



Regeneus Ltd  
ABN 13 127 035 358

ASX Half-Year Report for 6 months to 31<sup>st</sup> December 2017

Provided to the ASX under Rule 4.2.A.3

This report is to be read in conjunction with the Annual Report for the year ended 30<sup>th</sup> June 2017 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**

Results for announcement to the market

Half-Year Report

# Appendix 4D

Half-Year Report for the 6 months to 31<sup>st</sup> December 2017

Regeneus Ltd – ABN 13 127 035 358

## Reporting period

Report for the half-year ended 31<sup>st</sup> December 2017

Corresponding period is for the half-year ended 31<sup>st</sup> December 2016

## Results for announcement to the market

	Up / down	% Change		\$'000's
Revenues from ordinary activities	down	96%	to	353
Loss from ordinary activities after tax attributable to members	down	172%	to	(2,714)
Net loss from ordinary activities attributable to the members	down	172%	to	(2,714)
It is not proposed to pay any dividend				
Other income includes R&D incentive of \$1.2m (prior corresponding period \$0) Revenue in prior corresponding period includes AGC licence fee of \$7.6m and \$0.8m of one-off incremental costs incurred in securing this arrangement.				
Full details are in the attached accounts.				

## Net Tangible assets per security

The net tangible assets per security

31 <sup>st</sup> December 2017	2.6 cents
31 <sup>st</sup> December 2016	4.1 cents

## Independent review of the financial information

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



# Half-Year Report

## 31<sup>st</sup> December 2017



### Progenza Highlights

- Significant progress on transfer of Progenza technology to AGC as part of collaboration
- AGC established mirror Progenza production capability at Yokohama R&D Centre
- STEP trial manuscript to be published in Q3 FY18
- Regeneus Japan (50/50 JV with AGC) progressed discussions and due diligence with potential clinical development partners for Progenza in Japan
- Target for initial Progenza clinical development licence in H2 FY18

### Sygenus Highlights

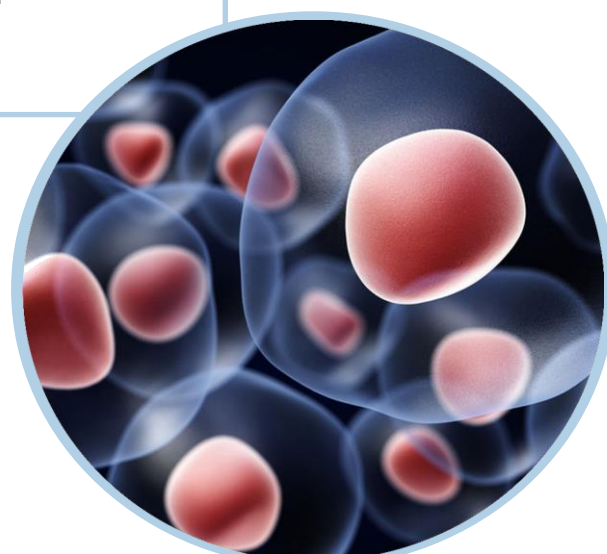
- Sygenus shows strong analgesic effects compared to morphine in post-operative pain model
- Sygenus gel shows positive results in acne study

### RGSH4K Highlights

- Recruitment closed for ACTIVATE trial
- Report on trial results in H2 FY18

### IP Highlights

- US patent granted for Sygenus for topical treatment of acne
- > 70 patents or patent applications across 14 families



### Summary Financial Results

- Licence revenues of \$0.4m in line with prior comparable period (FY16: \$0.5m – excluding AGC licence fee of \$7.6m)
- Operating loss of \$2.71m (FY16 profit of \$3.76m including AGC licence fee)
- Cash burn averaging \$1.79m per quarter (FY16: \$1.53m per quarter)
- Net cash used in operating activities of \$0.97m (FY16: \$0.32m)
- R&D tax incentive received \$2.61m (FY16: \$2.73m)
- Loan for R&D tax incentive being finalised ensuring near term 'cash runway'

### Table of Contents

01	Directors report	3
02	Auditors Independence Declaration	8
03	Consolidated Financial Statement	9
04	Notes to the Consolidated Financial Statements	13
05	Directors Declaration	18
06	Independent Auditor's Review Report	19
07	Corporate Directory	21

# 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 2017. 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
Leo Lee *	Non-executive Director

\* Leo Lee was appointed a non-executive director on 11 December 2017. Leo is a senior executive with over 20 years experience in pharmaceutical leadership, innovation, commercialisation, regulation and policy development. He has worked in North America and Asia and has spent the last 12 years living in Japan. Leo is President of Merck Serono, Japan and was previously President of Allergan, Japan.

## 2. Review of operations

### Overview and strategy

Regeneus is an ASX-listed clinical-stage regenerative medicine company developing a portfolio of novel cell-based therapies to address significant unmet medical needs in the human and animal health markets. Our initial focus is on osteoarthritis and other musculoskeletal disorders, oncology and dermatology. The portfolio of therapeutic products is being developed using the company's patented and scalable stem cell and immuno-oncology technology platforms.

Regenerative medicine is a rapidly growing multi-disciplinary specialty that aims to harness the power of stem cells and molecules to repair and regenerate damaged or diseased cells and tissues.

The Company's strategy is to unlock value in its clinical-stage human and animal pipeline products through developing novel and scalable technology product platforms underpinned by registered intellectual property; generating positive clinical data; and licensing to commercial partners at the optimal value inflection point. As these patented technologies have broad application, the Company has the opportunity to license the manufacturing and clinical development and commercialisation rights for a range of therapeutic indications in multiple territories, generating multiple revenue streams.

### Human health

#### Progenza technology transfer to AGC on track

Progenza is the Company's lead allogeneic stem cell therapy technology platform being developed for the treatment of osteoarthritis and other musculoskeletal disorders.

During the period, we made good progress on the transfer of Progenza technology to AGC as part of the collaboration signed with AGC in FY17. Under this collaboration, Regeneus granted AGC, a leading Japanese manufacturer of biopharmaceuticals, exclusive rights to manufacture Progenza for all clinical applications in Japan.

We are pleased that AGC has established a cell production facility at the AGC Yokohama Research Centre and have recruited a knowledgeable team with considerable previous cell therapy experience in Japan. The AGC team is able to replicate the processes for the Progenza production method used in the STEP trial in Australia and is underway with process development to further industrialise and scale-up the manufacturing process. This foundation work will help underpin AGC's goal of manufacturing Progenza under Current Good Manufacturing Process (cGMP) for clinical studies and commercial supply in Japan.

Substantial progress was made in the preparation of the materials for engagement with and briefing of the Japanese regulator (PMDA) about the manufacture of Progenza in Japan.

# 01 Directors' Report

## **Partnering Progenza in Japan**

During the period, we made substantial progress on advancing discussions and due diligence with potential licensees for the clinical development of Progenza in Japan. Regeneus Japan Inc, a 50/50 joint venture with AGC, has the exclusive rights for the clinical development and commercialisation of Progenza in Japan. We have been pleased with the interest in Progenza from Japanese pharmaceutical and healthcare companies. Japan continues to be the go-to market for regenerative medicine licensing and business development opportunities globally. This was further evidenced with the announcement in January 2018 of the intended acquisition of TiGenix, a Euronext-listed Belgium-based regenerative medicine company, by Takeda, Japan's largest pharmaceutical company, for US\$620m.

Our manufacturing collaboration with AGC, positive STEP trial data, and a granted Progenza patent in Japan, means we are very well placed to enter into our initial clinical development and commercialisation licence of Progenza in Japan in FY18.

The granting of this licence will trigger a milestone payment from AGC and drive the Phase 2 trial of Progenza for osteoarthritis in Japan and take advantage of the accelerated approval pathway for regenerative medicine products in Japan. We believe it will also enhance our licensing opportunities for Progenza for osteoarthritis in other key territories.

## **Chronic pain research**

Chronic pain is a symptom of osteoarthritis and Progenza, in the STEP trial, has shown promise in reducing pain for osteoarthritis sufferers. The Company is investigating the potential of stem cells and their secretions to reduce chronic pain unrelated to osteoarthritis and gain a deeper understanding of the mechanism of action.

Regeneus is part of a research consortium including Macquarie University and University of Adelaide that has received an Australian Research Council (ARC) linkage grant to undertake research into the use of the Progenza and Sygenus technologies to relieve chronic pain. The investigations are being led by Professor Mark Hutchinson of the University of Adelaide and Professor Ewa Goldys of Macquarie University.

The three year research project will seek to develop a better understanding of chronic pain and how stem cells and their secretions can be used to relieve chronic pain in animals and help lay the foundations for future human therapies.

Regeneus has patents and patent applications on the use of stem cells for the treatment of neuropathic pain.

## **Sygenus – cell secretions technology**

Sygenus is the Company's patented and scalable cell secretions technology platform. It utilises the molecules including cytokines, growth factors and exosomes that are secreted by donor mesenchymal stem cells. These bioactive molecules are known to reduce pain and inflammation and encourage accelerated healing and repair.

## **Sygenus showing strong analgesic effects**

In September 2017, the Company announced promising results from a study conducted by MD Biosciences showing Sygenus has a sustained analgesic effect above and beyond the anti-inflammatory effect. Sygenus applied topically to the wound area was tested head-to-head with morphine, the opioid analgesic. Sygenus showed a dose dependent analgesia with the beneficial effect of the high dose lasting for up to 3 hours. In comparison, morphine had lost its effect within 3 hours.

## **Sygenus topical gel shows positive results in improving the appearance of acne**

During the period, we undertook two studies with RCTS, a dermatology testing laboratory in Texas, to test the safety and tolerability of using Sygenus gel for topical application on acne.

On 6 February, we reported the topical use of Sygenus gel for 6 weeks in 33 healthy volunteers with mild to moderate acne was well tolerated and showed a significant effect on the appearance of acne lesions as early as 3 weeks. This positive data will assist our discussions with potential licensees of the technology for acne and other markets.

## **RGSH4K – human cancer vaccine**

RGSH4K is a cancer vaccine technology developed at the Bill Walsh Cancer Research Laboratory at the Kolling Institute of Medical Research at Royal North Shore Hospital in St Leonards, Sydney. The technology uses a patient's tumour to harness the body's own immune system against cancer cells. RGSH4K combines a patient's tumour proteins with a bacterial adjuvant for immune recognition.

During the period, we continued to recruit patients to the Phase 1 trial (ACTIVATE) of RGSH4K. The trial is a single centre, open label, Phase 1 dose escalating study to evaluate the safety, tolerability and preliminary efficacy of RGSH4K.

After discussion with the Principal Investigators, it was determined that a lower number of patients will provide sufficient clinical data to make conclusions on the primary endpoints of vaccine safety and tolerability and support subsequent development decisions. Accordingly, recruitment is now closed and we anticipate reporting on the study results by the end of June 2018.

We are also exploring combining RGSH4K with immune checkpoint inhibitors which could potentially stimulate highly effective immune responses against cancer cells.

## Animal health

### **CryoShot - allogeneic stem cells for canine osteoarthritis**

CryoShot is the company's lead cell therapy technology for the treatment of canine and equine osteoarthritis and other musculoskeletal disorders. Currently, a pre-pivotal trial assessing CryoShot as a treatment for canine osteoarthritis is being recruited. It is a placebo-controlled trial of 80 dogs conducted at 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.

During the period, we continued to recruit for the study. While recruitment has been slower than anticipated, actions are being taken to accelerate recruitment to ensure trial completion in 2018. Upon completion of the trial, our collaboration partner has an option to exclusively license the CryoShot technology. The terms of the licence include an upfront licence fee and development milestone payments to be agreed. If the option is exercised, the partner will be responsible for funding the pivotal trial and cGMP manufacture of CryoShot and will have exclusive global rights for sales and marketing for canine applications. Regeneus will additionally receive a royalty on all CryoShot sales.

### **Kvax - trials of animal cancer vaccine**

Kvax is a canine cancer vaccine technology similar to RGS4K.

During the period, recruitment continued for a 45 dog double-blind placebo controlled trial of Kvax in combination with chemotherapy for the treatment of canine lymphoma. Early indications are that there are no safety concerns. The trial is being conducted by SASH (Small Animal Specialist Hospital) in North Ryde, Sydney.

This trial is seeking to build upon the positive results from last year's Kvax trial for canine osteosarcoma which showed that Kvax was safe, tolerable and conferred increased progression free interval and survival compared to historically reported dogs with osteosarcoma treated with limb amputation only.

The Company continues to build up clinical data to support licensing opportunities for Kvax.

## **IP update**

In August 2017, the Company was granted a United States patent covering the use of the Company's stem cell secretions technology for the topical treatment of acne. The patent provides commercial rights in the US through to 2032. Corresponding patents have been granted in Australia, China, Japan and EU.

Regeneus has in excess of 70 patents or patent applications across multiple patent families relating to its regenerative medicine development products.

## 3. Financial results

### Operating results

The financial performance for the 6 months ending 31 December 2017 was in accord with expectation producing a loss of \$2.7m. There were no milestone deliverables during the 6 month period and accordingly the loss is reflective of the R&D investment in the Company's technologies, particularly Progenza. The AGC upfront licence fee of \$7.6m provided a material benefit to the 31 December 2016 results.

### Revenue and gross margin from continuing operations

Revenue of \$0.4m during the current period is for licence fees for the use of the Group's technology locally. In December 2016, revenue included \$0.5m for local technology licences as well as the first AGC licence fee payment of \$7.6m.

### 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 2017 is \$1.17m (31 December 2016: \$0). In prior years, while eligible R&D expenditure had been incurred, the Group did not recognise the R&D tax incentive on an interim basis as it was unable to reliably estimate the R&D tax incentive in prior half year periods. Refer note 7.

### Expenses from continuing operations

#### Research

Expenditure on research in the half-year period to 31 December 2017 was \$2.1m compared to 31 December 2016 of \$1.8m.

Research expenditure includes costs associated with product development as well as clinical trials. The focus over the last year has included product development and trial activity for each of the key platforms of Progenza, Sygenus and RGS4K. Research expenditure is anticipated to increase further as additional indications are considered for Progenza and the Japan development and technology transfer is completed.

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.

#### Selling

In prior years the selling expenses included costs associated with the early commercialisation of products. The Group is focussed on technology development for commercial licensing opportunities. These strategic arrangements are facilitated by senior executives rather than through sales activities.

#### Corporate

Corporate expenses at \$1.8m is significantly down on the prior year of \$2.2m. The prior year included \$0.8m of one off costs associated with securing the AGC licence. Corporate expenses, after allowing for the one-off Japanese transaction costs, have increased and this is due to staff increases and one-off payments totalling \$0.3m.

#### Occupancy

Occupancy expenditure at \$0.2m reflects the costs associated with the corporate office in Sydney.



# 01 Directors' Report

## Cash flows

The net outflows for the period were \$763k (2016: \$133k outflows).

	31 Dec 17 \$	31 Dec 16 \$	Movement \$
Cash flows from operating activities	(974,565)	(319,567)	(654,998)
Cash flows from investing activities	(102,275)	(14,091)	(88,184)
Cash flows from financing activities	313,650	200,546	113,104
<b>Net cash flows</b>	<b>(763,190)</b>	<b>(133,112)</b>	<b>(630,078)</b>

*Operating activities* – cash used in operating activities at \$975k was significantly higher than 31 December 2016 of \$320k. This increase is reflective of the reduction in non-commercial sales activity, slight decrease in R&D tax incentive and increased staffing costs required to facilitate the R+D activities.

*Financing activities* – cash provided by financing activities is the early repayment of shareholder loans, provided at the time of the IPO in August 2013, to exercise employee options, as a full recourse, 4 year interest free loan, maturing June 2018.

### *Significant changes in state of affairs*

There were no significant changes in the Group's state of affairs during the first-half FY17.

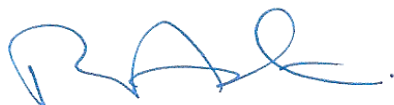
### *Events subsequent to the end of the reporting date*

There are no matters or circumstances that have occurred after 31 December 2017 and prior to the signing of this financial report that have significantly affected or may significantly affect the financial results presented.

### *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

20 February 2018



Level 17, 383 Kent Street  
Sydney NSW 2000

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

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

### 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 2017. I declare that, to the best of my knowledge and belief, there have been:

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

A handwritten signature in black ink that reads "Grant Thornton".

Grant Thornton Audit Pty Ltd  
Chartered Accountants

A handwritten signature in black ink that reads "L M Worsley".

L M Worsley  
Partner – Audit & Assurance

Sydney, 20 February 2018

Grant Thornton Audit Pty Ltd ACN 130 913 594  
a subsidiary or related entity of Grant Thornton Australia Ltd ABN 41 127 556 389

'Grant Thornton' refers to the brand under which the Grant Thornton member firms provide assurance, tax and advisory services to their clients and/or refers to one or more member firms, as the context requires. Grant Thornton Australia Ltd is a member firm of Grant Thornton International Ltd (GTIL). GTIL and the member firms are not a worldwide partnership. GTIL and each member firm is a separate legal entity. Services are delivered by the member firms. GTIL does not provide services to clients. GTIL and its member firms are not agents of, and do not obligate one another and are not liable for one another's acts or omissions. In the Australian context only, the use of the term 'Grant Thornton' may refer to Grant Thornton Australia Limited ABN 41 127 556 389 and its Australian subsidiaries and related entities. GTIL is not an Australian related entity to Grant Thornton Australia Limited.

Liability limited by a scheme approved under Professional Standards Legislation.

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

For the half-year ended 31 December	Note	31 Dec 17 \$	31 Dec 16 \$
Revenue		353,503	8,189,424
Cost of sales		-	(54,630)
Gross profit		353,503	8,134,794
Other income – R&D tax incentive	7	1,170,000	-
Research and development expenses		(2,133,411)	(1,842,541)
Selling expenses		-	(111,164)
Occupancy expenses		(237,599)	(192,494)
Corporate expenses	8	(1,851,090)	(2,219,661)
Finance costs		(1,575)	(11,565)
Share of loss on investments accounted for using equity method		(13,596)	-
Profit/(loss) before income tax		(2,713,768)	3,757,369
Income tax expense	9	-	-
Profit/(loss) for the period		(2,713,768)	3,757,369
Other comprehensive income		-	-
Total comprehensive profit/(loss) for the year		(2,713,768)	3,757,369
<b>Earnings per share</b>			
Basic earnings per share from continuing operations	10	(0.013)	0.018
Dilute earnings per share from continuing operations	10	(0.013)	0.017

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

## 03 Consolidated Statement of Financial Position

As at 31 December	31 Dec 17 \$	30 Jun 17 \$
<b>Current Assets</b>		
Cash and cash equivalents	3,371,946	4,135,136
Trade and other receivables	-	87,877
Inventories	17,616	21,948
R&D tax incentive receivable	1,170,000	2,608,222
Other current assets	1,119,122	1,407,741
<b>Total current assets</b>	<b>5,678,684</b>	<b>8,260,924</b>
<b>Non-current assets</b>		
Property, plant and equipment	544,625	610,127
Intangible assets	3,669	5,759
Investments	62,764	78,000
Other non-current assets	210,000	210,000
<b>Total non-current assets</b>	<b>821,058</b>	<b>903,886</b>
<b>Total assets</b>	<b>6,499,742</b>	<b>9,164,810</b>
<b>Current liabilities</b>		
Trade and other payables	780,522	743,209
Provisions	111,916	115,484
Other current liabilities	-	17,502
<b>Total current liabilities</b>	<b>892,438</b>	<b>876,195</b>
<b>Non-current liabilities</b>		
Provisions	214,707	188,707
<b>Total non-current liabilities</b>	<b>214,707</b>	<b>188,707</b>
<b>Total liabilities</b>	<b>1,107,145</b>	<b>1,064,902</b>
<b>Net assets</b>	<b>5,392,597</b>	<b>8,099,908</b>
<b>Equity</b>		
Issued capital	31,076,819	31,076,819
Accumulated losses	(27,343,452)	(24,629,684)
Reserves	1,659,230	1,652,773
<b>Total equity</b>	<b>5,392,597</b>	<b>8,099,908</b>

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

## 03 Consolidated Statement of Changes in Equity

For the half-year ended 31 December	Share capital \$	Share option reserve \$	Accumulated losses \$	Total attributable to parent owners \$	Total equity \$
Balance at 1 July 2016	31,076,819	1,624,566	(27,916,645)	4,784,740	4,784,740
Reported profit for the period	-	-	3,757,369	3,757,369	3,757,369
Employee share-based payment option expense	-	34,239	-	34,239	34,239
Balance at 31 December 2016	31,076,819	1,658,805	(24,159,276)	8,576,348	8,576,348
Balance at 1 July 2017	31,076,819	1,652,773	(24,629,684)	8,099,908	8,099,908
Reported loss for the period	-	-	(2,713,768)	(2,713,768)	(2,713,768)
Employee share-based payment option expense	-	6,457	-	6,457	6,457
Balance at 31 December 2017	31,076,819	1,659,230	(27,343,452)	5,392,597	5,392,597

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

## 03 Consolidated Statement of Cash Flows

For the half-year ended 31 December	31 Dec 17 \$	31 Dec 16 \$
<b>Operating activities</b>		
Receipts from customers	339,015	629,696
Payments to suppliers and employees	(3,928,470)	(3,673,037)
Interest received	8,242	3,229
R&D tax incentive refund	2,608,223	2,732,110
Finance costs	(1,575)	(11,565)
<b>Net cash (used in)/provided by operating activities</b>	<b>(974,565)</b>	<b>(319,567)</b>
<b>Investing activities</b>		
Payments for investments	-	(1,950)
Purchase of property, plant and equipment	(102,275)	(21,741)
Receipts from sale of property, plant and equipment		9,600
<b>Net cash used in investing activities</b>	<b>(102,275)</b>	<b>(14,091)</b>
<b>Financing activities</b>		
Receipts from shareholder loan	313,650	200,546
<b>Net cash provided by financing activities</b>	<b>313,650</b>	<b>200,546</b>
<b>Net change in cash and cash equivalents held</b>	<b>(763,190)</b>	<b>(133,112)</b>
Cash and cash equivalents at beginning of financial year	4,135,136	528,670
<b>Cash and cash equivalents at end of financial year</b>	<b>3,371,946</b>	<b>395,558</b>

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

# 04 Notes to the Consolidated Financial Statements

## 1. Nature of operations

Regeneus is a Sydney-based ASX listed clinical-stage regenerative medicine company, using stem cell and immuno-oncology technologies to develop a portfolio of cell-based therapies to address significant unmet medical needs in the human and animal health markets. Our initial focus is on osteoarthritis and other musculoskeletal disorders, oncology and dermatology disease.

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

## 2. General information and basis of preparation

The half-year consolidated financial statements of the Group are for the six months ended 31 December 2017 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 2017 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 15 February 2018.

## 3. Going concern basis of accounting

For the half-year ended 31 December 2017, the Group generated a loss after income tax of \$2.7m (2016: \$3.8m profit), had net cash outflows from operating activities of \$1.0m (2016: \$0.3m outflow); after taking into consideration the receipt of the R&D tax incentive of \$2.6m (2016: \$2.7m), and has accumulated losses of \$27.3m (30 June 2017: \$24.6m).

Having achieved an initial manufacturing license in 2016 and after due consideration of additional commercial licensing opportunities 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 2017 Regeneus had positive net assets of \$5.4m (30 June 2017: \$8.1m).

The Directors are expecting, by the end of FY18, that the Group will enter into a clinical development and commercialisation licence with a Japanese partner. This arrangement will provide upfront funding and future payments contributing to the Group's funding requirements for the next 18 months. The Directors continue to have a number of additional strategies available to maintain the Group in a positive cash flow position including further product licensing, advance funding of the R&D tax incentive or raising additional capital, including issuance of securities.

Should the above transactions or assumptions not materialise, there is material uncertainty whether the consolidated entity 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 2017.

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

# 04 Notes to the Consolidated 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 2017.

## 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 human and animal 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. Other income – 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% (2017: 43.5%) of eligible research and development expenditures.

In the 6 month period ended 31 December 2017, the Group for the first time estimated the R&D tax incentive income receivable following the lodgement of the 2018 tax return. This change has occurred as the Group has more certainty about the quantum of expenditure at the half year which might qualify under the program and has greater confidence in its internal systems and processes in order to enable it to reliably measure the eligible R&D expenditure at the 31 December 2017 half year.

	31 Dec 17 \$	31 Dec 16 \$
R&D tax incentive	1,170,000	-
Other income	1,170,000	-

## 8. Individually significant items of expenditure

There were no individually significant items of expenditure included in the profit for the half-year. The profit for the 2016 half-year included the following items that were unusual because of their nature, size or incidence; and are considered to be significant to the understanding of the financial performance. These amounts, relating to the Japan transaction, were included in Corporate expenses.

	31 Dec 17 \$	31 Dec 16 \$
Withholding tax	-	380,400
Legal, consulting and other professional fees	-	430,000
Significant items of expenditure	-	810,400



# 04 Notes to the Consolidated Financial Statements

## 9. Income tax expense

No income tax expense or liability has been recognised in the half-year accounts as the Group has available unused tax losses as at 30 June 2017 of \$3,143,290 (30 June 2016: \$8,602,086) which have not previously been brought to account.

## 10. 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 2017 and 31 December 2016.

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 17 \$	31 Dec 16 \$
Basic earnings per share from continuing operations	(0.013)	0.018
The weighted average number of ordinary shares used as the denominator on calculating the EPS	208,885,143	208,885,143
Diluted earnings per share		
Basic earnings per share from continuing operations	(0.013)	0.017
The weighted average number of ordinary shares used as the denominator on calculating the DEPS	208,885,143	218,207,187

At 31 December 2017 share options are not included in the diluted EPS calculation because they are anti-dilutive.

At 31 December 2016 due to the profitable result for the period the 9,322,044 share options were included in the diluted EPS calculation.

## 11. 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 2017, there were no shares issued. During the prior comparable period no shares were issued.

Shares issued and authorised are summarised as follows:

Share Capital	31 Dec 17 \$	30 Jun 17 \$
Fully paid shares	31,076,819	31,076,819
	<b>31,076,819</b>	<b>31,076,819</b>

The company has 9,622,044 options on issue to acquire ordinary shares in the company. These options are unlisted, restricted and summarised as follows:

Share options	31 Dec 17 Number	30 Jun 17 Number
Employee share option plans	9,622,044	9,622,044
	<b>9,622,044</b>	<b>9,622,044</b>

# 04 Notes to the Consolidated Financial Statements

## 12. 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 Sep 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 \$6,457 (Dec 2016: \$34,239), and relates, in full, to the current year value of the employee share option payments at their grant date net of options forfeited.

Share options granted under the option plans	31 Dec 17		30 Jun 17	
	Number	Weighted avg exercise price \$	Number	Weighted avg exercise price \$
Options outstanding at beginning of period	9,622,044	0.22	9,672,044	0.22
Forfeited	-	-	(50,000)	0.25
Outstanding at end of period	9,622,044	0.22	9,622,044	0.22
Exercisable at end of period	9,622,044	0.22	9,272,044	0.22

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.

## 04 Notes to the Consolidated Financial Statements

### 13. Related party transactions

At the time of the IPO in August 2013, the Company provided shareholder loans in connection with the funding of the exercise of employee options. The loans are full recourse interest-free loans for 4 years, with maturity extended to June 2018. Included within the shareholder loans in other current assets, are balances owing by the Directors as follows:

Related party loan receivable	31 Dec 17 \$	31 Dec 16 \$
John Martin	295,925	295,925
Graham Vesey	150,552	150,552
<b>Total related parties loans</b>	<b>446,477</b>	<b>446,477</b>

On 1 July 2016 the company entered into an R&D funding arrangement with Sherman Group Pty Ltd, a related party. The facility forward funded, via a loan, the Federal Government's research and development tax incentive for FY16. The loan was secured over the tax incentive receipt and as a first ranking charge over the Group's property. The facility allowed the company to draw down the lower of \$2.0m or 80% of the anticipated claim which at the time of implementing the facility was estimated at \$2.5m. While the final claim lodged was in excess of \$2.73m, the drawings made progressively over the following 2 months were limited to \$1.25m. Repayment of the loan (including interest) of \$1.26m was made on 12 September 2016.

### 14. Dividends

No dividends were paid during the period (2016: \$nil).

### 15. Contingent liabilities

The group had no contingent liabilities as at 31 December 2017 (31 December 2016: Nil).

### 16. Events after the reporting date

In the period since 31 December 2017 to the signing of the financial report, a material loan facility has been secured. The details of the arrangement are as follows:

On 15 February 2018, the Company agreed to enter into an R&D funding arrangement with Paddington St Finance Pty Limited, a related party. The facility forward funds, via a loan, the Federal Government's research and development tax incentive for FY18. The loan will be secured over the tax incentive receipt and as a first ranking charge over the Group's property. The facility allows the company to draw down the lower of \$2.0m or 80% of the anticipated claim which at the time of implementing the facility is estimated at \$2.5m. The draw downs are currently anticipated to be undertaken during the period May to July 2018. Full repayment of the loan, including interest, is anticipated to be completed by the end of September 2018.

Apart from the above, there are no other matters or circumstances that have arisen since 31 December 2017 that have significantly affected or may significantly affect either the entity's operations in future financial years, the results of those operations in future financial years or the entity's state of affairs in future financial years.

## 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 2017 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  
Roger Aston

Dated the 20<sup>th</sup> day of February 2018



Level 17, 383 Kent Street  
Sydney NSW 2000

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

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

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

### Report on 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 2017, 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, nothing has come to our attention that causes us to believe that the half year financial report of Regeneus Limited does not give a true and fair view of the financial position of the Group as at 31 December 2017, and of its financial performance and its cash flows for the half year ended on that date, in accordance with the *Corporations Act 2001*, including complying with Accounting Standard AASB 134 *Interim Financial reporting*.

#### Material Uncertainty Related to Going Concern

We draw attention to Note 3 in the financial statements, which indicates that the Group reported a net loss after income tax of \$2,713,768 during the half year ended 31 December 2017. As stated in Note 3, these events or conditions, along with other matters as set forth in Note 3, indicate that a material uncertainty exists that may cast doubt on the Group's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

#### 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.

Grant Thornton Audit Pty Ltd ACN 130 913 594  
a subsidiary or related entity of Grant Thornton Australia Ltd ABN 41 127 556 389

'Grant Thornton' refers to the brand under which the Grant Thornton member firms provide assurance, tax and advisory services to their clients and/or refers to one or more member firms, as the context requires. Grant Thornton Australia Ltd is a member firm of Grant Thornton International Ltd (GTIL). GTIL and the member firms are not a worldwide partnership. GTIL and each member firm is a separate legal entity. Services are delivered by the member firms. GTIL does not provide services to clients. GTIL and its member firms are not agents of, and do not obligate one another and are not liable for one another's acts or omissions. In the Australian context only, the use of the term 'Grant Thornton' may refer to Grant Thornton Australia Limited ABN 41 127 556 389 and its Australian subsidiaries and related entities. GTIL is not an Australian related entity to Grant Thornton Australia Limited.

Liability limited by a scheme approved under Professional Standards Legislation



## **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 2017 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*. 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 have complied with the independence requirements of the *Corporations Act 2001*.

A handwritten signature in black ink that reads "Grant Thornton".

Grant Thornton Audit Pty Ltd  
Chartered Accountants

A handwritten signature in black ink that reads "L M Worsley".

L M Worsley  
Partner - Audit & Assurance

Sydney, 20 February 2018

## 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 (Executive Director)  
Professor Graham Vesey (Executive Director)  
Barry Sechos (Non-executive Director)  
Dr. Glen Richards (Non-executive Director)  
Leo Lee (Non-executive Director)

## Company Secretary

Sandra McIntosh

## Website

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