Update Report

REGENEUS LTD

Taking important steps forward

regeneus
living regenerative medicine

Date: 8 December 2014

Name:	**Regeneus Ltd**
Country:	**Australia**
Price:	**AUD 0.14**
ISIN Code:	**AU000000RGS6**
Reuters Code:	**RGS.AX**
Market Cap (AUD m):	**26.2**
EV (AUD m):	**16.6**
Cash & cash eq. (AUD m):	**9.6**
Shares outstanding (m):	**208.1**
Average volume:	**247,514**
Free float:	**57%**
52-week Range:	**0.10-0.56**

AUD mln (1 USD = AUD 1.19)	**2012A**	**2013A**	**2014A**	**2015Q1**
Revenues	1.186	1.769	2.094	0.601
Net Loss/Profit	(3.266)	(5.195)	(7.522)	1.173
Net loss per share (cents)	(0.03)	(0.05)	(0.05)	0.01
R&D costs	(3.212)	(4.134)	(5.758)	(0.904)
Cash increase/(decrease)	(1.061)	(0.118)	2.097	7.094
Cash and marketable sec.	0.528	0.410	2.507	9.601

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Executive Summary

- **Regeneus Ltd (ASX: RGS)** is one of the leading biotech companies in Australia in the fast growing area of regenerative medicine. The company is developing and commercializing its proprietary technology platforms for autologous and off-the-shelf cell therapies using fat (adipose)-derived regenerative cells for the treatment of musculoskeletal and other inflammatory diseases in humans and animals. The company also has a proprietary autologous therapeutic cancer vaccine technology.

- Regeneus currently has three commercially available products in Australia: CryoShot® Canine and CryoShot® Equine for the veterinary market and HiQCell® for the human market. CryoShot® is an allogeneic off-the-shelf cell-based product. It has been used in trials to treat hundreds of cases of canine and equine osteoarthritis and tendinopathy. HiQCell® is a proprietary cell therapy that uses regenerative cells taken from a patient's own adipose tissue to treat musculoskeletal conditions with a focus on osteoarthritis (OA) and tendinopathy. It has already been used to treat more than 550 patients with over 1,200 human arthritic joints in clinical trials and commercial settings.

- The company is currently in a process to roll out several of its products in the US, Japan and Singapore. Recently, Regeneus announced it will launch HiQCell in Singapore. Singapore is a leading country for both local and international patient treatments in regenerative medicine. It is the first location for treatment of HiQCell outside of Australia.

- In November, new Japanese regenerative medicine laws came into effect, which provide a rapid approval process for regenerative medicine products. These laws offer clear benefits for Regeneus with its new allogeneic off-the-shelf cell therapy product for OA in humans called Progenza (PRG). With a rapidly ageing population and a shortage of effective non-surgical treatment options, we think that there is a substantial market for joint injections to treat OA in Japan. Regeneus is in a process to identify the right Japanese clinical and marketing partners to start a Phase II trial and product manufacture in Japan.

- In the past few months Regeneus has successfully raised AUD 6.3 million in equity to accelerate the development and commercialization of a number of its products. With a further AUD 3.7 million R&D tax rebate received, the company is well placed to advance its stem cell and cancer vaccine pipeline. We believe that Regeneus has sufficient capital to complete the preclinical work required for Progenza (PRG), its human cancer vaccine

Kvax and initiate first-in-man clinical studies with both candidates in 2015H1.

- Certain important news expected in the next 12 months could drive the stock up. Several key near-term milestones for each of Regeneus' programs are anticipated, including the start of a clinical Phase I/II study with PRG, seeking both a marketing partner for CryoShot® and a Japanese partner for PRG, and the start of a first-in-man safety study with Kvax as well as a US marketing study with Kvax in dogs.

- Based on sum-of-the-parts valuation, we believe Regeneus is gravely undervalued at the current share price of AUD 0.14. Using our valuation model, the Company's total value is AUD 206 million, or AUD 0.96 per share.

Company Overview

Regeneus Ltd (ASX:RGS) is a leading regenerative medicine company in Australia and one of the most important companies globally in the use of adipose derived stem cells for the treatment of musculoskeletal and inflammatory diseases in humans and animals. Founded in 2007 and trading publicly since September 2013, Regeneus is listed on the Australian Securities Exchange (ASX) under the symbol "RGS".

The company is at the forefront in the development and use of adipose derived stem cells for treatment of Osteoarthritis (OA) and other inflammatory diseases in humans and animals. For humans, the company has an autologous cell therapy on the market called HiQCell®. This product has already been used to treat more than 550 patients in both clinical trials and commercially. In September, HiQCell® was also launched in Singapore. The first treatments will commence within a few weeks.

Regeneus plans to start a clinical trial with its allogeneic adipose derived stem cell product, Progenza (PRG), in the first half of 2015. In April this year, the company received ethics approval to collect stem cells from human donor for this new off-the-shelf product for OA. It also got confirmation that PRG would be eligible for conditional approval under the new Japanese regulations for regenerative medicine.

Regeneus' lead product for the animal health market is CryoShot® Canine, a clinical stage allogeneic adipose derived stem cell product for the treatment of osteoarthritis in dogs. CryoShot® Canine is expected to start with a US registration trial in the first half of 2016. Next to CryoShot®, the company also has an autologous immunotherapy called Kvax for cancer in dogs. Kvax was officially

launched within the Australian veterinary market very recently. Following the launch in Australia, recruitment has commenced in a US marketing trial for Kvax in cooperation with VCA. VCA is the largest provider of pet health care services in the US.

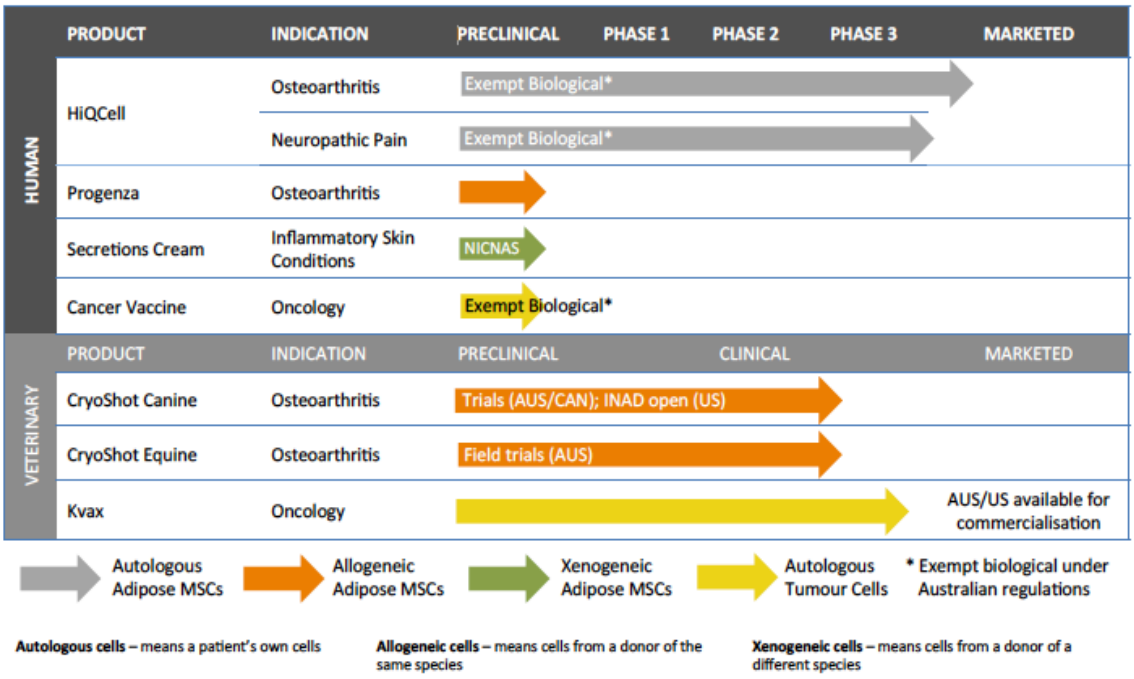
Business Strategy

The company is focused on the development of its proprietary regenerative cell therapies in order to provide medical specialists with the most innovative treatments of damaged and diseased tissues. Regeneus clearly sees the opportunity to capitalize on its first mover advantage in Australia to win a sizable market share in the fast growing regenerative medicine space.

With the completion of the early stage R&D phases for its product pipeline, the company will focus on partnering and commercialization. Currently, Regeneus is engaged with several companies for the distribution of its products HiQCell, Kvax and its stem cell secretions cream.

Product Pipeline

Regeneus already has an autologous stem cell-based therapy on the Australian market for humans (HiQCell®), since 2011. Also allogeneic stem cell-based therapies are available for animals (CryoShot® Canine and CryoShot® Equine) and in development for human use (human version of CryoShot® called PRG). These therapies are aimed at treating musculoskeletal conditions, including osteoarthritis, tendinopathy and other inflammatory diseases. Next to that, Regeneus also has the rights to develop and commercialize the autologous cancer vaccine Kvax. The Kvax canine cancer treatment is already available to Australian dog owners. In the US it has started a marketing trial together with VCA, the largest provider of pet health care services in the US.



Source: Regeneus

Regeneus has developed technology for the production of secretions from adipose tissue which will be used to develop a cream for topical treatment of skin

inflammatory conditions such as acne, rosacea, psoriasis, atopic dermatitis and insect stings and bites. Recently, Regeneus was granted a patent that provides protection for the company's stem cell secretion technology for the topical treatment of acne.

HiQCell®: Adipose derived autologous stem cell therapy in humans

Regeneus' lead human product is the HiQCell® therapy. To date, the use of the HiQCell® treatment for osteoarthritis and tendinopathy has shown very good results. Most patients with musculoskeletal conditions who received the therapy, experienced substantial improvements in their symptoms, in particular pain. The therapy involves harvesting a small amount of a patient's own stem cells (autologous) from their fat tissue. After separating and concentrating the regenerative cells, they are re-injected in OA-affected joints. The cell therapy procedure is supported by safety data from a randomized controlled clinical trial and long term safety and efficacy data is tracked through Australia's first Joint Registry for stem cell therapy.

In September Regeneus announced that it would open the HiQCell Regenerative Medicine Clinic in Singapore. The clinic will be located at the Camden Medical Center and will be the first location for treatment of HiQCell outside of Australia. Singapore is one of the leading hubs for medical services for local and international patients.

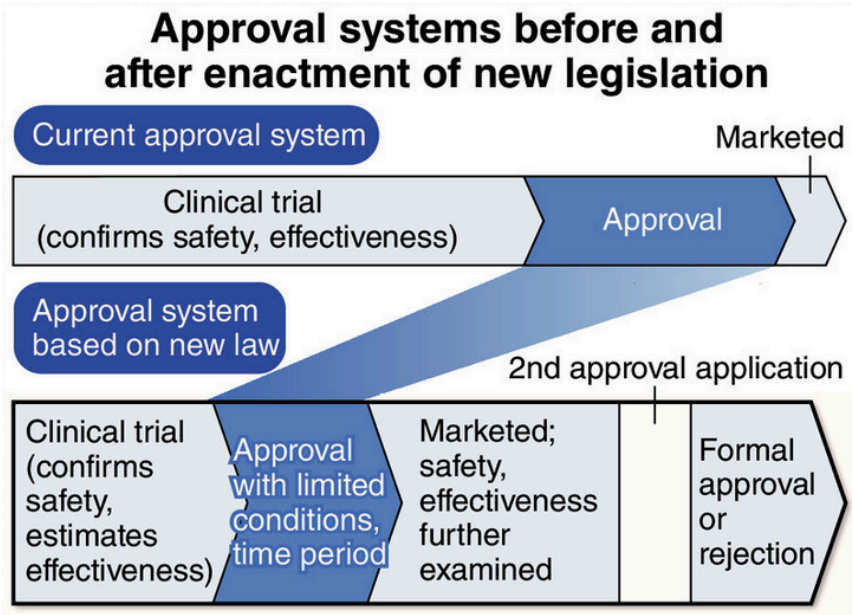
Regeneus is looking to expand its partnering and licensing option with HiQCell.

CryoShot for Human Use: PRG

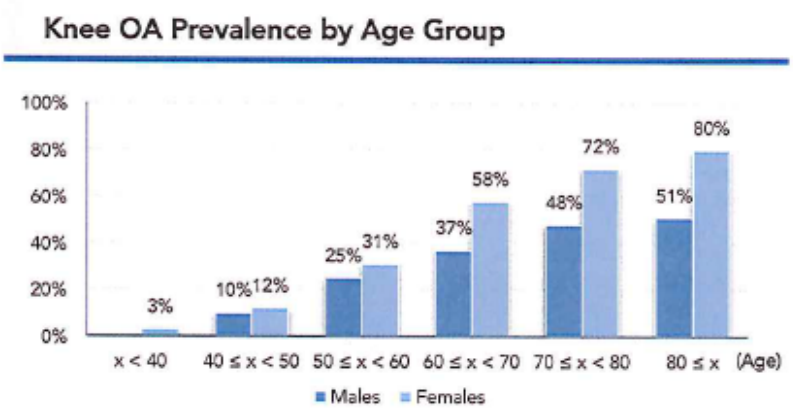
Next to its successful autologous therapy HiQCell, Regeneus is developing an allogeneic version that is based on the same adipose derived stem cell technology. Due to the fact that this product is allogeneic whereby cells are used from a donor,

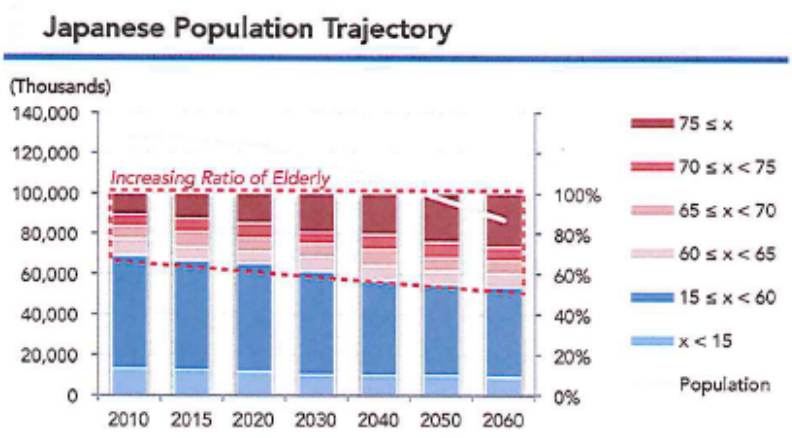
Regeneus needs to conduct clinical trials to demonstrate safety and efficacy. In April, Regeneus received ethics approval for collecting stem cells from human donors for first-in-man safety trial with its allogeneic product called PRG. This approval allows Regeneus to begin manufacturing the cells for its first-in-man clinical trial to assess initial safety and preliminary efficacy in human volunteers with knee OA. The company expects to start a clinical trial in such patients in the first half of 2015 with the first results ready by mid 2016.

An important reason for Regeneus to focus on the further development of an allogeneic stem cell therapy was the announcement of November last year that the Japanese parliament has passed new laws that provide a rapid approval process specifically designed for human stem cell therapies. Japan is the second largest healthcare market in the world. Under the new laws, there will be a separate approval channel for regenerative medicine products like cell therapies. Once you have demonstrated limited safety and efficacy data in humans, the new cell therapy can be approved for commercial use with data reporting requirements and potential for national insurance coverage.

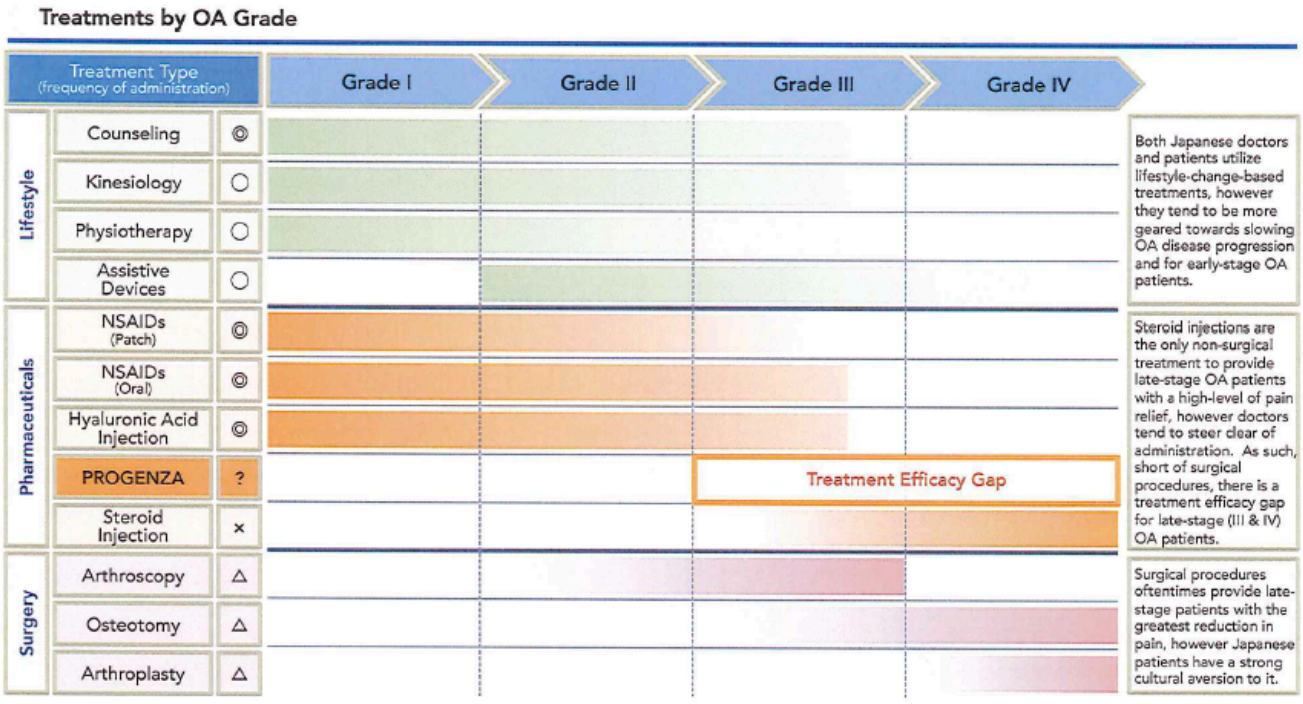


These new laws give Regeneus a great opportunity to fast-track the clinical trial and potential approval of its allogeneic stem cell therapy, Progenza (PRG) to treat osteoarthritis and other inflammatory musculoskeletal conditions into the Japanese market. As of November this year the Japanese laws have come into effect. Since the laws were passed last year, Regeneus already took several steps to identify Japanese partners for a phase II trial as well as manufacture in Japan. The company is preparing for ethics approval and the start of clinical trials for PRG in Australia in the first half of 2015.





Especially in Japan with a rapidly ageing population, with increased rates of bone and joint disease, there is a recognized shortage of effective non-surgical treatment options. With a population of 127 million people, **17% of population is over 65 (this percentage is expected to grow by 25% in the next three decades). 5% of the population has some form of arthritis**. Patients with OA are typically managed with non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics to alleviate OA symptoms and to control the pain in affected joints. Intra-articular injections with hyaluronic acid-based products (e.g. Artz (Seikugaku) USD 150 million sales in 2013) are also used extensively. A total joint arthroplasty (knee/hip replacement) is the ultimate treatment option when these therapies no longer provide symptomatic relief. Alternative mid-stage treatment options are therefore required, and the potential regenerative effects of mesenchymal stem cells (MSCs) could provide such an option.



Kvax: Regeneus' autologous cancer vaccine

In September 2012, Regeneus started a partnership with the Kolling Institute of Medical Research for the development of an autologous cancer vaccine. Regeneus and the Kolling Institute are working towards making the cancer vaccine available to veterinarians for treating cancer in dogs and to begin safety trials in humans. The partnership is also continuing to explore how stem cells can be used to enhance vaccines and other cancer treatments.

Kvax is a therapeutic cancer vaccine. A small amount of tumor from the dog is removed and sent to Regeneus' production facility. There a personalized vaccine is made using the dog's own tumor material. The vaccine is then administered at three week intervals over a 12 week period to stimulate the dog's immune system to recognize and attack the cancer cells. In September, Regeneus announced that Kvax was officially launched within the Australian veterinary market. Following the Australian launch, recruitment has started for a US marketing trial together with VCA. VCA is the largest provider of pet health care services in the US.

Regeneus also secured the exclusive global rights to develop a personalized therapeutic **human** cancer vaccine following the preclinical efficacy data in dogs. The company intends to start a first in man safety study in the first quarter of 2015. As the vaccine uses the patient's own tumor cells and can be prepared under the supervision of the treating specialist, the regulatory authorities in Australia may allow for an accelerated clinical study. This would mean that it is not necessary to go through expensive and time-consuming phase III trials.

Recent headlines

November 26, 2014:	New regenerative medicine lauws to fast track cell therapy approval take effect in Japan
November 24, 2014:	Regeneus concludes strategic review
November 14, 2014:	Acne treatment Patent Granted
November 10, 2014:	Board and Management changes
September 25, 2014:	Regeneus receives R&D tax incentive refund of AUD 3.7 million
September 23, 2014:	HiQCell to be launched in Singapore
September 11, 2014:	US marketing trials with Kvax canine cancer treatment starts
August 27, 2014:	AFL approves use of Regeneus' HiQCell for injured players
August 21, 2014:	Regeneus and Cryosite partner for the development and manufacture of human stem cell products
August 19, 2014:	HiQCell shows continuing significant patient improvement at 2 years post treatment
August 15, 2014:	Regeneus successfully closes AUD 6 million private placement
July 8, 2014:	Regeneus secures exclusive worldwide rights for new therapeutic human cancer vaccine
June 30, 2014:	Regeneus enters into agreement for US marketing trial of Kvax
May 14, 2014:	Regeneus stem cells show promise for chronic neuropatic pain sufferers
April 8, 2014:	Ethics approval for procurement for off-the-shelf OA treatment
April 4, 2014:	Regeneus partners with US manufacturer for its Kvax canine cancer vaccine
March 26, 2014:	HiQCell® shows continuing patient improvements at 12 month post treatment
March 6, 2014:	Kvax Cancer vaccine shows safety and efficacy in animals
January 22, 2014:	Regeneus partners with Lonza for manufacturing CryoShot® for US FDA trial

SWOT Analysis

Strengths

Strong proprietary IP coupled with a point-of-care business provides Regeneus with the potential to produce innovative products at a lower cost and at an accelerated rate compared to traditional drug pathways.

Regeneus' products are already commercially available within the veterinary and human health market with demonstrated safety and efficacy. Over 1,200 joints across more than 550 patients have been treated with the HiQCell® product in Australia

Strong management and highly experienced in the development and early stage commercialisation of new therapeutics.

Weaknesses

HiQCell® is not covered Medicare or any other reimbursement schemes.

Operating losses cumulating year-on-year

Opportunities

Regenerative medicine technologies have the potential to create less costly and more effective treatments for some of the most widespread and debilitating conditions.

Regeneus' technology may be able to be applied to other indications such as in cancer and auto-immune diseases and inflammatory conditions such as neuropathic pain.

Threats

Uncertainty about the outcome of clinical trial of the products

Higher level of expenditure than budgeted

Financials

For the first quarter of the fiscal year 2015, Regeneus reported revenues of AUD 0.6 million. Net profit amounted to AUD 1.173 million thanks to the R&D Tax Incentive of AUD 3.7 million it received. The Australian government's R&D tax incentive scheme effectively reimburses 45% of eligible R&D costs and companies can receive one-off, lump-sum cash payments each year, related to R&D expenses in the prior year. For Regeneus, this is recorded as an income tax benefit on the P&L

R&D expenditure increased to AUD 0.9 million due to Research costs associated with Progenza (PRG) for the Japanese market and research that was undertaken as part of the new Cryosite agreement.

Besides the receved R&D Tax Incentive, Regeneus successfully raised AUD 6.3 million in equity to accelerate the development and commercialization of a number of its products. This resulted in a total cash position of AUD 9.6 million by the end of the first quarter of fiscal year 2015. We believe that Regeneus has sufficient capital to complete the preclinical work required for Progenza (PRG), its human cancer vaccine Kvax and initiate first-in-man clinical studies with both candidates in 2015H1.

Valuation

We valued Regeneus using the sum-of-the-parts valuation approach for each drug in the pipeline, adjusted for corporate overheads. We adopted the Net Present Value (NPV) Approach to value each drug, considering each drug under development as a separate project. We have increased our NPV calculation for Regeneus due to the increased market perspectives for Progenza (mainly Japanese market) and arrive at a fair market value of AUD 206 million or AUD 0.96 per share using the SOTP valuation method, which makes the Company significantly undervalued compared to the current market value of AUD 24 million.

Product	Market Launch	Success probability	NPV	Probability based NPV	NPV per share
HUMAN USE					
HiQCell				59	**0.26**
Australia	2011	100%	25	25	0.09
Singapore	2014	100%	8	8	0.04
Japan	2016	70%	25	18	0.09
EU	2017	50%	15	8	0.04
Progenza	2017	25%	250	63	**0.30**
Kvax cancer vaccine	2019	15%	250	38	**0.18**
ANIMAL USE					
CryoShot				31	**0.15**
Australia	2012	100%	10	10	0.05
USA	2016	70%	30	21	0.10
Kvax cancer vaccine	2016	50%	30	15	**0.07**
Total				206	**0.96**

Assumptions

To calculate the value of the Company, we estimated market size for each indication, expected market share of each drug, average medication cost, and life cycle of all drugs. Probability of approval is also considered to incorporate the chances of failure while calculating the NPV of the drug. Cost of capital and terminal growth rate assumptions: For valuation purposes, we estimated the cost of capital at 10%. We have calculated the cost of capital as the weighted average of cost of equity and debt. To derive the cost of equity, we assumed a 14.9% equity risk premium and a 1.5% risk-free rate (10-year T-bond yield). A beta of 1.0 was assigned to Regeneus; we believe this adequately reflects the risks associated with the Company. We used a 1.5% growth rate to arrive at the terminal value in the DCF.

We also use different probabilities of success dependent on the development stage. Next to that, we use specific probabilities of success per clinical phase. This is also dependent on the historical success ratios for the various indications. The table below gives an overview of the probabilities uses. We use probability estimates that a specific drug successfully concludes a phase. When we multiply the probability for each phase to move to a next phase, the probability of a market launch is calculated.

Glossary

Adult (or somatic) stem cell:	**An undifferentiated cell found in a differentiated tissue that can renew itself and differentiate (with certain limitations) to give rise to all the specialized cell types of the tissue from which it originated**
Allogeneic	**Taken from different individuals of the same species**
Autologous	**Donor and recipient are the same person**
Bone marrow stromal cells	**A mixed population of stem cells found in bone marrow that does not give rise to blood cells but instead generates bone, cartilage, fat, and fibrous connective tissue**
Cell-based therapies	**Treatment in which stem cells are induced to differentiate into the specific cell type required to repair damaged or destroyed cells or tissues**
Chondrocyte:	**Chondrocytes are cells derived from mesenchymal stem cells, are found in cartilage and are the cells responsible for producing the cartilaginous matrix.**
Differentiation	**The process whereby an undifferentiated embryonic cell acquires the features of a specialized cell such as a heart, liver, or muscle cell**
Directed differentiation	**Manipulating stem cell culture conditions to induce differentiation into a particular cell type**
FDA:	**Food and Drug Administration based in Rockville, Maryland, US, responsible for the drug approval process in the US.**
In vitro:	**In glass or plastic vessels rather than in living systems.**

In vivo:	**In living systems.**
Mesenchymal stem cells (MSCs):	**Cells which are derived from embryonic mesoderm that go onto form connective tissue in the body. Mesenchymal stem cells are self renewing and have the ability to become chondrocytes (cartilage cells), osteoblasts (bone cells) adipocytes (fat cells) and fibroblasts (connective tissue cells). in tissue culture.**
Multipotent:	**Ability of a single stem cell to develop into more than one cell type of the body**
Neurons:	**Nerve cells, the structural and functional unit of the nervous system. A neuron consists of a cell body and its processes, an axon and one or more dendrites. Neurons function by starting and conducting impulses. Neurons transmit impulses to other neurons or cells by releasing neurotransmitters at synapses.**
Phase I clinical trial:	**Clinical trial to test a new biomedical intervention in a small group of people for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).**
Phase II clinical trial:	**Clinical trial to study a new biomedical intervention in a larger group of people to determine efficacy and to further evaluate its safety.**
Pre-Clinical Trial:	**Laboratory test of a new drug candidate or a new invasive medical device on animals or cell cultures that is conducted to gather evidence justifying a clinical trial.**
Plasticity:	**The ability of stem cells from one adult tissue to generate the differentiated cell types of another tissue.**
Pluripotent:	**Ability of a single stem cell to give rise to all of the various cell types that make up the body. Pluripotent cells cannot make so-called "extra-embryonic" tissues such as the amnion,**

	chorion, and other components of the placenta.
Regenerative medicine:	**A treatment in which stem cells are induced to differentiate into the specific cell type required to repair damaged or destroyed cell populations or tissues.**
Somatic cell:	**Any body cell other than gametes (egg or sperm).**
Stem cells :	**Cells with the ability to divide for indefinite periods in culture and to give rise to specialized cells.**
Stromal cells:	**Non-blood cells derived from blood organs, such as bone marrow or fetal liver, which are capable of supporting growth of blood cells in vitro. Stromal cells that make the matrix within the bone marrow are also derived from mesenchymal stem cells.**
Transdifferentiation:	**The process by which stem cells from one tissue differentiate into cells of another tissue.**
Undifferentiated:	**A cell that has not yet generated structures or manufactured proteins characteristic of a specialized cell type**

Analyst: Marcel Wijma MSc
Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.

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