# Regeneus Ltd

ABN 13 127 035 358

ASX Half-Year Report for 6 months to 31st December 2015

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 2015 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.

**Contents**

Rule 4.2.A.3

# Appendix 4D

Half-Year Report for the 6 months to 31st December 2015

Regeneus Ltd – ABN 13 127 035 358

## 1 – Reporting period

Report for the half-year ended 31st December 2015
Corresponding period is for the half-year ended 31st December 2014

## 2 – Results for announcement to the market

| | | Up / down | % Change | | $'000's |
|---|---|---|---|---|---|
| 2.1 | Revenues from ordinary activities | down | 30% | to | 881 |
| 2.2 | Loss from ordinary activities after tax distribution to members | down | 46% | to | (3,095) |
| 2.3 | Loss from ordinary activities attributable to the members | down | 46% | to | (3,095) |
| 2.4 | It is not proposed to pay any dividend | | | | |
| 2.6 | Revenue decreased due to the winding down of HiQCell activities offset by a slight increase in licence fee income. Expenses decreased significantly due to ongoing cost containment, particularly in SGA and lower expenditure in research and development. | | | | |

Full details are in the attached accounts

## 3 – Net Tangible assets per security

The net tangible assets per security

| | |
|---|---|
| 31st December 2015 | 2.5 cents |
| 31st December 2014 | 4.3 cents |

## 9 – Independent review of the financial information

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

regeneus

living regenerative medicine

# Half-Year Report
# 31st December 2015

Regeneus Ltd
ABN 13 127 035 358

# Contents

# First-half highlights and milestones

## Commencement of first-in-human clinical trials for human health

- STEP trial - Progenza allogeneic stem cells for human osteoarthritis
  - Fully enrolled Cohort 1
  - Positive safety for Cohort 1, supporting opening Cohort 2
  - Enrolment for Cohort 2 progressing well
- ACTIVATE trial - RGSH4K human cancer vaccine
  - Tumour bank established
  - First patient safely dosed
  - Enrolment is ongoing

## Commencement of clinical trials for animal health

- CryoShot pre-pivotal trial - allogeneic stem cells for canine osteoarthritis
  - Commenced recruitment for pre-pivotal trial of CryoShot for canine osteoarthritis at University of Pennsylvania
- Kvax trial - canine cancer vaccine for lymphoma
  - Commenced recruitment for Kvax canine cancer vaccine trial for lymphoma at Small Animal Specialist Hospital

## Progress on partnering and licensing

- Entered into agreement with top 5 animal health pharma to partner the development and worldwide commercialisation of CryoShot for canine osteoarthritis
- Exclusive licence of next-generation cell identification and selection technology for high potency secreting stem cells developed at Centre for Nanoscale BioPhotonics at Macquarie University
- Advanced discussions with potential manufacturing and commercial partners for Progenza in Japan

## Key patents granted

- Patent granted in Australia covering allogeneic stem cells for the treatment of osteoarthritis and other inflammatory conditions in humans and animals
- Patent granted in Australia covering cancer vaccine technology for the treatment of cancers in humans and animals

## Financial highlights

- Loss from ordinary activities (before tax) down 46% to $3.1m (PCP $5.7m)
- Reduced cost base to average quarterly cash burn of $1.5m from $2.8m in FY14
- Receipt of $3.4m R&D tax incentive for FY15 ($3.7m in FY14)

## Milestones for next 12 months

| | |
|---|---|
| • Complete recruitment for STEP trial | H2 FY16 |
| • Secure manufacturing and commercial partner for Progenza in Japan | H2 FY16 |
| • Report on preliminary safety for Progenza STEP trial | H2 FY16 |
| • Report on Kvax osteosarcoma trial | H2 FY16 |
| • Report on CryoShot Canine pre-pivotal trial | H1 FY17 |
| • Complete recruitment for ACTIVATE cancer vaccine trial | H1 FY17 |

# 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 2015. 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 |
|---|---|
| Dr. Roger Aston | Non-executive Chairman, Chair of the Remuneration and Nominations Committee |
| John Martin | CEO and Executive Director |
| Professor Graham Vesey | CSO and Executive Director |
| Barry Sechos | Non-executive Director, Chair of the Audit and Risk Committee |
| Dr. Glen Richards | Non-executive Director |

## 2. Review of operations

### Strategy

Regeneus is an ASX-listed clinical-stage regenerative medicine company developing cell-based therapies to treat unmet medical needs with a focus on osteoarthritis and other musculoskeletal disorders and oncology diseases for both humans and animals.

The Company is focused on unlocking value in its clinical-stage human and animal pipeline products through generating positive clinical data, technology development and partnering.

During the half-year, the Company achieved significant clinical development and commercial milestones that build upon the efforts over the last financial year.

### Human health

#### Progenza - allogeneic stem cells for human osteoarthritis

The half-year saw the successful completion of the first cohort of 10 patients in the STEP trial. Enrolment is now open to the second and final cohort of 10 patients. The STEP trial (Safety, Tolerability and Efficacy of Progenza) is the first clinical trial of Progenza for knee osteoarthritis.

The completion of Cohort 1 and opening of enrolment to Cohort 2 demonstrates excellent progress towards the clinical development of the Company's allogeneic stem cell therapy. It is anticipated that Cohort 2 will be recruited before the end of FY16.

The trial includes 20 participants with knee osteoarthritis treated at two different doses of cells. Participants receive ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint. One in five patients receive a placebo injection. The primary objective of the trial is to evaluate the safety and tolerability of Progenza. The secondary objectives are to investigate the effect of Progenza on knee pain and function, quality of life, knee joint structures using magnetic resonance imaging and osteoarthritis biomarkers. Participants will be monitored for 12 months.

Progenza is a scalable platform technology that has the potential to be used as an off-the-shelf treatment option for musculoskeletal disorders and inflammatory or immune-mediated conditions that have limited treatment options. The company has demonstrated the capacity to produce millions of doses from a single donor.

In November 2015, the Company was granted a key Australian patent covering the use of Progenza for the treatment of osteoarthritis and other inflammatory conditions for human and animal applications. The patent is also being pursued for grant in other key territories.

### Japan strategy for Progenza

Regeneus has identified Japan as a key target market for the clinical development, manufacturing and partnering of Progenza. In late 2014, laws were enacted in Japan that reform the pharmaceutical and medical regulations providing an accelerated approval process specifically designed for regenerative medicine products, such as Progenza. These new laws allow for the conditional marketing approval of regenerative medicine products that demonstrate safety and probable efficacy without the need for Phase 3 trials. These new laws have resulted in increased R&D investment in Japan and partnering activity over the last 12 months.

Regeneus is in advanced discussions with potential Japanese partners for the manufacture, clinical development and commercialisation of Progenza in Japan.

### RGSH4K - human cancer vaccine

In October 2015, a first-in-human clinical trial for RGSH4K was commenced and the first patient was dosed. The trial, known as ACTIVATE, is a single centre, open label, Phase 1 dose escalating study to evaluate the safety, tolerability and preliminary efficacy of RGSH4K. This technology uses a patient's tumour to harness the body's own immune system to fight cancer cells. As part of the trial, the Company has established a tumour bank to enable the banking of both previously collected and new tumours. These tumours are used as source material for the manufacture of the cancer vaccine by the Company.

In December 2015, an Australian patent was granted covering the use of the cancer vaccine technology for the treatment of a range of cancers in humans and animals. The patent is also being pursued for grant in other key territories.

### Cell secretions cream for inflammatory conditions

During the first-half, the Company focused its efforts on demonstrating the capacity to produce the cell secretions at commercial scale and identifying and testing the optimal base formulation. The Company has partnered with the CSIRO on scale up manufacturing. Clinical testing is planned for the second half of FY16.

Partnering discussions are progressing well, with a commercially available cosmetic cream, regulated under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), being planned to be available in Q2 FY17.

### HiQCell - autologous cell therapy for human osteoarthritis

In keeping with the Company's announced strategy of transitioning from autologous to allogeneic cell therapy technologies for the treatment of osteoarthritis, the Company has ceased offering HiQCell services for osteoarthritis to medical specialists and no longer collect data in the Joint Registry.

Furthermore, there is continuing uncertainty regarding the regulation of autologous cell therapies in Australia. The Therapeutic Goods Administration (TGA) has not provided any further public guidance following the publication on 29 April 2015 of the submissions it received to its discussion paper on the regulation of autologous stem cell therapies issued in January 2015.

## Animal health

### CryoShot - allogeneic stem cells for canine and equine osteoarthritis

In November 2015, the Company announced it had secured a partner to jointly fund a pre-pivotal study assessing CryoShot as a treatment for canine osteoarthritis. This study will be undertaken at the University of Pennsylvania School of Veterinary Medicine. The results of the trial will be used to finalise the design of a pivotal US Food and Drug Administration (FDA) trial with good manufacturing practice (GMP) grade product. The initial results of the study are anticipated in Q1 FY17.

Upon completion of the study, the animal health partner has a period in which to exercise its option to enter into an exclusive licence over the CryoShot technology. Under the terms of the licence, Regeneus will receive an upfront licence fee and be entitled to other developmental milestone payments to be agreed at the time. The animal health partner will be responsible for funding the pivotal study and GMP manufacture of CryoShot and have exclusive global rights for sales and marketing for canine applications. Regeneus will receive a royalty on all CryoShot sales.

### Kvax - autologous canine cancer vaccine

During the first-half, the Company's focus has been on conducting clinical trials for Kvax. Recruitment is now completed in the small osteosarcoma trial being conducted by Dr. Phil Bergman at VCA in the USA. A review of clinical data from the trial will be expected before the end of FY16.

In November 2015, the Company initiated a 45 dog trial of Kvax in combination with chemotherapy for the treatment of canine lymphoma. The trial will be conducted at Small Animal Specialist Hospital (SASH) in Sydney.

## Technology development

In November 2015, the Company announced that it had entered into a licence and collaboration agreement with Macquarie University to develop and commercialise a new cell identification and selection technology for high secreting stem cells. Researchers at the Centre for Nanoscale BioPhotonics at Macquarie University developed this technology. The Company will fund further collaborative development of the technology and its applications.

# 3. Financial results

### Operating results
The net loss before tax for the half-year period, from continuing operations was $3.1m (31 December 2014: $5.7m).

The current half-year results are substantially better than the 2014 half-year. The improvement reflects the containment of costs and the wind down of HiQCell activities. Additionally, FY14 included non-recurring redundancy costs in excess of $0.5m.

### Revenue from continuing operations
Revenue during the current period was $881k, a decrease of $385k over the same prior period (2014: $1,267k). The reduction of revenue is due to a number of key factors including the wind down of HiQCell activities and changes in third party R&D licence agreements.

Licence fee income in 6 months to December 2015 of $577k was slightly higher than the prior year (2014: $548k), reflecting the licence option fee received for CryoShot offset by the arrangements with Cryosite being finalised. HiQCell revenue at $170k was $358k below the prior year revenue of $528k.

### Cost of sales
The cost of sales reflects the direct manufacture of both the allogeneic product - CryoShot and the autologous product Kvax. The reduction in cost of sales by $432k is predominantly due to the cessation of HiQCell services.

## Expenses from continuing operations

#### Research
The comparative expenditure on research in the half-year period to 31 December 2015 was $1.9 million compared to 31 December 2014 of $3.2 million.

Research expenditure includes costs associated with product development as well as clinical trials. In the 6 months to 31 December 2014 there was significant expenditure incurred in the development of Progenza necessary for the clinical trial. The development of Progenza included outsourced expenditure associated with the Cryosite research arrangement. In the current period the expenditure is significantly less as it is more reflective of the clinical trials being undertaken. These trials are longer term in nature and expenditure will be incurred over an extended period.

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

#### Selling
In accord with the transition from HiQCell the necessity to incur significant marketing expenditure has ceased. The current year costs are reflective of licensing and business development activities associated with product licensing including CryoShot and Progenza.

#### Corporate
Corporate expenses have declined slightly, 2015: $1.4 million, 2014: $1.5 million. These costs include patent costs, ASX and other regulatory costs as well as the corporate staff.

#### Occupancy
Occupancy expenditure at $248k is well down year on year (2014: $449k). This is the result of reduction in premises required for HiQCell in Australia and Singapore.

# 01 Directors' Report

### Income tax
There has been no accrual included in these results for the R&D tax incentive for the year to 30th June 2016 as it is unable to be estimated with sufficient certainty to meet accounting standard requirements. Currently, the financial year best estimate for the R&D tax incentive is $2.5m compared to $3.4m in FY15. The higher incentive in the prior year is mainly due to the level of R&D activity involved in the development of the manufacture of Progenza.

### Cash flows
The net inflows for the period were $394k (2014: $4,231k).

| | 31 Dec 15 $ | 31 Dec 14 $ | Movement $ |
|---|---|---|---|
| Cash flows from operating activities | 578,252 | (1,956,621) | 2,534,873 |
| Cash flows from investing activities | (184,215) | 19,777 | (203,992) |
| Cash flows from financing activities | - | 6,167,899 | (6,167,899) |
| **Net cash flows** | **394,037** | **4,231,055** | **(3,837,018)** |

*Operating activities* – cash from operating activities was positive in the 6 months to 31 December 2015 due to the reduction in cash expenditure and the receipt of the R&D tax incentive of $3.4m (2014: $3.7m). Net cash used in operating activities prior to the R&D tax incentive is $2.8m (2014:$5.7m).

*Investing activities* – capital expenditure of $150k was incurred in exercising the option associated with the office fitout.

*Financing activities* – there were no material financing activities in the 6 months ended 31 December 2015. In the prior comparable period the amount of $6.2m is the result of proceeds from the capital raising in the period, net of the costs.

*Significant changes in state of affairs*
There were no significant changes in the Group's state of affairs during the first-half FY16.

*Events subsequent to the end of the reporting date*
No other significant events have occurred since balance date.

*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 8 of this report.

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

Roger Aston

Non-executive Chairman

26 February 2016

Grant Thornton

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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 2015, 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.

Grant Thornton

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

LMWorsley.

L M Worsley
Partner - Audit & Assurance

Sydney, 26 February 2016

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

| Consolidated statement of profit or loss and other comprehensive income for the half year ended 31 December 2015 | | | |
|---|---|---|---|
| | Note | 31 Dec 15 $ | 31 Dec 14 $ |
| Revenue | | 881,360 | 1,266,633 |
| Cost of sales | | (117,952) | (549,936) |
| **Gross profit** | | **763,408** | **716,697** |
| Research and development expenses | | (1,931,899) | (3,230,849) |
| Selling expenses | | (249,267) | (1,252,589) |
| Occupancy expenses | | (247,894) | (449,218) |
| Corporate expenses | | (1,419,781) | (1,493,788) |
| Finance costs | | (9,934) | (27,541) |
| **Loss before income tax** | | **(3,095,367)** | **(5,737,288)** |
| Income tax benefit | | - | - |
| **Loss for the period** | | **(3,095,367)** | **(5,737,288)** |
| Other comprehensive income | | - | (11,942) |
| **Total comprehensive loss for the year** | | **(3,095,367)** | **(5,749,230)** |

| Earnings per share | | | |
|---|---|---|---|
| Basic earnings per share from continuing operations | 7 | (0.015) | (0.029) |
| Dilute earnings per share from continuing operations | 7 | (0.015) | (0.029) |

These financial statements should be read in conjunction with the accompanying notes.

# 04 Consolidated Statement of Financial Position

| Consolidated statement of financial position as at 31 December 2015 | | | |
|---|---|---|---|
| | Note | 31 Dec 15 $ | 30 Jun 15 $ |
| **Current assets** | | | |
| Cash and cash equivalents | | 3,406,849 | 3,012,812 |
| Trade and other receivables | | 24,713 | 66,571 |
| Inventories | | 73,714 | 98,975 |
| Current tax assets | | - | 3,417,566 |
| Other current assets | | 202,886 | 532,458 |
| **Total current assets** | | **3,708,162** | **7,128,382** |
| **Non-current assets** | | | |
| Property, plant and equipment | | 941,884 | 891,883 |
| Intangible assets | | 16,942 | 26,110 |
| Other non-current assets | | 1,575,669 | 1,532,886 |
| **Total non-current assets** | | **2,534,495** | **2,450,879** |
| **Total assets** | | **6,242,657** | **9,579,261** |
| **Current liabilities** | | | |
| Trade and other payables | | 759,111 | 781,101 |
| Provisions | | 95,369 | 109,868 |
| Other current liabilities | | 100,000 | 368,570 |
| **Total current liabilities** | | **954,480** | **1,259,539** |
| **Non-current liabilities** | | | |
| Provisions | | 56,892 | 47,588 |
| **Total non-current liabilities** | | **56,892** | **47,588** |
| **Total liabilities** | | **1,011,372** | **1,307,127** |
| **Net assets** | | **5,231,285** | **8,272,134** |
| **Equity** | | | |
| Issued capital | 8 | 31,076,819 | 31,076,819 |
| Accumulated losses | | (27,438,140) | (25,295,813) |
| Reserves | | 1,592,606 | 2,491,128 |
| **Total equity** | | **5,231,285** | **8,272,134** |

These financial statements should be read in conjunction with the accompanying notes.

# 05 Consolidated Statement of Changes in Equity

| Consolidated statement of changes in equity for the half-year ended 31 December 2015 | Share capital $ | Share option reserve $ | Accumulated losses $ | Foreign currency translation reserve $ | Total equity $ |
|---|---|---|---|---|---|
| **Balance at 1 July 2014** | **24,908,920** | **2,190,377** | **(18,792,423)** | **1,154** | **8,308,028** |
| Loss for the period | - | - | (5,737,288) | - | (5,737,288) |
| Other comprehensive income | - | - | - | (11,942) | (11,942) |
| Employee share-based payment option expense | - | 244,400 | - | - | 244,400 |
| Issue of ordinary shares (net of transaction costs) | 6,167,899 | - | - | - | 6,167,899 |
| Transfer from reserves to retained earnings for options forfeited | - | (103,131) | 103,131 | - | - |
| **Balance at 31 December 2014** | **31,076,819** | **2,331,646** | **(24,426,580)** | **(10,788)** | **8,971,097** |
| **Balance at 1 July 2015** | **31,076,819** | **2,491,128** | **(25,295,813)** | **-** | **8,272,134** |
| Loss for the period | - | - | (3,095,367) | - | (3,095,367) |
| Other comprehensive income | - | - | - | - | - |
| Employee share-based payment option expense | - | 54,518 | - | - | 54,518 |
| Transfer from reserves to retained earnings for options forfeited | - | (953,040) | 953,040 | - | - |
| **Balance at 31 December 2015** | **31,076,819** | **1,592,606** | **(27,438,140)** | **-** | **5,231,285** |

These financial statements should be read in conjunction with the accompanying notes.

# 06 Consolidated Statement of Cash Flows

| Consolidated statement of cash flows for the half-year ended 31 December 2015 | 31 Dec 15 $ | 31 Dec 14 $ |
|---|---|---|
| **Cash flows from operating activities** | | |
| Receipts from customers | 915,797 | 1,198,721 |
| Payments to suppliers and employees | (3,767,920) | (6,937,000) |
| Interest received | 22,743 | 82,037 |
| R&D tax refund | 3,417,566 | 3,730,576 |
| Other expense | - | (3,414) |
| Finance costs | (9,934) | (27,541) |
| **Net cash provided by / (used in) operating activities** | **578,252** | **(1,956,621)** |
| **Cash flows from investing activities** | | |
| Receipts from short-term deposit | - | 77,754 |
| Purchase of property, plant and equipment | (200,256) | (149,250) |
| Sale of property, plant and equipment | 16,041 | 812 |
| Purchase of intangibles | - | (14,839) |
| Deposits | - | 105,300 |
| **Net cash (used in) / provided by investing activities** | **(184,215)** | **19,777** |
| **Cash flows from financing activities** | | |
| Proceeds from issue of shares - net of costs | - | 6,167,899 |
| **Net cash provided by financing activities** | **-** | **6,167,899** |
| Net change in cash and cash equivalents held | 394,037 | 4,231,055 |
| Cash and cash equivalents at beginning of financial year | 3,012,812 | 2,507,497 |
| **Cash and cash equivalents at end of the half-year** | **3,406,849** | **6,738,552** |

These financial statements should be read in conjunction with the accompanying notes.

# 07 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 for human and animal health markets, with a focus on osteoarthritis and musculoskeletal disorders as well as oncology and dermatology diseases. The portfolio of therapeutic products is being developed using the Group's proprietary stem cell and immuno-oncology technology platforms.

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 license 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 2015 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 2015 and any public announcements made by the Group during the half-year in accordance with continuous disclosure requirements arising under the Australian Stock 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 2016.

## 3. Going concern basis of accounting

For the half-year ended 31 December 2015, the Group incurred a loss after income tax of $3.1m (2014: $5.7m), had net cash inflows from operating activities of $0.6m (2014: $2.0m outflow); which is a direct result of the receipt of the R&D tax incentive of $3.4m (2014: $3.7m), and has accumulated losses of $27.4m (30 June 2015: $25.3m). Notwithstanding the losses incurred and the small operating cash flow, 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. As at 31 December 2015, Regeneus had positive net assets, positive current assets and a cash balance of $3.4m.

The Directors have a number of strategies in progress to maintain the Group in a positive cash flow position. A short term facility is currently being finalised that forward funds, via a loan, the Federal Government's research and development tax incentive for FY16. If this is made available it will allow the Company to draw down up to $2.0m to be repaid upon receipt of the incentive which is anticipated Q2 FY17. Additionally, the Company is in advanced negotiations with a large Japanese company regarding the licensing of its Progenza mesenchymal stem cell therapy technology for the Japanese market. The Directors expect to receive a significant upfront licencing fee on entering this licence agreement with further milestone payments.

The Directors continue to monitor other available funding strategies including product licensing and raising additional capital if necessary to ensure available funds for ongoing operations.

Should the above transactions or assumptions not materialise, there is material uncertainty whether the Group will continue as a going concern and therefore whether it will realise its assets and extinguish its liabilities in the normal course of business and at the amounts stated in these financial statements.

## 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 2015.

The accounting policies have been applied consistently throughout the Group for the purposes of preparation of these half-year financial statements.

## 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 2015.

## 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. In previous periods the Group reported segments of Human Health and Veterinary Health. This segregation of information provided no benefit to the CODM. 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 human and veterinary health. Initial focus is osteoarthritis and other musculoskeletal disease as well as oncology 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. 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 2015 and 31 December 2014 .

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:

| Earnings per share | 31 Dec 15 $ | 31 Dec 14 $ |
|---|---|---|
| Basic earnings per share from continuing operations | (0.015) | (0.029) |
| The weighted average number of ordinary shares used as the denominator on calculating the EPS | 208,885,143 | 200,602,429 |
| **Diluted earnings per share** | | |
| Basic earnings per share from continuing operations | (0.015) | (0.029) |
| The weighted average number of ordinary shares used as the denominator on calculating the DEPS | 208,885,143 | 200,602,429 |

Share options have not been included in the diluted EPS calculation because they are anti-dilutive.

## 8. 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.

During the six months to 31 December 2015, there were no shares issued. During the prior comparable period the following shares were issued:

- 24,492,066 shares at $0.26 were issued as part of a capital raising program.

Shares issued and authorised are summarised as follows:

| Share Capital | 31 Dec 15 $ | 30 Jun 15 $ |
|---|---|---|
| Fully paid shares | 31,076,819 | 24,908,920 |
| New shares issued during the period (net of transaction costs) | - | 6,167,899 |
| | **31,076,819** | **31,076,819** |

Issue costs of $200,056 associated with the issue of shares in 2014 have been directly paid from the proceeds of the issues. These costs have been deducted from the issued capital in the statement of financial position, rather than charged as an expense of the Company, as they are considered to form part of the net equity raised.

The company has 9,672,044 options on issue to acquire ordinary shares in the company. These options are unlisted, restricted and summarised as follows:

| Share options | 31 Dec 15 Number | 30 Jun 15 Number |
|---|---|---|
| Employee share option plans | 9,672,044 | 15,564,865 |
| Unlisted options | - | 3,846,154 |
| | **9,672,044** | **19,411,019** |

The unlisted options expired 15 August 2015.

## 9. 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 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 was calculated using a binomial options pricing model. For the options outstanding at period end, the following inputs were used:

| Grant date | 1 Jul 2010 | 1 Jan 2011 | 21 Feb 2011 | 1 Jul 2011 |
|---|---|---|---|---|
| Share price at date of grant | $0.136 | $0.136 | $0.136 | $0.280 |
| Volatility | 45% | 45% | 45% | 45% |
| Option life | 10 years | 10 years | 10 years | 10 years |
| Dividend yield | 0% | 0% | 0% | 0% |
| Risk free investment rate | 5.10% | 5.60% | 5.60% | 5.30% |
| Fair value at grant date | $0.085 | $0.086 | $0.085 | $0.180 |
| Exercise price at date of grant | $0.136 | $0.136 | $0.136 | $0.280 |

| Grant date | 16 Sept 2013 | 4 Dec 2013 | 21 Nov 2014 |
|---|---|---|---|
| Share price at date of grant | $0.250 | $0.470 | $0.160 |
| Volatility | 65% | 65% | 244% |
| Option life | 5 years | 5 years | 5 years |
| Dividend yield | 0% | 0% | 0% |
| Risk free investment rate | 3.40% | 3.50% | 2.80% |
| Fair value at grant date | $0.156 | $0.327 | $0.179 |
| Exercise price at date of grant | $0.250 | $0.250 | $0.160 |

Included under employee benefits expenses in the profit or loss, relating to employee share options is $54,517 (Dec 2014: $244,400), and relates, in full, to the current year value of the employee share option payments at their grant date net of options forfeited.

| | 31 Dec 15 | | 30 Jun 15 | |
|---|---|---|---|---|
| Share options granted under the option plans | Number | Weighted avg exercise price $ | Number | Weighted avg exercise price $ |
| Options outstanding at beginning of period | 15,564,865 | 0.210 | 15,464,865 | 0.210 |
| Granted | - | - | 900,000 | 0.160 |
| Exercised | - | - | - | - |
| Forfeited | (5,892,821) | 0.198 | (800,000) | 0.261 |
| **Outstanding at end of period** | **9,672,044** | **0.217** | **15,564,865** | **0.210** |
| **Exercisable at end of period** | **8,872,044** | **0.220** | **14,329,865** | **0.207** |

Options forfeited predominantly related to share options previously granted to eligible participants. Cessation of employment or contract has resulted in these options no longer being exercisable.

## 10. Dividends

No dividends were paid during the period (2014: $nil).

## 11. Contingent Liabilities

The group had no contingent liabilities as at 31 December 2015 (31 December 2014: Nil).

## 12. Events after the reporting date

There are no events that have occurred after 31 December 2015 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

# 08 Directors' 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 2015 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:

Chairman
Roger Aston

Dated the 26th day of February 2016.

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Sydney NSW 2000

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## Independent Auditor's Review Report
## To the Members of Regeneus Limited

We have reviewed the accompanying half-year financial report of Regeneus Limited ("Company"), which comprises the consolidated financial statements being the consolidated statement of financial position as at 31 December 2015, 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, notes comprising a summary of significant accounting policies, other explanatory information and the directors' declaration of the consolidated entity, comprising both the Company and the entities it controlled at the half-year's end or from time to time during the half-year.

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

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

### Auditor's responsibility

Our responsibility is to express a conclusion on the consolidated half-year financial report based on our review. We conducted our review in accordance with the 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 Regeneus Limited consolidated entity's financial position as at 31 December 2015 and its performance for the half-year ended on that date; and complying

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with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of Regeneus Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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.

**Independence**

In conducting our review, we complied with the independence requirements of the Corporations Act 2001.

**Conclusion**

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

a giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and of its performance for the half-year ended on that date; and

b complying with Accounting Standard AASB 134 Interim Financial Reporting and Corporations Regulations 2001.

**Material uncertainty regarding going concern**

Without qualification to the conclusion expressed above, we draw attention to Note 3 to the financial report which sets out the basis on which the Directors have determined that the consolidated entity is a going concern.

The consolidated entity incurred a net loss of $3,095,367 and had cash inflows from operating activities of $578,252 for the period ended 31 December 2015; which is a direct result of the receipt of the R&D tax incentive of $3.4m (2014: $3.7m). As at 31 December 2015 the consolidated entity had cash of $3,406,849.

In Note 3, it is stated that the consolidated entity has a number of strategies in progress to maintain the consolidated entity in a positive cash flow position.

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These conditions, along with other matters set forth in Note 3, indicate the existence of a material uncertainty which may cast significant doubt about the Company's and the consolidated entity's ability to continue as a going concern and therefore, the Company and the consolidated entity may be unable to realise their assets and discharge their liabilities in the normal course of business, and at the amounts stated in the financial report.

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GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

LWorsley.

L M Worsley
Partner - Audit & Assurance

Sydney, 26 February 2016

# Corporate Directory

## Registered Office and Principal Place of Business

25 Bridge Street
Pymble, NSW 2073, Australia

## Board of Directors

Dr. Roger Aston (Non-executive Chairman)
John Martin (Chief Executive Officer)
Professor Graham Vesey (Executive Director)
Barry Sechos (Non-executive Director)
Dr. Glen Richards (Non-executive Director)

## Company Secretary

Sandra McIntosh

## Website

regeneus.com.au

## Lawyers

Dibbs Barker
Level 8, 123 Pitt 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 Stock Exchange
ASX Code: RGS