

## Commercialisation of novel therapies

Regeneus Ltd is a clinical-stage regenerative medicine company. For the past twelve months the company has focused on commercialisation of its stem-cell related therapy – Progenza – culminating with an agreement in August 2020 with Kyocera Corp. of Japan for exclusive rights to commercialise RGS' cell preparation technology as a regenerative product for treating patients with knee osteoarthritis. Kyocera will pay RGS \$13m up-front with a further \$14m in milestone payments in addition to a royalty stream from future Progenza sales. RGS aims to develop a portfolio of novel (Stem) cell-based therapies focused on the areas of neuropathic pain including osteoarthritis and various skin conditions. The company holds patents in Europe, the US, Japan and Australia for its Sygenus skin treatment which targets adipose-derived cell secretions including age-spots and wrinkles. RGS raised \$5.5m in a rights issue and placement in November 2019 to support the commercial licence discussion for Progenza. Following the Kyocera deal RGS has sufficient cash to fund operations until the commercial launch of Progenza OA in Japan.

### Business model

RGS expects to generate revenues from R&D grants, product licencing, development milestones, and other royalty streams from commercialisation of Progenza and potentially Sygenus. RGS continues to develop regenerative novel cell-based therapies aimed at the treatment of inflammatory pain and skin afflictions. Kyocera will work toward global commercialisation of Progenza through a Phase II trial with payments to RGS as regulatory and development milestones are passed. RGS expect this cashflow to be sufficient to support RGS operations until commercialisation of Progenza OA (Progenza for knee osteoarthritis) in Japan.

### Recent company commentary

In August 2020, Regeneus announced it had signed a licence and collaboration agreement with Japan's Kyocera Corp which allows Kyocera to exclusively develop and commercialise Progenza for the treatment of knee osteoarthritis in Japan. Regeneus will receive approximately \$27m (US\$19m) in upfront, development and regulatory milestones consisting of \$13m in upfront and execution payments, data package delivery and establishing Standard Operating Procedures, of which \$1.6m was received in March and reported in the FY20 financial year. An additional \$1.3m is due this quarter and the balance (\$11.1m) in the FY21 year. Another \$14m will become payable in regulatory and development milestones. Longer term, Regeneus and Kyocera have agreed to a high single digit/double-digit royalty regime for all future Progenza osteoarthritis sales in Japan. The company has noted that Japan's osteoarthritis market is forecast to grow to US\$350m by 2026. The company has also announced that the US Patent and Trademark office had in August allowed a new patent for Sygenus.

### Stage I moving to Stage II, Stage III = the World?

RGS and its peers are in similar stages of commercialisation, highlighting the relative youth and small scale of the Biotechnology sector in Australia. Few companies in the sector are cashflow positive. The path to success is generally to prove a product to a stage where a larger company can fund the next level of development at a lower risk of failure. RGS has successfully moved to stage two of this process.

#### Historical earnings and ratios

Year end	Revenue (A\$m)	EBITDA (A\$m)	NPAT Rep. (A\$m)	EPS Rep. (c)	EV/Sales (x)	EV/EBITDA (x)	P/E (x)
06/17a	10.0	3.7	3.3	1.53	2.0	5.4	9.5
06/18a	0.6	(5.1)	(5.2)	(2.42)	42.0	n.a.	n.a.
06/19a	0.0	(5.4)	(6.0)	(2.88)	n.m	n.a.	n.a.
06//20a	1.7	(0.8)	(1.1)	(0.38)	11.2	n.a.	n.a.

Source: Company data

## Biotechnology

4 September 2020

### Share details

ASX Code	RGS
Share price (3-Sep)	\$0.185
Market Capitalisation	\$51.4M
Shares on issue	277.8M
Net cash at 30/06/2020	\$0.9M
Free float	62%

### Share performance (12 months)



### Upside Case

- Successful Stage II trials of Progenza OA
- Commercial manufacture of Progenza OA
- Global distribution of Progenza

### Downside Case

- Stage II trial unsuccessful
- Sygenus not commercialised
- Small development pipeline

### Catalysts/upcoming events

AGM 14<sup>TH</sup> October 2020

Finalising development/regulatory milestones for Progenza to receive full payment from Kyocera

### Comparable companies (Aust/NZ)

Neuren Pharma (ASX:NEU), Opthea (ASX:OPT), Paradigm BioPh (ASX:PAR), PYC Therapeutics (ASX:PYC)

### Top 5 shareholders

Graham Vesey	5.72%
Leo Lee	4.86%
Barry Sechos	2.77%
Thomas Mechtshheimer	2.21%
SMC Capital Pty Ltd	1.88%

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# FINANCIAL SERVICES GUIDE

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**of**

**BR SECURITIES AUSTRALIA PTY LTD**

**ABN 92 168 734 530**

**AFSL 456663**

**Effective Date: 26<sup>th</sup> November 2018**

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- our services
- how we transact with you
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- complaint processes

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