

Tuesday 31 August 2021

The Manager
Market Announcement Office
Australian Securities Exchange Limited
20 Bridge Street
Sydney NSW 2000

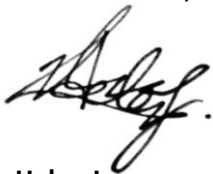
**REGENEUS LTD (ASX:RGS)
RESULTS FOR THE YEAR ENDED 30 JUNE 2021**

Attached for immediate release to the market is the Regeneus Ltd Appendix 4E - Preliminary final report-unaudited for the year ended 30 June 2021.

Regeneus advises it is relying on the reporting relief granted by ASIC under ASIC Corporations (Extended Reporting and Lodgement Deadlines—Listed Entities) Instrument 2020/451, as amended by ASIC Corporations (Amendment) Instrument 2020/1080 and ASIC Corporations (Amendment) Instrument 2021/315), to extend the lodgement date for its audited Financial Statements and Annual Report to no later than 31 October 2021.

Regeneus will make a further announcement to the market if it becomes aware that there will be a material difference between its unaudited Financial Statements being lodged today and its audited Financial Statements.

Yours faithfully



Helen Leung
Company Secretary

This announcement was authorised by the Board of Directors of Regeneus Ltd.



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Regeneus Ltd

ABN 13 127 035 358

Appendix 4E

Preliminary final report - unaudited

Year ended 30 June 2021

Appendix 4E and Unaudited Preliminary Final Report for the year ended 30 June 2021

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Regeneus Ltd

Regeneus Ltd (ASX: RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell technologies to develop a portfolio of novel cell-based therapies to address significant unmet medical needs in the human health markets with a focus on osteoarthritis and other musculoskeletal disorders, neuropathic pain and dermatology.

Appendix 4E Statement

Reporting Period

Report for the full year to 30 June 2021. Corresponding period is for the full year ended 30 June 2020.

Results for announcement to the market			
	Current	Change	Change
	\$'000	\$'000	%
Revenue from ordinary activities	7,067	5,404	325%
Profit from ordinary activities after income tax attributable to members	2,153	3,222	301%
Net profit for the year attributable to members	2,153	3,222	301%

	2021	2020
	Cents	Cents
Basic earnings per share	0.007	(0.004)
Diluted earnings per share	0.007	(0.004)
Net tangible asset backing (liabilities) per ordinary share	0.790	(0.050)

Review of Operations

Highlights

- Entered into a Licence and Collaboration Agreement with Kyocera Corporation to exclusively develop and commercialise Progenza™ for treatment of knee osteoarthritis (OA) in Japan. Payments received from Kyocera in FY2021 include AU\$1.4M on entering the Agreement and a milestone payment of AU\$5.6M in October 2020 on delivery of the initial Progenza™ OA data package.
- An R&D Tax Incentive of AU\$676k was received from the Australian Tax Office for FY2020.
- Successful CEO transition, with the appointment of experienced executive and healthcare entrepreneur Karolis Rosickas to lead Regeneus' next phase of growth and Mr Leo Lee remaining as non-executive director on the Board of Regeneus.
- Initiated US FDA pre-IND consultation preparation process, entered into a manufacturing agreement for the US GMP final product and started to conduct the required non-clinical work for the US market.
- Research collaboration entered into with Raymond Purves Bone and Joint Research Laboratories at the Kolling Institute of Medical Research, Australia.
- Australian Department of Defence provided AU\$300k funding to develop Sygenus, Regeneus' stem cell bioactive secretome technology, for combat casualty care with first in human study on pain.
- Regeneus' Progenza™ IP portfolio strengthened in FY2021 with key patents awarded for the treatment of pain in Europe and Japan. An Australian patent was also awarded covering use of biomarkers to monitor disease progression in patients undergoing mesenchymal cell therapy for inflammatory conditions.
- Patent portfolio protection extended for Regeneus' second platform technology Sygenus, including US patent awarded for treatment of broad range of non-inflammatory conditions with adipose derived secretions. Patents were also awarded in Canada, Hong Kong and China.
- Up To AU\$4.5M secured in three-stage placement with New Life Sciences Capital, LLC (**New Life Sciences**) to fund initiation of Progenza™ Osteoarthritis (OA) Phase 2 trial in the US and for general working capital needs. At commencement 1,353,982 and 1,900,000 shares were issued and are in relation to the convertible financial instrument that has been made to raise AU\$1.5M. Second and third placements are planned to follow in 6 and 12 months. The third placement is subject to the mutual agreement of Regeneus and New Life Sciences. Prior to commencement of the first placement New Life Sciences was issued 3,800,000 options.
- Issued 22.46 million shares to Japan-based manufacturer AGC Inc (AGC) related to the previously agreed option to convert upfront payments of US\$2.5M to equity ownership on termination of AGC-Regeneus agreement in December 2019 with AGC becoming the single largest shareholder in Regeneus.

Commentary on Results

The Group's operating results for the year was a profit of AU\$2.2M (FY20: Loss of AU\$1.1M). The improved result and first-time profit for the Company reflects the transformative Licence and Collaboration Agreement that the Company entered with Kyocera in FY21 to develop Progenza™ OA in Japan.

Revenue of AU\$7.1M in the year (FY20: AU\$1.7M) results from the receipt of two payments from Kyocera under the terms of the Memorandum of Understanding and the Licence and Collaboration Agreement.

The Company received an AU\$5.6M milestone payment from Kyocera in October 2020 for the successful completion of the data pack delivery process, in addition to AU\$1.4M received from Kyocera in August 2020 on completion of the execution of the Licence and Collaboration Agreement.

The Consolidated Statement of Financial Position net assets is equal to AU\$2.41M (FY20: net deficit AU\$0.1M).

The significant improvement over the 12 month period is predominantly reflective of the increase in cash to AU\$3.8M (FY20: U\$1M) and a reduction in current liabilities to AU\$1.3M (FY20: AU\$3.6M). This improvement results from receipt of milestone payments from Kyocera during the year, reduction in borrowing as a result of the repayment of the Director's loan of AU\$1.1M and receipt of the initial investment of AU\$1.5M from New Life Sciences under the institutional placement agreement entered into in May 2021.

Corporate expenses of AU\$3.95M were in line with prior year expenses (FY20 AU\$3.44M), which include: corporate employees, Directors, IP, compliance, depreciation and business development costs.

Research and development expenditure for the year was AU\$1.3M (FY20 AU\$1.2M). R&D activities include staff and other costs associated with product research, GMP manufacture and the conduct of clinical trials for the Company's products.

During the year the loan facilities available to the Company of AU\$4M were cancelled.

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. A second investment of AU\$1.5M will be made on or before 12 November 2021 giving New Life Sciences the right to subscribe for further shares in the Company with an aggregate value of AU\$1.59M. In addition, New Life Sciences may make a third investment of AU\$1.5M on or before 12 May 2022, subject to the mutual consent of the parties, which gives New Life Sciences the right to subscribe for further Shares with an aggregate value of AU\$1.5M.

At the commencement of the first placement, 1,353,982 and 1,900,000 shares were issued to New Life Sciences. The 1,353,982 shares were issued in payment of the commencement fee of \$153,000 payable to New Life Sciences. The 1,900,000 shares issued were in relation to the initial placement shares. Finally, 3,800,000 options were issued immediately before the first placement as part of the commencement transactions and can be exercised any time over a period of 36 months.

The investments contemplated by each of the placements referred to above are subject to conditions customary for investment placement agreements of the nature entered into with New Life Sciences.

Additional Information

Details of controlled entities

During the financial year ended 30 June 2021, no new subsidiaries were acquired.

Details of Associates and Joint Venture Entities

During the financial year ended 30 June 2021, no new Associates or Joint Venture Entities were created.

Dividends

No dividends are being proposed or have been paid in the current year (2020: Nil).

Accounting Standards

Australian Accounting standards and International Financial Reporting Standards have been used in preparing the information contained in this Appendix 4E.

Significant Accounting Policies

Accounting policies, estimation methods and measurement bases used in the Appendix 4E are the same as those used in the last annual report and the last half-year report.

Contingencies

The Group contingencies are broadly in line with those disclosed in the last annual report.

Audited Annual Accounts

This report is based on the consolidated financial statements that are in the process of being audited by Grant Thornton Audit Pty Ltd. These accounts are not expected to be qualified.

The Company is in the process of obtaining a valuation of a derivative financial instrument which arose as part of the placement agreement with New Life Science.

The accounting treatment of this financial instrument will depend on the valuation received by the Company and may mean a change to the financial results shown in the audited financial statements, once completed, compared to those set out in this Unaudited Preliminary Final Report.

Comparative Information

The comparative financial information has been presented on a consistent basis with the prior year audited Financial Statements.

Other Significant Information

There is no other significant information requiring disclosure in the preliminary report.

Consolidated Statement of Comprehensive Income

For the year ended 30 June	2021	2020
	\$	\$
Revenue	7,067,026	1,663,345
Other income	888,796	722,232
Research and development expenses	(1,295,851)	(1,237,657)
Occupancy expenses	(282,609)	(262,972)
Corporate expenses	(3,947,475)	(3,439,261)
Finance costs	(75,039)	(271,471)
Gain on Disposal of Regeneus Japan Inc	-	7,077
Loss on disposal of fixed assets	-	(17,622)
Fair value decrease in institutional placement	(178,540)	-
Gain on settlement of AGC Inc contract liability	266	1,854,783
Realised foreign exchange loss on contract liability	(82,664)	(87,500)
Foreign exchange gain	59,101	-
Profit/(loss) before income tax	2,153,011	(1,069,046)
Income tax (expense) / benefit	-	-
Profit/(loss) for the year	2,153,011	(1,069,046)
Other comprehensive (expense) / income	-	-
Total comprehensive income / (loss) for the year	2,153,011	(1,069,046)

Earnings per share	2021	2020
Basic earnings per share		
Earnings per share from continuing operations	0.007	(0.004)
Diluted earnings per share		
Earnings per share from continuing operations	0.007	(0.004)

Consolidated Statement of Financial Position

As at 30 June	2021	2020
	\$	\$
Current Assets		
Cash and cash equivalents	3,792,695	981,845
Trade and other receivables	-	1,466,400
R&D incentive receivable	751,428	429,394
Other current assets	112,152	36,421
Financial assets at amortised cost	570,227	570,227
Total current assets	5,226,502	3,484,287
Non-current assets		
Property, plant and equipment	20,849	61,805
Right of use assets under lease	12,992	18,367
Intangible assets	-	-
Investments accounted for using the equity method	-	-
Total non-current assets	33,841	80,172
Total assets	5,260,343	3,564,459
Current liabilities		
Trade and other payables	1,108,116	946,268
Provisions	183,379	141,122
Borrowings	-	1,100,000
Lease liabilities	5,296	5,117
Contract liabilities	-	1,440,000
Total current liabilities	1,296,791	3,632,507
Non-current liabilities		
Lease liabilities	8,547	13,843
Provisions	16,738	49,071
Borrowings	1,528,206	-
Total non-current liabilities	1,553,491	62,914
Total liabilities	2,850,282	3,695,421
Net assets/(liabilities)	2,410,061	(130,962)
Equity		
Issued capital	38,286,543	36,358,675
Other contributed equity	-	1,797,017
Accumulated losses	(36,479,839)	(38,718,175)
Reserves	603,357	431,521
Total equity	2,410,061	(130,962)

Consolidated Statement of Changes in Equity

For the year ended 30 June	Share capital \$	Other contributed equity \$	Share option reserve \$	Retained earnings \$	Total equity \$
Balance at 1 July 2019	31,076,819	-	412,065	(37,875,379)	(6,386,495)
Reported loss for the year	-	-	-	(1,069,046)	(1,069,046)
Reported other comprehensive income (expense)	-	-	-	-	-
Total comprehensive income (loss) for the	-	-	-	(1,069,046)	(1,069,046)
Employee share-based payment option	-	-	245,706	-	245,706
Transfer from reserves to retained earnings for options lapsed	-	-	(226,250)	226,250	-
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 30 June 2020	36,358,675	1,797,017	431,521	(38,718,175)	(130,962)
Balance at 1 July 2020	36,358,675	1,797,017	431,521	(38,718,175)	(130,962)
Reported profit for the year	-	-	-	2,153,011	2,153,011
Reported other comprehensive income (expense)	-	-	-	-	-
Share options issued as part of institutional placement with New Life Sciences	-	-	47,423	-	47,423
Employee share-based payment options issued	-	-	442,228	-	442,228
Employee share-based payment option 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 transactions costs	131,117	-	-	-	131,117
Balance at 30 June 2021	38,286,543	-	603,357	(36,479,839)	2,410,061

Consolidated Statement of Cash Flows

For the year ended 30 June	2021 \$	2020 \$
Operating activities		
Receipts from customers	6,607,361	1,639,344
Payments to suppliers and employees	(4,523,817)	(4,760,104)
Interest received	12	780
Other income and COVID-19 Cash Flow Boost	37,500	50,000
R&D repayments	(147,342)	-
R&D incentive refund	676,591	1,491,498
Finance costs paid	(231,671)	(339,104)
Net cash provided by / (used in) operating activities	2,418,634	(1,917,586)
Investing activities		
Purchase of property, plant and equipment	(7,784)	-
Receipts from sale of property, plant and equipment	-	5,430
Payment for outstanding 50% equity interest in Regeneus Japan	-	(25,494)
Sale of subsidiary	-	36,246
Net cash (used in) / provided by investing activities	(7,784)	16,182
Financing activities		
Proceeds from related party loan	-	20,000
Repayment of related party loan	(1,100,000)	(1,300,000)
Proceeds from issue of shares	-	3,881,856
Proceeds from institutional placement	1,500,000	-
Receipts from shareholder loan	-	25,930
Net cash provided by financing activities	400,000	2,627,786
Net change in cash and cash equivalents held	2,810,850	726,382
Cash and cash equivalents at beginning of financial year	981,845	255,463
Cash and cash equivalents at end of financial year	3,792,695	981,845

Corporate Directory

Registered Office and Principal Place of Business

2 Paddington Street
Paddington NSW 2021

Board of Directors

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

Company Secretary

Hang Ling (Helen) Leung

Website

regeneus.com.au

Lawyers

Dentons Australia Limited
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