

# OZEQUITIES NEWSLETTER

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## **FEATURE**

### **Week's Special**

**RGS: PRESTIGIOUS MANAGEMENT, PRODUCTS INCLUDE ADIPOSE TISSUE GENERATED STEM CELL TREATMENT FOR ARTHRITIS IN DOGS AND HORSES BOTH AUTOLOGOUS AND ALLOGENEIC AS WELL AS FOR AGEING HUMANS + REVOLUTIONARY STEM CELL ENHANCED AUTOLOGOUS CANCER TREATMENT, OTHERS IN R&D PIPELINE**

**By Jenny Prabhu and Gerald Stanley**

Regeneus Ltd, founded in 2007 by veterans of the biotech industry, listed on September 19, with a current portfolio of stem cell treatments for horses and dogs, where field trials have achieved remarkable success.

Regeneus joins MLA (via its MediVet takeover) on the boards, offering mesenchymal stem cell treatments for horses and dogs for the treatment of osteoarthritis and other conditions, using both autologous (patient's own cells) and allogeneic (donor cells or "off the shelf" product- Regeneus is trialing its CryoShot an allogeneic (donor cells) "off the shelf" product for canine and equine musculoskeletal conditions).

Regeneus also offers autologous fast turnaround treatment for humans afflicted with arthritis.

### *Early mover advantage in a large market for Veterinary treatment of arthritis*

Stem cell treatment for arthritis in animals is likely to become the treatment of choice in the future, since all current treatments have very limited success in treating the pain and crippling of animals with osteoarthritis (Regeneus also has FDA approval to begin a clinical trial, to be conducted by the University of Pennsylvania, for CryoShot in dogs to commence early next year). So far field trials have been conducted by around 70 Veterinary practices in Australia with considerable success.

While the internet carries several advertisements for stem cell treatment by various companies offered for dogs and horses, the market is vast - eg: On August 27 profitable and expanding Veterinary practice clinic chain Greencross Ltd reported it present, with 97 veterinary businesses it has only 3.5% of the Australian market with some 2,700 Australia wide vet clinics currently- not to speak of global expansion - and stem cell treatment could well become routine for valuable animals and family pets.

### *Ageing human populations a "gold mine" for stemcell treatment vs surgery*

With arthritis of hips and knees a fairly universal problem for ageing humans and with surgery only partially effective and needing long periods of rehab, the stem cell opportunity will be seized on with alacrity.

Regeneus already has an autologous (patients' own cells from adipose tissue) treatment for arthritis, HiQCell, that offers a comparatively fast turnaround - from extraction of a small amount of tissue via mini liposuction to tissue culture in the laboratory while the patient waits, to injection into the affected joints - all within a couple of hours.

A tie-up with listed company Cryosite also enables adults to store their cells (harvested comparatively painlessly via mini liposuction from adipose tissue) for possible use later.

Regeneus has one granted patent, and expects to have a number of granted patents within the next 4/5 years.

In the R&D pipeline there is also a stem cell enhanced treatment for cancerous tumours already trialled with success on dogs.

An anti inflammatory serum in the R&D pipeline has been successfully trialled on dogs, and is being developed to include treatment of conditions such as acne.

The company is led by prestigious directors and management and has a strong partnership with Macquarie University (Executive Chairman John Martin, and CEO Prof Graham Vesey were co-founders and Directors of biotech spin outs from Macquarie University, BTF - a world first precise microbiology testing product- later sold to French pharma bioMerieux). Regeneus retains its ties with the Macquarie facilities.

The float money is expected to be sufficient for the next two years, revenue is rising, and the company could be cash flow positive by year 3 after the float.

### REGENEUS LTD - A SNAPSHOT

Regeneus Ltd listed on September 19, closing at 27c on volume of 1,381,288 shares after raising \$10.5 million via the issue of 42 million shares at 25c a share for around 135.798 million shares on issue.

Regeneus has developed an allogeneic (donor cell) "off the shelf" product for canine and equine musculoskeletal conditions (**CryoShot**) from adipose tissue. Regeneus has found adipose tissue to be a good source of regenerative cells with a much higher concentration of mesenchymal cells than in bone marrow - and easy to harvest via mini liposuction.

Significant quantities of CryoShot can be produced from a small amount of adipose tissue derived from a donor animal. Donor tissue is processed and cultured to isolate and increase the regenerative cells before being cryogenically frozen and stored in liquid nitrogen. It is delivered to veterinary clinics in cryogenically frozen form and is stored at the clinic and thawed prior to injection.

CryoShot was introduced in FY2012 on a pre-registration commercial basis and is currently being trialled through selected veterinary clinics in Australia. Early results in dogs on the usage of CryoShot have been positive with reduction in pain and improvement in mobility within 10 days of treatment with no need for further surgery or ongoing medication.

There is a potentially large global opportunity for a veterinary product for use in musculoskeletal and pain management. The potential uses of CryoShot extends to pain management, as an anti-inflammatory and as an adjunct to existing surgical treatments such as arthroscopy.

In Australia, CryoShot is distributed as a pre-registration veterinary product for trialling purposes under an AVPMA permit. Regeneus intends to register the product for broader market penetration and has initiated discussion with regulators in Australia, Europe and the US. There is currently no cell-based product that is registered globally in the veterinary market.

Early results for CryoShot have been very positive with demonstration of similar treatment outcomes to an AdiCell treatment.

Owners responding in 42 questionnaires have noticed dramatic effects on the reduction of pain in their animals. Most of the effect happens within the first ten days, but improvement continues past the two month mark.

The greatest effects are in the group that has cultured cells injections plus *concentrated secretions* application. This is the area where the company believes it has a strong patent position.

*The human population of arthritis sufferers - development of an off the shelf product*

In the Company's experience, the veterinary market is a good proxy for the human market and the experience of transitioning from a point-of-care to an off the shelf product has provided Regeneus with the opportunity to refine production and logistics of delivering an off the shelf product for human treatment.

*R&D pipeline*

\*The R&D pipeline includes the key initiative for the use of its CryoShot platform to develop a human off the shelf product for musculoskeletal and other inflammatory conditions.

*HiQCell for humans*

Regeneus has also successfully developed and commercialised through its network of medical specialists an autologous (patient's own cells) "point of care" cell therapy to treat musculoskeletal conditions in humans (**HiQCell**) - with arthritis no less a scourge for the growing global population of ageing humans. It is a unique and relatively simple same-day treatment that involves injecting a mixture of regenerative cells (including MSCs) into affected joints and/or tendons. It has both an anti-inflammatory and immune regulatory function, which reduces pain and creates an environment in which tissues can be repaired. It is targeted for use in the treatment of osteoarthritis and tendinopathy.

*Cell Secretions based products*

The company is also developing a **cell secretions based product** for the treatment of skin inflammatory conditions like acne.

\*Secretions are molecules (includes cytokines and growth factors) that are secreted by regenerative cells. Regeneus has developed technology and protocols for the production of secretions from adipose tissue.

Recent studies indicate that the therapeutic value of MSCs is largely due to these secretions. Company research indicates that when secretions are applied to skin, it has a localised anti-inflammatory effect, accelerates wound healing and reduces scarring.

\*Regeneus is developing a cream that contains secretions for topical treatment of a variety of skin conditions including acne.

*Development of an Oncology Vaccine product (KollVax)*

In early 2013 Regeneus announced a collaboration with the Kolling Institute of Medical Research on a cancer vaccine. The vaccine involves removal of the tumor or a biopsy to produce a personalised vaccine. It is believed that the vaccine stimulates the body's immune system to see the cancer cells as foreign, and helps prevent further growth of the tumour as well as development of new tumours. Preliminary findings show that Regeneus prepared regenerative cells have a positive impact on the effect of the cancer vaccine. A safety trial involving over 30 dogs with a variety of cancer types was also conducted. No adverse effects or safety issues occurred and in many cases the vaccine appeared to extend the lifetime of the dog beyond the expected survival time.

The autologous vaccine is a platform technology and it may be possible to use this autologous vaccine for any number of different tumour types. Regeneus holds the exclusive worldwide rights to commercialise this cancer vaccine in the animal health market and holds the first right of refusal for the human health market.

*Intellectual Property Portfolio*

Regeneus has filed 9 families of patent applications covering current products including HiQCell and CryoShot and a range of future products.

One of the earliest patent applications has been examined and was accepted by the Australian Patent Office in September 2009, it is currently under opposition from Norwood Immunology in Australia.

Regeneus has submitted an amendment to the claims in the patent application.

The corresponding patent has been granted in New Zealand.

**REGENEUS LTD FINANCIALS**

Last Traded price 28c.  
 Shares Issued 183.9m.  
 Market Cap 51.5m.  
 Year ended June 30, Values in \$m's

<b>INCOME</b>	<b>2013 Int</b>	<b>2012</b>	<b>2011</b>
Op Revenue	0.87	1.19	0.78
Op Profit (loss)	(3.60)	(3.26)	(1.72)
Net profit (loss)	(3.60)	(3.26)	(1.72)

<b>BALANCE SHEET</b>	Proforma <b>Dec. 2012</b>
Current Assets	14.69
Non Current Assets..	0.64
Current Liabilities	1.03
Non Current Liabilities	-
Net Assets & Shareholders' Funds	14.30
Intangibles	0.05
Net Tangible Assets	14.25
Gearing (Net of Cash) %	.nil
NTA per share (cents)	7.8
Shares Issued (m's)	183.9

**Board of Directors**

**John Martin**, Executive Chairman, has served on the Board of the Company since early 2009 and has worked closely with the founders to develop and grow the business since that time. He was appointed Chairman in 2010. John has over 20 years of corporate and commercial experience including roles as CEO and director of ASX listed and private companies and executive and corporate partner of Allens. He has advised and worked with emerging technology and high growth companies for over 12 years including being a co-founder and Director of biotech spin outs from Macquarie University, BTF and Proteome Systems. He is currently a principal of The Channel Group, chairman of Ai-Media and director of Eagle Eye Solutions (Asia Pacific).

**Professor Graham Vesev**, CEO, is a co-founder and founding CEO of Regeneus and has served on the Board since incorporation. Graham is a successful biotechnology entrepreneur, technology innovator and inventor on various patents in the biotechnology area and a highly regarded scientist. He has been the primary driver of the Company's R&D programs, product innovation and development and IP portfolio. Prior to co-founding Regeneus, Graham was a co-founder and executive Director of BTF, a highly successful Sydney-based biotechnology company and was responsible for developing BTF's product and patent portfolios. In 2007, BTF was acquired by bioMerieux, a French multinational diagnostic company. Graham is an Adjunct Professor at Macquarie University.

**Associate Professor Ben Herbert**, non exec director is a co-founder and founding Director of the Company and has served on the Board since incorporation. Ben is a Vice-Chancellor Innovation Fellow and Director of Regenerative Science at Macquarie University where he leads a stem cell research group that collaborates on R&D projects with the Company. He is a regular presenter at conferences and in the media on regenerative medicine and stem cell technologies. Ben was previously a Director of the Proteomics Technology Centre of Expertise at the University of Technology, Sydney, co-founder of Proteome Systems and a key member of the team that set up Australia's first proteomics facility, Australian Proteome Analysis Facility at Macquarie University in 1995.

**Dr Roger Aston**, non exec director, is one of the most experienced and commercially astute people in drug commercialisation in Australia. Roger brings more than 20 years experience in the pharmaceutical and healthcare industries in senior roles in the United Kingdom, Asia- Pacific and Australia.

Roger has held executive, non-executive Director or chairman positions on a number of boards including Peptech Limited (Arana), Cambridge Antibody Technology Limited, Clinuvel Limited, Halcygen Limited, Cambridge Drug Discovery, and pSivida Limited.

He started his career at major pharmaceutical company Wellcome (now Glaxo Smith Kline) and has also worked for QinetiQ Limited. Roger also served on the federal government's IRD board sub-committee for biologicals. Roger was formerly CEO of Mayne Pharma Group Limited and currently is a Director and CEO of Pitney Pharmaceuticals Pty Ltd, Chairman of BioLife Limited, Chairman of Immuron Limited, Director of IDT Limited, Chairman of Cynata Limited and Chairman elect of NeuroDiscovery Limited.

**Barry Sechos**, non exec director, has served as an alternate Director since 2011 and became a full Director in June 2012. He has over 25 years experience as a director, business executive and corporate lawyer. Barry is a Director of the Sherman Group (a strategic investor in the Company), a privately owned investment company. Barry is also a Director of See-Saw Films a film production and finance group and winner of the 2011 Academy Award for Best Picture, Transmission Films a film distribution company, Direct Cash Payments Inc. an ATM deployment company listed on the Toronto Stock Exchange and Sherman Contemporary Art Foundation a charitable cultural organization. He previously held various positions with the Aberdeen Asset Management / EquitiLink Funds Management Group including Director of Aberdeen Asset Management, General Counsel and Compliance Officer to EquitiLink Group and EquitiLink International Management. Barry commenced his professional career as a commercial lawyer at Allen Allen & Hemsley in Sydney, Singapore and London.

#### **Senior Management**

The company has a highly experienced senior management team, some of whom have been involved with the business since inception:

**John Martin** – Executive Chairman

**Prof Graham Vesey** – CEO

**Murray McInnes**, Chief Financial Officer and responsible for all of the financial aspects of the group including budgeting, financial and strategic analysis, reporting and monitoring financial performance. Murray has over 25 years of financial management experience. He began his career in the finance industry before establishing his own consultancy in Australia. Murray has focused his business on SME start up, high growth companies across a diverse range of industries including pharmaceuticals, wine, legal, software, tourism, FMG, retail and franchising and manufacturing. Murray's more recent engagements have included CFO of Smarts Group Pty - sold to NASDAQ in 2011, advisor to Endeavour Shipbrokers (Australia's largest privately owned brokerage) on its sale to the UK listed ACM and CFO of Centaman Systems Pty Ltd - sold to Jonas Software, Canada.

**Steven Barbera**, Commercial Development Director at Regeneus, responsible for the business and service offering of HiQCell in Australia. In this capacity he brings perspective in integrating the scientific knowledge of the Company within the commercial healthcare environment. Steven has extensive general management and Board Director experience in consumer product and service related national and global businesses, at various stages of their development from start-ups through to sophisticated multi-category offerings, notably in the beverages and apparel industries. He has completed studies in Business and Marketing and holds an MBA from Simon Business School at University of Rochester (USA).

**Dr Richard Lilischkis**, Clinical Development Director - Human Health where he is responsible for the clinical development of the Company's point-of-care cell therapy (HiQCell) and new indications. Richard is also responsible for the international expansion of the Company's human treatments. He is a former Associate Professor of cell biology in Germany and biotechnology entrepreneur with a track record of bringing new biological products to market. After founding and profitably running Multiblock GmbH, a German-based pathology diagnostics company, he moved to Australia and joined Prof Graham Vesey at BTF. Richard built BTF's European business from scratch, generating trust in and reputation of BTF's

products amongst many major multinational pharmaceutical companies, resulting in substantial sales growth in Europe and internationally.

**Duncan Thomson**, is the Head of the Veterinary Health business unit where he is responsible for the development and commercialisation of the Company's point-of-care (AdiCell) and off-the-shelf (CryoShot) cell therapy products. He is a trained veterinarian with extensive practical experience in Australia and the UK. Upon completion of his MBA he worked for Novartis Animal Health in Switzerland, the US and Australia in senior strategic marketing and sales roles. Duncan has in previous roles, built sales and marketing teams in the US and Australia and achieved strong sales growth for a variety of newly launched and established vet products.

**Dr Charlotte Morgan** is Head of Laboratory, R&D. Charlotte is responsible for the research and development of new products, in conjunction with CryoShot production within the laboratory of the Company. Charlotte has extensive experience as a research scientist and the management of research teams to develop IP and convert conceptual products through to finished products for global distribution. After working with Thames Water's research laboratory in the UK, Charlotte moved to Australia and joined Prof Graham Vesey at BTF where Charlotte led the R&D team that developed the highly successful BioBall product range.

**Sandra McIntosh** is the Office/HR Manager and the Company Secretary. Sandra has been with the company since 2009. Sandra has 20 years management experience in HR, Customer Service and Finance. Sandra previously worked with Prof Graham Vesey at BTF. Sandra is currently studying a Graduate Diploma of Applied Corporate Governance with Chartered Secretaries Australia.

**Major shareholders:**

Prof Vesey with 7.8%