduced. Accordingly, an expected credit loss allowance has been made.

Included within the shareholder loan are balances owing by the Directors of AU\$150,552.

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 20 \$	31 Dec 19 \$
Operating activities		
Interest received	12	781
Licence fee revenue	7,043,025	-
Other fee revenue	24,000	-
Total revenue	7,067,037	781
Other income		
R&D tax incentive	233,827	260,688
Federal Government initiatives and grants	37,500	-
Other income	271,327	260,688

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% (2019: 43.5%) of eligible research and development expenditures.

Income tax expense

No income tax expense or liability has been recognised in the half-year accounts. The Group's accounting profit as at 31 December 2020 is AU\$4,420,237, for which the intention is to utilise the unused tax losses as at 30 June 2020 of AU\$13,500,231 (30 June 2019: AU\$12,259,956) 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 20 \$
Accounting profit before tax	4,420,237
Tax rate	27.5%
Prima facie tax payable on profit before income tax	(1,215,565)
Application of tax losses not previously recognised	1,215,565
Income tax expense	-

Earnings per share

Both the basic and diluted earnings per share have been calculated using the profit attributable to shareholders of the parent company (Regeneus Ltd) as the numerator, i.e., no adjustments to profits were necessary during the six-month period to 31 December 2020 and 30 June 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 20 \$	31 Dec 19 \$
Basic earnings per share from continuing operations	0.015	(0.005)
The weighted average number of ordinary shares used as the denominator on calculating the EPS	291,617,985	253,762,521
Diluted earnings per share		
Diluted earnings per share from continuing operations	0.015	(0.005)
The weighted average number of ordinary shares used as the denominator on calculating the DEPS	291,617,985	253,762,521
At 21 December 2020 share entires are not included in the diluted EDS calculation because they are anti-	dilutivo (2010: pil)	

At 31 December 2020 share options are not included in the diluted EPS calculation because they are anti-dilutive. (2019: 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.

1	2	Shares		\$	
	Share Capital	31 Dec 20	30 June 20	31 Dec 20	30 June 20
	Beginning of the period	277,824,988	208,885,143	36,358,675	31,076,819
	Shares issued and fully paid	22,459,393	68,939,845	1,796,751	5,281,856
_	Closing balance	300,284,381	277,824,988	38,155,426	36,358,675

The company has 14,260,270 options on issue to acquire ordinary shares in the company. These options are unlisted, restricted and summarised as follows:

Share options	31 Dec 20 Number	30 Jun 20 Number
Employee share option plan	3,980,770	1,001,674
Share option agreement	10,279,500	16,000,000
	14,260,270	17,001,674

11. Other Contributed equity

In December 2019, the agreements with AGC were terminated. The termination of the agreements gave rise to AGC being entitled to be issued shares in Regeneus to the value of up to US\$2.5M. AGC confirmed that they would be prepared to be issued with shares in Regeneus based on a valuation of AU\$0.16 per share. This gave rise to an estimated entitlement of AGC to receive 22,462,712 ordinary shares in Regeneus.

The prevailing price of Regeneus shares at the time of the agreement was AU\$0.08 giving rise to Other contributed equity of AU\$1,797,017.

In September 2020, a total of 22,459,393 ordinary shares were issued to AGC to the value of up to \$US\$2.5M. Therefore, the issuing of the shares gave rise to share capital of AU\$1,796,751. As such an adjustment to the estimated figure previously recorded in December 2019 was adjusted in this half-year period.

	Sha	\$	\$	
Other Contributed Equity	31 Dec 20	30 June 20	31 Dec 20	30 June 20
Beginning of the period	22,462,712	-	1,797,017	-
Shares to be issued	(3,319)	22,462,712	(266)	1,797,017
Shares issued	(22,459,393)	-	(1,796,751)	-
Closing balance	-	22,462,712	-	1,797,017

Share-based payments 12.

All share-based remunera	ation will be settle	ed in equity. The	e Group has no le	egal or constr	uctive obligat	ion to repurch	ase or settle
the options.			•		•		
The fair value of share op the fair value of share opt model. For the options outstanding	ions dated 1 July	2020, 14 Octo	ber 2020 & 2 Nov				
Grant date	31 Jan 2019	1 Oct 2019	1 July 20	14 Oct 20	14 Oct 20	2 Nov 20	2 Nov
Share price at date of grant	\$0.155	\$0.069	\$0.07	\$0.16	\$0.16	\$0.125	\$0.
Volatility	57%	91%	75%	65%	65%	75%	7
Option life	5 years	5 years	5 years	5 years	5 years	5 years	5 ує
Dividend yield	0%	0%	0%	0%	0%	0%	
Risk free investment rate	1.90%	0.75%	0.40%	0.32%	0.32%	0.28%	0.2
Fair value at grant date	\$0.067	\$0.044	\$0.037	\$0.100	\$0.091	\$0.072	\$0.
Exercise price at date of grant	\$0.20	\$0.10	\$0.10	\$0.1075	\$0.14	\$0.14	\$0
Employee benefits expen AU\$161,786).	ses in the profit o	or loss includes		9,150 relating	ı to employee	share options	`
Share options granted under	er the option plans		Numbe	Weighte exercise p	Ÿ	Number	Weighted a exercise p
Options outstanding at beg	inning of period		17,001,674	<u> </u>	0.18	7,671,674	0
Granted			12,010,270)	0.13	15,750,000	O
Forfeited / lapsed			(14,751,674))	0.13	(6,420,100)	0
			4.4.000.070		0.14	17,001,674	0
Outstanding at end of period	od		14,260,270		0.14	17,001,074	U

7	\	31 De	c 20	30 Jun :	20
Ī	Share options granted under the option plans	Number	Weighted avg exercise price \$	Number	Weighted avg exercise price \$
	Options outstanding at beginning of period	17,001,674	0.18	7,671,674	0.20
	Granted	12,010,270	0.13	15,750,000	0.15
-	Forfeited / lapsed	(14,751,674)	0.13	(6,420,100)	0.13
	Outstanding at end of period	14,260,270	0.14	17,001,674	0.18
1	Exercisable at end of period	-	-	1,001,674	0.14

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.

Related party transactions 13.

On the 28 February 2019, the Company received loans from the Directors totalling AU\$2.5M in an arms-length arrangement. The loans were unsecured and repayable on the earlier of 2 March 2020 or 10 days after a capital raise sufficient to fund repayment of the loans of the Company and support the working capital requirements of the Company for the 12 months during the 2019 period, as reasonably determined by the Board of Directors.

During September 2019, a successful capital raising was undertaken and AU\$1.4M of the Directors Loans were converted to shares. The interest associated with these loans was paid out in March 2020 in accordance with the original loan arrangements.

The remaining AU\$1.1M loan was renegotiated as part of a new AU\$4M loan facility, AU\$2M provided by Leo Lee and a further AU\$2M provided by Paddington St Finance Pty Ltd.

However, in light of the recent licence and collaboration agreement with Kyocera the Company made a final principal repayment of AU\$1.1M to Leo Lee and cancelled the loan facilities totalling AU\$4M with Paddington St Finance Pty Ltd & Leo Lee.

I	Related party loan payable	31 Dec 20 \$	30 Jun 20 \$
Ų	Paddington St Finance Pty Ltd	-	-
	Leo Lee	-	1,100,000
/	Barry Sechos	-	
	Glen Richards	-	
	Total related parties loans payable	-	1,100,000

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.

	31 Dec 20	30 Jun
	\$. 233 _5	
Shareholder Loan	870,227	870,2
Expected credit loss allowance	(300,000)	(300,0
Shareholder loan	570,227	570,2

Related party loan receivable	31 Dec 20 \$	30 Jun 20 \$
Graham Vesey	150,552	150,552
Total related parties loans receivable	150,552	150,552

14. Dividends

No dividends were paid during the period (2019: \$nil).

15. Contingent liabilities

Recently 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\$50K.

Other than the above, the Group had no contingent liabilities as at 31 December 2020 (31 December 2019: AU\$25K).

16. Events after the reporting date

Alan Dunton, Non-executive Director resigned on 24 February 2021. Dr Dunton had been granted 1M unlisted options on 1 September 2020. These options lapse immediately as the vesting conditions for the options was not met.

Other than this, there has not arisen in the interval between 31 December 2020 and the date of this report, any event that would have had any material effect on the Financial Statements at 31 December 2020.

05 Director's Declaration

Directors' declaration

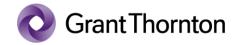
- 1. In the opinion of the Directors of Regeneus Ltd:
 - a. the consolidated financial statements and notes of Regeneus Ltd are in accordance with the Corporations Act 2001, including:
 - i) giving a true and fair view of its financial position as at 31 December 2020 and of its performance for the half-year 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 26 February 2021.



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Independent Auditor's Review Report

To the Members of Regeneus Limited

Report on the review of the half year-financial report

Conclusion

We have reviewed the accompanying half-year financial report of Regeneus Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2020, 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 Limited does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the Regeneus Limited's financial position as at 31 December 20XX 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.

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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 2020 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.

Grant Thornton Audit Pty Ltd Chartered Accountants

N J Bradley

Partner – Audit & Assurance

Sydney, 26 February 2021

Registered Office and Principal Place of Business

2 Paddington Street Paddington, NSW 2021, Australia

Board of Directors

Barry Sechos (Non-executive Chairman)
Leo Lee (Executive Director)
Professor Graham Vesey (Executive Director)
Dr. Glen Richards (Non-executive Director)
Dr. John Chiplin (Non-executive Director)
Dr. Alan Dunton (Non-executive Director)

Company Secretary

Sandra McIntosh

Website

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Patent Attorneys

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

Share Registry

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Stock Exchange Listing

Australian Securities Exchange ASX Code: RGS