

Thursday 31 August 2023

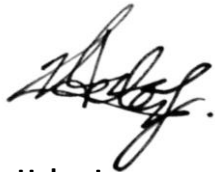
The Manager
Market Announcement Office
Australian Securities Exchange Limited
20 Bridge Street
Sydney NSW 2000

REGENEUS LTD (ASX:RGS)
RESULTS FOR THE YEAR ENDED 30 JUNE 2023

Attached for immediate release to the market is the Regeneus Ltd Appendix 4E - Preliminary final report-unaudited for the year ended 30 June 2023.

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.



Regeneus Ltd

ABN 13 127 035 358

Appendix 4E

Preliminary final report - unaudited

Year ended 30 June 2023

For personal use only

Appendix 4E and Unaudited Preliminary Final Report for the year ended 30 June 2023

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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 2023. Corresponding period is for the full year ended 30 June 2022.

Results for announcement to the market			
	Current	Change	Change %
Revenue from ordinary activities	-	-	-
Loss from ordinary activities after income tax attributable to members	(3,376,883)	932,847	22%
Net loss for the year attributable to members	(3,376,883)	932,847	22%

	2023 Cents	2022 Cents
Basic earnings per share	(0.011)	(0.014)
Diluted earnings per share	(0.011)	(0.014)
Net tangible asset backing (liabilities) per ordinary share	(0.59)	(0.22)

Review of Operations

Highlights

- Regeneus has completed a collaboration with the Australian Department of Defence to advance the development of Sygenus topical product for military applications.
- The Company received a notice of termination from Kyocera under the Collaboration and Licence Agreement entered into on 8 August 2020. Regeneus is exploring options to continue the development of Progenza in Japan.
- Regeneus entered into non-binding share merger discussions with Cambium Medical Technologies, LLC (CMT) in the United States. Both companies are in advanced stages of negotiating binding merger documentation.
- The Company continued business development efforts to find partners for Progenza in the United States, South Korea, and China in FY2023.
- Regeneus continued development of Progenza's chemistry, manufacturing, and controls (CMC) aspects, including an additional potency assay to demonstrate the benefit of adding the bioactive secretome to the Progenza product. These studies will support future regulatory filings.
- An R&D Tax Incentive of AU\$1.1M was received from the Australian Tax Office for FY2022.
- Regeneus obtained prefinancing of AU\$347k from Radium Capital, representing 80% of the anticipated Research & Development Tax Incentive Rebate for the first 9 months of FY2023.
- Regeneus has reached an agreement to settle the AU\$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of AU\$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio. The cash payment of A\$400,000 was made on 1st March 2023. The transfer of the 700,000 Sangui Bio shares is subject to shareholder approval.
- The Company's operations were further optimized by reducing headcount and operating expenses.

Commentary on Results

Research and Development (R&D) activities

- Research and development expenditure for the year was AU\$473k (FY22 AU\$1.86M). R&D activities include staff and other costs associated with product research, manufacture of investigational drug products and the conduct of preclinical trials.
- Regeneus has concluded the collaboration programme with the Australian Department of Defence further to the grant funding announced in December 2020. The Company is exploring the next steps to develop a topical product for military and other applications.
- The Company continued CMC development activities for Progenza to support future regulatory filings.

Termination of Kyocera Collaboration Agreement in Japan

- On 27 January 2023 Regeneus received a notice of termination (Notice) from Kyocera under the Collaboration and Licence Agreement. The Notice purports to terminate the Agreement for Kyocera's failure to meet its Development Target relating to establishment of first Standard Operating Procedures for the manufacture of Progenza for the clinical trial to be held in Japan by the required date – being 30 September 2022.
- The Company does not accept that Kyocera has any right to terminate the Agreement.
- As a result of the purported termination of the Licence Agreement, Kyocera has indicated that no further milestone or other payments will be made under the Licence Agreement.
- Regeneus is exploring options to find an alternative partner to develop Progenza for knee osteoarthritis in Japan.

Merger with Cambium Medical Technologies, LLC

- Regeneus has signed a non-binding indicative offer letter to merge with Cambium Medical Technologies, LLC (CMT). CMT is a United States-based, clinical-stage regenerative medicine company developing a Phase 3-ready biologic therapeutic, Elate Ocular®, to treat dry eye disease. Please refer to the ASX announcement on 28 April 2023 for more details about the proposed transaction.
- The mutual due diligence process and the negotiation of binding merger documentation are in the final stages.
- Subject to agreement on binding merger documentation and shareholder approval, Regeneus expects to complete the merger transaction with Cambium Medical Technologies in November 2023.

Financial performance

- Regeneus recorded other income of AU\$1,044,689 (FY22: AU\$638,006), a year over year increase of 63.7%.
- The Company reported a net loss of AU\$3,376,883 (FY22: net loss of AU\$4,309,730), a year over year reduction of 21.6%.
- Regeneus' total cost base decreased from AU\$4.9M in FY22 to AU\$2.6M in FY23, reflecting significant cost saving measures implemented in FY2023, in addition to operational efficiency improvements executed in FY2022.
- As the group has not been able to obtain sufficient appropriate evidence to support the value of the Sangui Bio investment, the group has decided to impair the carrying value of the investment from \$1.75M to nil.

Financial position

- Regeneus ended FY2023 with AU\$302,792 cash balance (FY22: AU\$95,122).
- Regeneus has reached an agreement to settle the AU\$2 million outstanding loan and interest payable to Paddington St Finance under the PSF Facility, in exchange for the payment of AU\$400,000 in cash and the transfer from Regeneus to Paddington St Finance of 700,000 shares in Sangui Bio. The transfer of the Sangui Bio shares in part payment of moneys owing under the PSF Facility is subject to Regeneus receiving the required shareholder approval.
- The Company obtained prefinancing of \$347k from Radium Capital representing 80% of the Research & Development Tax Incentive Rebate for the first 9 months of FY2023. The Company is expecting a total FY2023 Research & Development Tax Incentive rebate of approximately \$480k. This amount is expected to be received in September 2023. After repayment of the Radium Capital loan, the Company will have additional cash of approximately \$140k.

Additional Information

Details of controlled entities

During the financial year ended 30 June 2023, no new subsidiaries were acquired.

Details of Associates and Joint Venture Entities

During the financial year ended 30 June 2023, no new Associates or Joint Venture Entities were created.

Dividends

No dividends are being proposed or have been paid in the current year (2022: 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.

Audited Annual Accounts

This report is based on the consolidated financial statements that are in the process of being audited by Stantons International Audit and Consulting Pty Ltd. The audit opinion will contain a qualified opinion as described below.

Basis for Qualified Opinion

The consolidated entity assigned a non-core patent application for an equity interest in Sangui Bio Pty Limited. The investment's fair value at 30 June 2021 was estimated at \$1.75 million based on a recent capital raise then. This investment is included as a non-current financial asset. As this investment is in a private company, Management was unable to estimate the fair value of the investment at 30 June 2022. As a result, the previous auditors were unable to obtain sufficient and appropriate audit evidence to state that the investment had been stated at fair value as at 30 June 2022, which constituted a departure from the Australian Accounting Standards. As at 30 June 2023 the Directors have impaired this investment to nil.

Comparative Information

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

Consolidated Statement of Comprehensive Income

For the year ended 30 June	2023 \$	2022 \$
Revenue		-
Other income	1,044,689	638,006
Research and development expenses	(473,415)	(1,861,129)
Corporate expenses	(1,775,691)	(2,788,989)
Finance costs	(290,202)	(72,656)
Gain on disposal of fixed assets	14,960	7,725
Loss on Shareholders loan	-	(131,556)
Impairment on Shareholders loan	(69,273)	-
Merger Expenses	(76,107)	-
Fair value increase in institutional placement	-	(17,391)
Loss on extinguishment of financial liability	-	(62,398)
Fair value increase (decrease) on investments	(1,750,000)	-
Realised foreign exchange loss	(2,274)	(17,576)
Foreign exchange gain (loss)	430	(3,766)
Profit/(loss) before income tax	(3,376,883)	(4,309,730)
Income tax (expense) / benefit	-	-
Profit/(loss) for the year	(3,376,883)	(4,309,730)
Other comprehensive (expense) / income	-	-
Total comprehensive income / (loss) for the year	(3,376,883)	(4,309,730)

Earnings per share	2023	2022
Basic earnings per share		
Earnings per share from continuing operations	(0.011)	(0.014)
Diluted earnings per share		
Earnings per share from continuing operations	(0.011)	(0.014)

Consolidated Statement of Financial Position

As at 30 June	2023 \$	2022 \$
Current Assets		
Cash and cash equivalents	302,792	95,122
Trade and other receivables	-	110,797
R&D incentive receivable	382,913	447,023
Other current assets	28,071	65,236
Other Financial Assets	-	69,273
Total current assets	713,776	787,451
Non-current assets		
Other Financial Assets (NCA)	-	1,750,000
Property, plant and equipment	708	9,730
Right of use assets under lease	-	7,617
Total non-current assets	708	1,767,347
Total assets	714,484	2,554,799
Current liabilities		
Trade and other payables	501,173	309,943
Provisions	81,254	160,780
Borrowings	1,947,015	1,000,000.00
Lease liabilities	-	5,858
Contract liabilities	-	-
Total current liabilities	2,529,442	1,476,581
Non-current liabilities		
Lease liabilities	-	2,510
Provisions	-	917
Total non-current liabilities	-	3,427
Total liabilities	2,529,442	1,480,008
Net (liabilities)/assets	(1,814,958)	1,074,791
Equity		
Issued capital	38,618,762	38,618,762
Accumulated losses	(42,277,006)	(38,951,310)
Reserves	1,843,287	1,407,339
Total equity	(1,814,958)	1,074,791

Consolidated Statement of Changes in Equity

For the year ended 30 June	Share capital \$	Share option reserve \$	Retained earnings \$	Total equity \$
Balance at 1 July 2021	38,258,870	535,384	(34,648,789)	4,145,465
Reported loss for the year	-	-	(4,309,730)	(4,309,730)
Shares issued for institutional placement	359,892	-	-	359,892
Employee share-based payment options	-	913,865	-	913,865
Employee share-based payment option	-	(34,701)	-	(34,701)
Transfer from reserves to retained earnings for options lapsed	-	(7,209)	7,209	-
Balance at 30 June 2022	38,618,762	1,407,339	(38,951,310)	1,074,791
Balance at 1 July 2022	38,618,762	1,407,339	(38,951,310)	1,074,791
Reported loss for the period	-	-	(3,376,883)	(3,376,883)
Employee share-based payment options expense	-	506,348	-	506,348
Employee share-based payment option forfeited	-	(19,214)	-	(19,214)
Transfer from reserves to retained earnings for options lapsed	-	(51,187)	51,187	-
Balance at 30 June 2023	38,618,762	1,843,286	(42,277,006)	(1,814,958)

Consolidated Statement of Cash Flows

For the year ended 30 June	2023 \$	2022 \$
Operating activities		
Receipts from customers	123,457	20,000
Payments to suppliers and employees	(1,763,190)	(4,399,277)
Interest received	39	1
Grant / Other Income	28,000	-
R&D repayments	-	-
R&D incentive refund	1,050,303	829,411
Finance costs paid	(98,266)	(41,407)
Net cash provided by / (used in) operating activities	(659,657)	(3,591,272)
Investing activities		
Payments for merger	(76,917)	-
Purchase of property, plant and equipment	-	(8,466)
Receipts from sale of property, plant and equipment	27,975	-
Net cash (used in) / provided by investing activities	(48,942)	(8,466)
Financing activities		
Proceeds from related party loan	600,000	1,000,000
Proceeds from third party loan	347,015	-
Proceeds from / (repayment of) institutional placement	-	(1,262,700)
Transaction costs related to Borrowings	(30,749)	(30,000)
Receipts from Shareholder loan	-	194,865
Net cash provided by financing activities	916,266	(97,835)
Net change in cash and cash equivalents held	207,667	(3,697,574)
Cash and cash equivalents at beginning of financial year	95,122	3,792,695
Cash and cash equivalents at end of financial year	302,789	95,122

Notes to the Consolidated Financial Statements

1. 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:

The Company has undertaken further restructuring measures in 2023 to reduce monthly operating expenses.

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

Regeneus also expects an R&D Tax Incentive rebate after the 30 June 2023 Financial Year closes. The Company obtained prefinancing of \$347k from Radium Capital representing 80% of the R&D Tax Incentive rebate for the first 9 months of FY2023. The Company is expecting a total FY2023 R&D Tax Incentive rebate of approximately \$480k. This amount is expected to be received in September 2023. After repayment of the Radium Capital loan, the Company will have additional cash of approximately \$140k.

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

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

Regeneus has signed a non-binding indicative offer letter to merge with Cambium Medical Technologies, LLC (CMT). CMT is a United States-based, clinical-stage regenerative medicine company developing a Phase 3-ready biologic therapeutic, Elate Ocular®, to treat dry eye disease. Both companies are in advanced stages of negotiating binding merger documentation. The mutual due diligence process and the negotiation of binding merger documentation are in the final stages.

Subject to agreement on binding merger documentation and shareholder approval, Regeneus expects to complete the merger transaction with Cambium Medical Technologies in November 2023.

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

At this time, the Directors are of the opinion that no asset is likely to be realised for an amount less than the amount at which it is recorded in the Appendix 4E as at 30 June 2023. Accordingly, no adjustments have been made to the Financial Report relating to the recoverability and the classification of liabilities that might be necessary should the Group not continue as a going concern.

2. Contingencies

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

Other than the above, the Group had no contingent liabilities as at 30 June 2023 (30 June 2022: Nil).

3. Other financial assets (Investment)

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

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

As noted above, Regeneus has reached an agreement to settle the balance of all moneys owing to Paddington St Finance under the PSF Facility (following the cash repayment of \$400,000 made by the Company to Paddington St Finance on 1st March 2023) in exchange for the transfer from Regeneus to Paddington St Finance of the 700,000 shares in Sangui Bio. The transfer of the Sangui Bio shares to Paddington St Finance is subject to Regeneus receiving the required shareholder approvals. As at 30th June 2023 the balance of moneys owing under the PSF Facility was \$1,754,135.38.

4. Other Significant Information

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

Corporate Directory

Registered Office and Principal Place of Business

16 Goodhope Street
Paddington NSW 2021

Board of Directors

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

Company Secretary

Hang Ling (Helen) Leung

Website

regeneus.com.au

Lawyers

Dentons Australia Limited
77 Castlereagh Street
Sydney NSW 2000

Auditors

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

Patent Attorneys

Spruson & Ferguson
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Sydney, NSW 2000

Share Registry

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Level 12, 680 George Street
Sydney, NSW 2000

Stock Exchange Listing

Australian Securities Exchange
ASX Code: RGS