Regeneus Ltd

ABN 13 127 035 358

ASX Half-Year Report for 6 months to 31st December 2016

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 2016 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 2016

Regeneus Ltd – ABN 13 127 035 358

1 – Reporting period

Report for the half-year ended 31st December 2016
Corresponding period is for the half-year ended 31st December 2015

2 – Results for announcement to the market

		Up / down	% Change		$'000's
2.1	Revenues from ordinary activities	Up	829%	to	8,189
2.2	Profit from ordinary activities after tax attributable to members	Up	221%	to	3,757
2.3	Net profit from ordinary activities attributable to the members	Up	221%	to	3,757
2.4	It is not proposed to pay any dividend				
2.6	Revenue includes AGC licence fee of $7.6m. Expenses include $0.8m of one-off incremental costs incurred in securing this arrangement.				

Full details are in the attached accounts

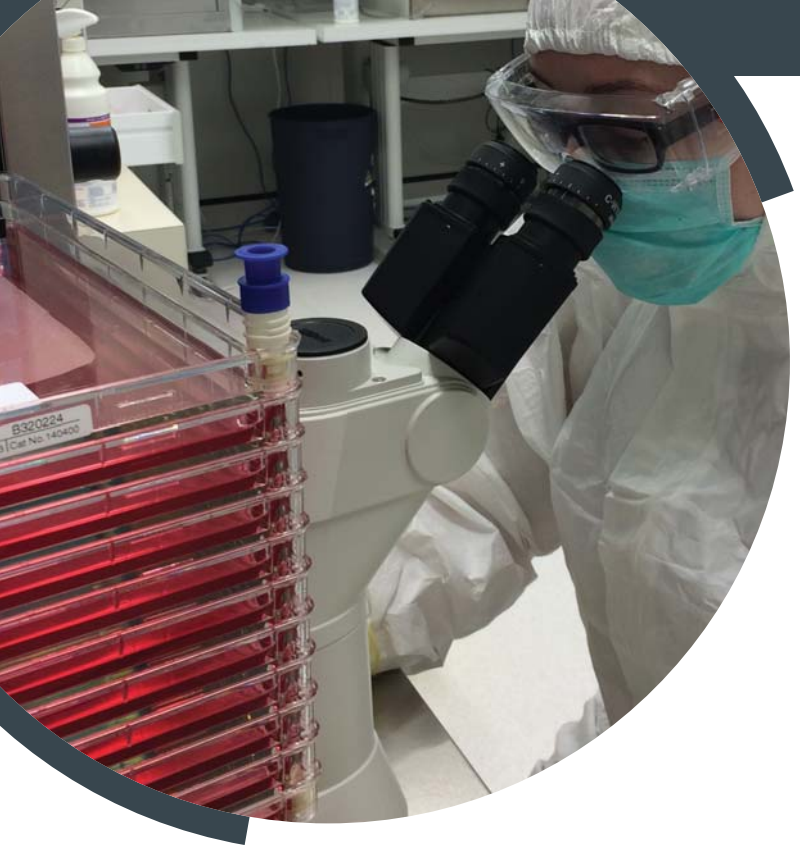
3 – Net Tangible assets per security

The net tangible assets per security

31st December 2016	4.1 cents
31st December 2015	2.5 cents

9 – Independent review of the financial information

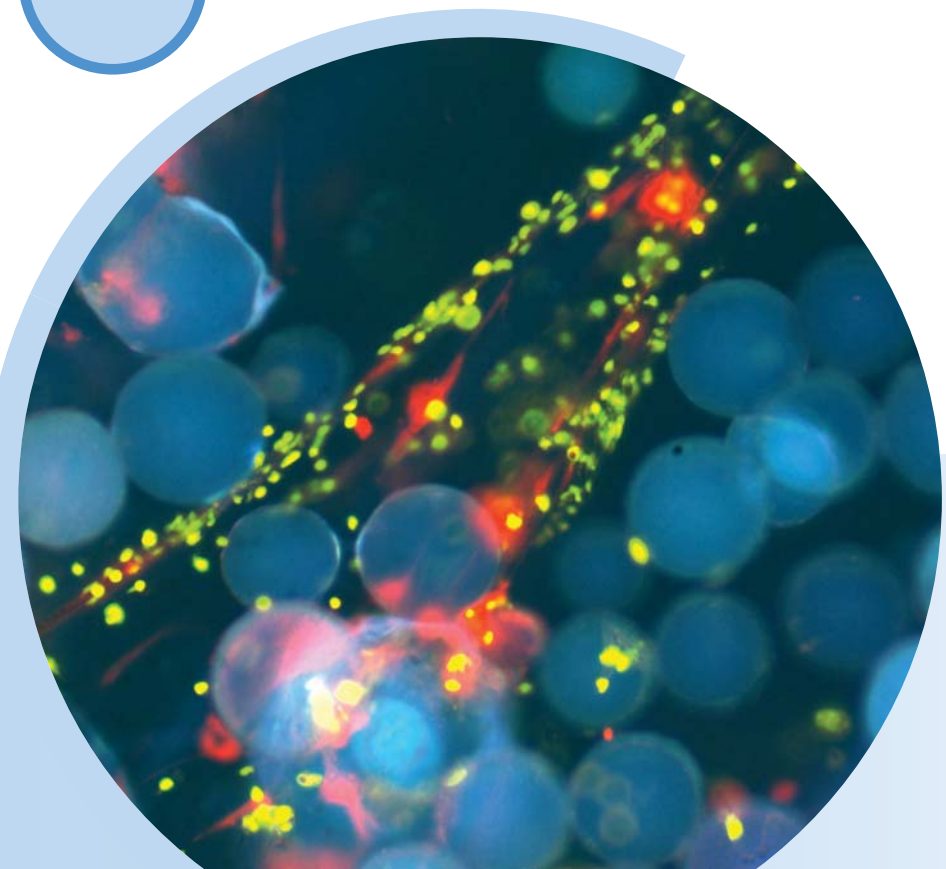
The independent audit review is attached to the half-year financial statements.



regeneus

living regenerative medicine

Half-Year Report
31st December 2016



Contents

First-half highlights and milestones

Progress on first-in-human clinical trials

Progenza STEP trial - allogeneic stem cell therapy for osteoarthritis
- Ongoing monitoring of all participants of both cohorts
- Final reporting of trial results in Q4 FY17

RGSH4K ACTIVATE trial - autologous cancer vaccine
- Ongoing banking of tumours
- Recruitment to the trial is ongoing with patients treated in each of the 3 dose cohorts safely

Update on strategic partnering and licensing

- Secured strategic collaboration and licensing agreement with Japan's Asahi Glass Co. Ltd (AGC) for exclusive manufacture of Progenza stem cell product for clinical applications in Japan
- Agreed to establish 50/50 JV with AGC for licensing of clinical development rights for Progenza in Japan
- Advanced discussions with potential partners for clinical development and marketing of Progenza for osteoarthritis and other indications in Japan
- Entered into Australian Research Council linkage grant funded collaborative research project with Macquarie University and University of Adelaide to explore Progenza use in the treatment of chronic pain

Progress on animal health trials

CryoShot pre-pivotal trial - allogeneic stem cell therapy for canine osteoarthritis
- Achieved 50% recruitment with 40 of the 80 dogs enrolled into the trial at University of Pennsylvania
- Results of the trial to be used to finalise the design of a pivotal US FDA trial

Kvax trial - autologous canine cancer vaccine
- Completed a small trial for treatment of canine osteosarcoma in USA with VCA, which showed that Kvax is well tolerated and confers increased progression free interval and survival

Technology development and patents granted

- European patent covering the use of the Company's stem cell secretions technology for the topical treatment of acne
- Grant of 3 patents and 2 accepted in overseas territories
- Regeneus now has in excess of 50 patents in patent applications across 14 patent families relating to its regenerative medicine development portfolio

Financial highlights

- Upfront licence fee of US$5.5m (AUD$7.6m) received from AGC
- First profit of $3.8m reported, improvement driven by upfront licence payment (FY15 loss $3.1m)
- Quarterly cash used in operations (excluding R&D tax incentive) maintained at $1.5m
- Receipt of $2.7m R&D tax incentive for FY16 ($3.4m in FY15)
- Secured 18 month funding runway

Anticipated milestones for next 12 to 18 months

- Advance clinical partnering discussions for Progenza in Japan - Ongoing
- Commence donor procurement and process development for manufacturing Progenza for Phase 2 trial in Japan - Q4 FY17
- Report on Progenza osteoarthritis STEP trial - Q4 FY17
- Commence Progenza chronic pain preclinical study - Q4 FY17
- Undertake preclinical trials for human secretions technology for inflammatory skin conditions - Q4 FY17
- Complete recruitment and report on CryoShot Canine pre-pivotal trial - H2 FY18
- Complete recruitment and report on ACTIVATE clinical trial - H2 FY18

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 2016. 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

Overview and strategy

Regeneus is an 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, with a focus on osteoarthritis (OA) and other musculoskeletal disorders, oncology and dermatology disease.

The Company's strategy is to unlock value in its clinical-stage human and animal pipeline products through generating positive clinical data, technology development and partnering at key value inflection points.

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

Human health

Progenza - allogeneic stem cell therapy technology platform

Progenza is a scalable platform technology that has the potential to be used as an off-the-shelf treatment option for osteoarthritis and other musculoskeletal disorders and inflammatory or immune-mediated conditions that have limited treatment options.

Progenza is made from expanded allogeneic mesenchymal stem cells (MSCs) from human adipose (fat) tissue and contains the bioactive secretions of the cells including growth factors, cytokines and exosomes. Progenza is designed to work by reducing inflammation and promoting repair and healing in the damaged or diseased tissue. The Company has demonstrated the scalability of the technology and the capability to produce millions of doses of cells and secretions from a single donor.

Progenza - STEP trial

The STEP trial is a randomised, double-blind placebo-controlled single ascending dose clinical trial in which, the primary objective of the trial is to evaluate the safety, tolerability and preliminary efficacy of intra-articular Progenza in adults with symptomatic knee OA. The trial involved 20 participants receiving ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint.

The secondary objectives are to investigate the effect of Progenza on knee pain and function, quality of life and knee joint structures using magnetic resonance imaging (MRI) and osteoarthritis biomarkers. Recruitment was completed in April 2016 and participants will be monitored for up to 12 months, with the trial results anticipated in Q4 FY17.

As previously reported, an interim safety review for both dose cohorts in the trial did not show any safety concerns.

These results will be an important addition to our clinical partnering discussions in Japan.

Partnering Progenza in Japan

Regeneus previously identified Japan as a key target market for the partnering of clinical development, manufacturing and marketing of Progenza. The targeting of Japan was largely driven by legislative changes in late 2014 when laws were enacted that reformed the pharmaceutical and medical regulations, providing an accelerated approval process specifically designed for regenerative medicine products such as Progenza. These laws allow for the conditional marketing approval of regenerative medicine products that demonstrate safety and probable efficacy without the need for expensive and lengthy Phase 3 trials. These laws have resulted in the Japanese regenerative medicine market being the most dynamic in the world, experiencing increased R&D investment and an unprecedented number of licensing deals, manufacturing tie-ups and merger & acquisition activities involving Japanese pharmaceutical companies with in excess of 10 such deals taking place in 2016 alone.

On 29 December 2016, Regeneus was delighted to announce a strategic collaboration and licensing agreement with AGC for the exclusive manufacture of Progenza for all clinical applications in Japan and a 50% interest in Regeneus Japan Inc. that has the exclusive clinical development and marketing rights for Progenza in Japan. AGC will be responsible for the manufacture of Progenza for a proposed Phase 2 trial for osteoarthritis in Japan.

Regeneus Japan is in advanced discussions with potential Japanese partners for the clinical development and marketing of Progenza in Japan for osteoarthritis and a range of other inflammatory indications.

Progenza - chronic pain research

Chronic pain is a symptom of osteoarthritis and Progenza has shown promise in reducing pain for osteoarthritis sufferers. The Company is investigating the potential of Progenza to reduce chronic pain not related to osteoarthritis.

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 technology platform to relieve chronic pain.

The three year research project will seek to develop a better understanding of chronic pain and how it affects women and men differently and how stem cells specially selected for their cytokine profiles 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 and has had previous clinical success with the use of stem cells for the treatment of facial neuropathic pain. The outcomes of this research project are expected to lead to the development of allogeneic off-the-shelf stem cell products that have been tailored for the treatment of chronic pain in both animal and human markets.

RGSH4K - cancer vaccine

RGSH4K is an autologous cancer vaccine developed from technology licensed from the Kolling Institute of Medical Research. The technology uses a patient's tumour to harness the body's own immune system against cancer cells. RGSH4K modifies a patient's tumour proteins to couple them to a bacterial adjuvant for immune recognition.

Future research plans include exploration of combining RGSH4K with immune checkpoint inhibitors which could potentially stimulate highly effective immune responses against cancer cells.

RGSH4K - ACTIVATE trial

The ACTIVATE Phase 1 trial of RGSH4K commenced in October 2015. ACTIVATE is a single centre, open label, Phase 1 dose escalating study to evaluate the safety, tolerability and preliminary efficacy of RGSH4K. As part of the trial, the Company has established a tumour bank to enable banking of both previously collected and new tumours. Patients with tumour banked will only be able to receive the RGSH4K injections when they reach end-stage disease after having exhausted all standard treatments. Recruitment to the trial is open and ongoing. Patients have been treated safely in all 3 dose cohorts.

Cell secretions for inflammatory skin conditions

The Company's secretions technology utilises the molecules including cytokines, growth factors and exosomes that are secreted by mesenchymal stem cells and can reduce pain and inflammation and encourage healing and repair. The secretions have been developed as a topical application for the treatment of inflammatory skin conditions such as acne, and wound healing. These skin conditions are some of the most promising and near-term areas for cell-based regenerative medicine products. In August 2016, the Company was granted a European patent covering the use of the Company's stem cell secretions technology for the topical treatment of acne.

In the second half of FY17, the Company will commence preclinical and clinical studies for human secretions technology, further enhancing the opportunity to explore partnering discussions for the development and commercialisation of cell secretions for topical applications in both therapeutic and cosmetic markets.

Animal health

CryoShot - allogeneic stem cells for canine and equine osteoarthritis

CryoShot is an allogeneic off-the-shelf stem cell therapy made from expanded allogeneic MSCs from canine or equine adipose tissue. CryoShot is designed to work by reducing inflammation and promoting repair and healing in the damaged or diseased tissue. It is a scalable technology that has the proven capability to produce commercial quantities of doses of cells from a single donor.

Extensive field trials in Australia have now been completed, with over 4,000 canine and equine treatments administered through 90 participating veterinary practices to dogs and horses with osteoarthritis and other musculoskeletal disorders. Regeneus has entered into an option agreement with a leading animal health company to develop CryoShot.

CryoShot - pre-pivotal canine trial at University of Pennsylvania

In November 2015, recruitment commenced for a pre-pivotal trial assessing CryoShot as a treatment for canine osteoarthritis. The pre-pivotal placebo controlled trial for CryoShot conducted at University of Pennsylvania School of Veterinary Medicine is 50% recruited. The results of the trial will be used to finalise the design of a pivotal US Food and Drug Administration (FDA) trial.

Upon completion of the trial, our collaboration partner has an option to exclusively licence the CryoShot technology. The terms of the licence include an upfront licence fee and development milestone payments to be agreed. The partner will be responsible for funding the pivotal trial and GMP 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 an autologous therapeutic canine cancer vaccine. In October 2016, Dr. Phil Bergman at Veterinary Centres of America (VCA) in the USA completed a trial of Kvax in the treatment of osteosarcoma. 13 dogs were treated with multiple doses of Kvax following amputation of the affected limb. The median progression-free interval (PFI) was 125 days and overall survival (OS) was 182 days. The investigator concluded that Kvax was well-tolerated and appears to confer improved PFI and OS compared to a historical control group who only had limb amputation.

In November 2015, the Company initiated a 45 dog double-blind placebo controlled trial of Kvax in combination with chemotherapy for the treatment of canine lymphoma to investigate the ability to extend the remission times for dogs with lymphoma. Recruitment for this trial is open and ongoing.

The Company is exploring partnering options for Kvax.

IP update

In August 2016, the European Patent Office granted a patent covering the use of the Company's stem cell secretions technology for the topical treatment of acne. The patent, entitled "Compositions of adipose tissue-derived secretions for use in the topical treatment or prevention of acne", provides commercial rights in Europe through to 15 March 2032. This is the first Regeneus patent to be granted in Europe and follows the grant of this patent in Australia in October 2014. The patent is also being pursued for grant in other key territories including USA and Japan.

Regeneus has in excess of 50 patents or patent applications across 14 patent families relating to its regenerative medicine development products.

During the period, the Company assigned a non-core patent application relating to the use of cytokines as biomarkers in red blood cells for a 30% interest in a new venture, Sangui Bio Pty Ltd. The assignee company was established by a third party research group who developed the initial intellectual property under a research collaboration with the Company. Sangui Bio intends to continue to undertake further research to develop the IP. The Company has no involvement in the Board or management of Sangui Bio.

3. Financial results

Operating results
The performance for the 6 months ending 31 December was a profit of $3.8m. This is a material improvement on the prior corresponding period (31 December 2015: loss of $3.1m).

The current half-year results include the upfront licence fee from AGC, of $7.6m, which was received in January 2017.

Revenue from continuing operations
Revenue during the current period included the AGC licence fee of $7.6m. The underlying revenue of $0.5m was down on the prior year (2015: $0.9m) and this reflects the move away from early stage commercial activities to focus on targeted clinical research programs and licensing opportunities.

Cost of sales
Cost of sales reflects the direct manufacture of CryoShot and Kvax. The reduction in cost of sales is due to the focus on generating further clinical data and a reduction of early stage commercial activities.

Expenses from continuing operations

Research
Expenditure on research in the half-year period to 31 December 2016 was $1.8m compared to 31 December 2015 of $1.9m.

Research expenditure includes costs associated with product development as well as clinical trials. The focus over the last year has been progressing several clinical trials including Progenza and RGSH4K. These clinical trials are longer term in nature and the expenditure is incurred over an extended period. Research expenditure is anticipated to increase as further activities are commenced for each of the product platforms of Progenza, RGSH4K and Secretions.

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
Selling expenses is now limited to the costs incurred in early activities in product licensing. Prior years expenses included costs associated with the early commercialisation of products.

Corporate
Corporate expenses in the current year include costs associated with securing the first major licensing opportunity for Progenza with AGC in Japan. There were $0.8m of one-off transaction costs incurred in securing this arrangement including withholding tax, legal fees, consulting fees and IP costs. Withholding tax of $0.4m was retained by the Japanese taxation authorities. There has been no accrual in these results for foreign withholding tax credits (FITC) for the year end 30 June 2017 as the Group is unable to estimate with sufficient certainty the recoverability of that tax asset to meet accounting standard requirements. Accordingly, withholding tax incurred, has been expensed.

Corporate expenses, after allowing for the one-off Japanese transaction costs, have been maintained below prior periods.

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

R&D tax incentive

There has been no accrual included in these results for the R&D tax incentive for the year to 30th June 2017 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 $2.7m in FY16. The incentive is consistent with the prior year mainly due to the level of R&D activity involved in the development of the manufacture of Progenza.

Cash flows

The net outflows for the period were $133k (2015: $394k inflows).

	31 Dec 16 $	31 Dec 15 $	Movement $
Cash flows from operating activities	(319,567)	578,252	(897,819)
Cash flows from investing activities	(14,091)	(184,215)	170,124
Cash flows from financing activities	200,546	-	200,546
Net cash flows	**(133,112)**	**394,037**	**(527,149)**

Operating activities – cash used in operating activities was $0.3m compared to cash provided by operating activities to 31 December 2015 of $0.6m. The $0.9m reduction in cash from Operating activities predominantly reflects the lower R&D Tax Incentive receipt for the 2016 claim year of $2.7m (FY15 claim: $3.4m).

Financing activities – cash provided by financing activities includes several amounts received totalling $0.2m which was the early repayment of shareholder loans, provided at the time of the IPO in August 2013, to exercise employee options, as a full recourse, interest free loan for 4 years, maturing July 2017.

Significant changes in state of affairs

In December 2016, the Group entered into a strategic collaboration and licensing agreement with AGC, which included a US$5.5m (A$7.6m) upfront payment, which was received in January 2017. There were no other significant changes in the Group's state of affairs during the first-half FY16.

Events subsequent to the end of the reporting date

Under the terms of the collaboration and licensing agreement announced on 29 December 2016, the Company received the upfront payment of US$5.5m on 20 January 2017. The remaining US$11m is receivable on the achievement of specific development and approval milestones.

In early February, AGC purchased 50% of the issued capital in Regeneus Japan Inc. The purpose of this entity is to sub-licence the development and marketing rights of Progenza for osteoarthritis and all other clinical indications in Japan. Regeneus and AGC will share upfront licence fees, milestone payments and royalties from sub-licensing the development and commercialisation of Progenza for osteoarthritis and all other clinical indications in Japan. AGC will be responsible for funding the manufacture of Progenza for the proposed Phase 2 trial for osteoarthritis in Japan under specific conditions.

Other than the above, there are no other matters or circumstances that have occurred after 31 December 2016 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 9 of this report.

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

Roger Aston

Non-executive Chairman

22 February 2017

Grant Thornton

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
W 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 2016, 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

A Sheridan
Partner - Audit & Assurance

Sydney, 22 February 2017

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 2016			
	Note	31 Dec 16 $	31 Dec 15 $
Revenue		8,189,424	881,360
Cost of sales		(54,630)	(117,952)
Gross profit		**8,134,794**	**763,408**
Research and development expenses		(1,842,541)	(1,931,899)
Selling expenses		(111,164)	(249,267)
Occupancy expenses		(192,494)	(247,894)
Corporate expenses	7	(2,219,661)	(1,419,781)
Finance costs		(11,565)	(9,934)
Profit/(loss) before income tax		**3,757,369**	**(3,095,367)**
Income tax expense	8	-	-
Profit/(loss) for the period		**3,757,369**	**(3,095,367)**
Other comprehensive income		-	-
Total comprehensive profit/(loss) for the year		**3,757,369**	**(3,095,367)**

Earnings per share			
Basic earnings per share from continuing operations	9	0.018	(0.015)
Dilute earnings per share from continuing operations	9	0.017	(0.015)

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 2016		
	31 Dec 16 $	30 Jun 16 $
Current assets		
Cash and cash equivalents	395,558	528,670
Trade and other receivables	7,611,380	21,774
Inventories	14,287	30,076
Current tax assets	-	2,732,110
Other current assets	1,456,008	190,054
Total current assets	**9,477,233**	**3,502,684**
Non-current assets		
Property, plant and equipment	644,945	801,562
Intangible assets	8,229	11,254
Investments	1,950	-
Other non-current assets	210,000	1,619,307
Total non-current assets	**865,124**	**2,432,123**
Total assets	**10,342,357**	**5,934,807**
Current liabilities		
Trade and other payables	1,498,514	906,312
Provisions	100,013	99,273
Total current liabilities	**1,598,527**	**1,005,585**
Non-current liabilities		
Provisions	167,482	144,482
Total non-current liabilities	**167,482**	**144,482**
Total liabilities	**1,766,009**	**1,150,067**
Net assets	**8,576,348**	**4,784,740**
Equity		
Issued capital	31,076,819	31,076,819
Accumulated losses	(24,159,276)	(27,916,645)
Reserves	1,658,805	1,624,566
Total equity	**8,576,348**	**4,784,740**

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

05 Consolidated Statement of Changes in Equity

For the half-year ended 31 December 2016	Share capital $	Share option reserve $	Accumulated losses $	Foreign currency translation reserve $	Total attributable to parent owners $	Total equity $
Balance at 1 July 2015	**31,076,819**	**2,491,128**	**(25,295,813)**	**-**	**8,272,134**	**8,272,134**
Reported loss for the period	-	-	(3,095,367)	-	(3,095,367)	(3,095,367)
Employee share-based payment option expense	-	54,518	-	-	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**	**5,231,285**
Balance at 1 July 2016	**31,076,819**	**1,624,566**	**(27,916,645)**	**-**	**4,784,740**	**4,784,740**
Reported profit for the year	-	-	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**

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

06 Consolidated Statement of Cash Flows

For the half-year ended 31 December 2016		
	31 Dec 16 $	31 Dec 15 $
Operating activities		
Receipts from customers	629,696	915,797
Payments to suppliers and employees	(3,673,037)	(3,767,920)
Interest received	3,229	22,743
R&D tax refund	2,732,110	3,417,566
Finance costs	(11,565)	(9,934)
Net cash (used in)/provided by operating activities	**(319,567)**	**578,252**
Investing activities		
Payments for investments	(1,950)	-
Purchase of property, plant and equipment	(21,741)	(200,256)
Receipts from sale of property, plant and equipment	9,600	16,041
Net cash used in investing activities	**(14,091)**	**(184,215)**
Financing activities		
Receipts from shareholder loan	200,546	-
Net cash provided by financing activities	**200,546**	**-**
Net change in cash and cash equivalents held	(133,112)	394,037
Cash and cash equivalents at beginning of financial year	528,670	3,012,812
Cash and cash equivalents at end of financial year	**395,558**	**3,406,849**

Note: This statement should be read in conjunction with the notes to the 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 2016 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 2016 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 16 February 2017.

3. Going concern basis of accounting

For the half-year ended 31 December 2016, the Group generated a profit after income tax of $3.8m (2015: $3.1m loss), had net cash outflows from operating activities of $0.3m (2015: $0.6m inflow); after taking into consideration the receipt of the R&D tax incentive of $2.7m (2015: $3.4m), and has accumulated losses of $24.2m (30 June 2016: $27.9m). Notwithstanding the small operating cash outflow, the Directors have prepared the financial statements on a going concern basis which contemplates continuity of normal activities and realisation of assets and the settlement of liabilities in the normal course of business.

As at 31 December 2016, as a result of the strategic collaboration and licensing agreement entered into with AGC on 29 December 2016, the Group had positive net assets of $8.6m, positive net current assets of $7.9m and a cash balance of $0.4m.

The licensing agreement with AGC provides Regeneus with US$16.5m; US$5.5m as an upfront payment (recognised as at 31 December 2016) with the remaining US$11m subject to achievement of specific development and approval milestones. Subsequent to year end, the upfront payment of US$5.5m was received which provides cash to support ongoing operations.

The Directors have a number of strategies in progress to assist them in achieving the specific development and approval milestones including progressing current partnership discussions for the clinical development and commercialisation of Progenza for osteoarthritis and other inflammatory disorders in Japan. Further licensing of clinical development and commercialisation of Progenza and the achievement of the specific development and approval milestones from AGC would contribute to the Group's funding requirements over the next 18 months.

The Directors continue to monitor other available funding strategies including further product licensing, funding of R&D and raising additional capital, including the issuance of securities, if necessary, to ensure available funds for ongoing operations.

Should the above transactions or assumptions not materialise, there is significant doubt 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 2016.

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 2016.

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 Animal 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 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. Individually significant items of expenditure

Profit for the half-year includes the following items that are 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, are included in Corporate expenses.

	31 Dec 16 $	31 Dec 15 $
Withholding tax	380	-
Legal, consulting and other professional fees	430	-
Significant items of expenditure	**810**	**-**

8. 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 amounting to $8,603,798 as at 30 June 2016 which have not previously been brought to account.

9. 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 2016 and 31 December 2015.

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 16 $	31 Dec 15 $
Basic earnings per share from continuing operations	0.018	(0.015)
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	0.017	(0.015)
The weighted average number of ordinary shares used as the denominator on calculating the DEPS	218,207,187	208,885,143

9,322,044 share options are included in the diluted EPS calculation.

At 31 December 2015 share options were not included in the diluted EPS calculation because they were anti-dilutive.

10. Share capital

The share capital of Regeneus Ltd consists only of fully paid ordinary shares; the shares do not have a par value. All shares are equally eligible to receive dividends and the repayment of capital and represent one vote at the shareholders' meeting of Regeneus Ltd.

During the six months to 31 December 2016, 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 16 $	30 Jun 16 $
Fully paid shares	31,076,819	31,076,819
	31,076,819	**31,076,819**

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 16 Number	30 Jun 16 Number
Employee share option plans	9,672,044	9,672,044
	9,672,044	**9,672,044**

11. 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 $34,239 (Dec 2015: $54,518), 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 16		30 Jun 16	
	Number	Weighted avg exercise price $	Number	Weighted avg exercise price $
Options outstanding at beginning of period	9,672,044	0.22	15,564,865	0.21
Forfeited	-	-	(5,892,821)	0.20
Outstanding at end of period	**9,672,044**	**0.22**	**9,672,044**	**0.22**
Exercisable at end of period	**9,322,044**	**0.22**	**8,872,044**	**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.

12. Related party transactions

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.

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 maturing July 2017. Included within the shareholder loans are balances owing by the Directors as follows:

Related party loan receivable	31 Dec 16 $	31 Dec 15 $
John Martin	295,925	295,925
Graham Vesey	150,552	150,552
Total related parties loans	**446,477**	**446,477**

13. Dividends

No dividends were paid during the period (2015: $nil).

14. Contingent liabilities

The group had no contingent liabilities as at 31 December 2016 (31 December 2015: Nil).

15. Events after the reporting date

Under the terms of the collaboration and licensing agreement with AGC announced on 29 December 2016, the Company received the upfront payment of US$5.5m on 20 January 2017. The remaining US$11m is receivable on the achievement of specific development and approval milestones.

In early February, AGC purchased 50% of the issued capital in Regeneus Japan Inc. The purpose of this entity is to sub-licence the development and marketing rights of Progenza for osteoarthritis and all other clinical indications in Japan. Regeneus and AGC will share upfront licence fees, milestone payments and royalties from sub-licensing the development and commercialisation of Progenza for osteoarthritis and all other clinical indications in Japan. AGC will be responsible for funding the manufacture of Progenza for the proposed Phase 2 trial for osteoarthritis in Japan under specific conditions.

Other than the above, there are no other matters or circumstances that have occurred after 31 December 2016 and prior to the signing of this financial report that have significantly affected or may significantly affect the financial results presented.

08 Directors' Declaration

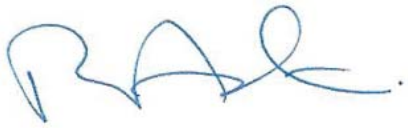
Directors' declaration

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 2016 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 22nd day of February 2017.

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
W www.grantthornton.com.au

INDEPENDENT AUDITOR'S REVIEW REPORT TO THE MEMBERS OF REGENEUS LIMITED

We have reviewed the accompanying half-year financial report of Regeneus Limited (the Company), which comprises the consolidated financial statements being the statement of financial position as at 31 December 2016, and the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a statement or description of 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 consolidated entity's financial position as at 31 December 2016 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.

Grant Thornton

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 2016 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*.

Grant Thornton

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

A Sheridan
Partner - Audit & Assurance

Sydney, 22 February 2017

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 (Executive Director)
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