

Regeneus

Several interested parties in Japan

Regeneus has revised expected timing of an osteoarthritis (OA) clinical development licence deal for Progenza in Japan to Q4 CY18 (vs Q218); it is currently in active discussions with several parties. A licence deal would trigger a US\$5m milestone payment from partner AGC and would effectively see Progenza commence a Phase II trial in knee OA in Japan. Regeneus is in separate discussions with potential licensees for other indications and territories for Progenza, as well as for its other pipeline products. We roll forward our rNPV model to FY19, which lifts our valuation to A\$181m (vs A\$170m) or A\$0.87/share. Depending on the terms, we estimate an OA licence deal could add up to ~A\$50m to our valuation.

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (A\$)	DPS (A\$)	P/E (x)	Yield (%)
06/17	10.0	3.3	0.02	0.0	N/A	N/A
06/18	0.6	(5.2)	(0.02)	0.0	N/A	N/A
06/19e	7.8	2.2	0.01	0.0	N/A	N/A
06/20e	1.6	(4.2)	(0.02)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding exceptionals and share-based payments.

Protracted negotiations preceded AGC deal in Japan

Regeneus is no stranger to protracted negotiations with Japanese companies. It successfully concluded a manufacturing licence agreement and JV with AGC in Japan in December 2016, after commencing partnering discussions the previous year, making it only the 17th Australian company to secure a significant technology licence in Japan in the past 20 years. It is well placed to achieve an OA licence deal in Japan, with a granted patent and manufacturing partner (AGC) in place, and promising signs of efficacy in the successful Phase I trial of Progenza in knee OA.

High regenerative medicine deal values in Japan

Japan has seen several high-value regenerative medicine deals. The most relevant is the January 2015 licence deal between Kolon Life Science and Mitsubishi Tanabe Pharma for the Japanese rights to a cell and gene therapy for knee OA, for US\$24m upfront, US\$410m in milestones and a double-digit royalty. In June Athersys expanded its Japan-focused stem cell therapy agreement with Healios that began in 2016, taking total upfronts to US\$35m and milestones to ~US\$360m.

Partnering other indications/territories/products

While the main partnering focus is Progenza for OA in Japan, Regeneus is also seeking to partner Progenza for additional territories and indications (including nerve pain); Progenza patents granted or allowed in the US, Australia, Japan and New Zealand will aid these partnering initiatives. It is also seeking partners for Sygenus for inflammatory skin conditions and for its RGS4K cancer vaccine.

Valuation: Increased to A\$181m, A\$0.87 per share

We roll forward our model and lift our valuation to A\$181m (vs A\$170m), or A\$0.87 per share (vs A\$0.82/share). A deal comparable to the Kolon/Mitsubishi deal (with half of milestone payments for development and regulatory hurdles) would increase our valuation to ~A\$231m or A\$1.06/share. An A\$1.9m loan and \$2.2m R&D rebate will provide funds to end CY18 (quarterly cash burn A\$1.7m). If the OA licence deal is delayed beyond Q4 CY18, additional funding will be needed.

Japan deal near term

Pharma & biotech

4 September 2018

Price **A\$0.18**

Market cap **A\$38m**

US\$0.75/A\$

Net cash (A\$m) at 30 June 2018 0.1

Shares in issue 208.9m

Free float 87%

Code RGS

Primary exchange ASX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (15) 41.7 41.7

Rel (local) (16.2) 34.8 27.7

52-week high/low A\$0.2 A\$0.1

Business description

Regeneus is an Australia-based, clinical-stage regenerative medicine company developing innovative cell-based therapies for the human and animal health markets. It is focused on osteoarthritis and other musculoskeletal disorders, oncology and dermatology diseases.

Next events

JV sublicenses clinical development partner in Japan Q4 CY18

Progress Progenza licencing discussions for additional indications and territories TBA

Progress Sygenus licencing discussions TBA

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Exhibit 1: Financial summary

	A\$'000s	2016	2017	2018	2019e	2020e
Year end 30 June		AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS						
Sales, royalties, milestones						
Revenue		1,735	9,994	575	7,784	1,632
Cost of Sales		(292)	(55)	0	(17)	(15)
Gross Profit		1,444	9,939	575	7,767	1,617
R&D expenses		(4,309)	(4,456)	(3,957)	(3,957)	(4,115)
SG&A expenses		(3,578)	(3,570)	(3,937)	(3,774)	(3,948)
R&D tax incentive		2,732	2,608	2,165	2,176	2,263
EBITDA		(3,360)	4,856	(4,806)	2,340	(4,047)
Operating Profit (before GW and except.)		(3,696)	4,527	(5,150)	2,214	(4,182)
Intangible Amortisation		(15)	(5)	(4)	(1)	(0)
Exceptionals		0	0	0	0	0
Other		15	(1,309)	(40)	0	0
Operating Profit		(3,696)	3,212	(5,194)	2,213	(4,183)
Net Interest		122	58	9	(26)	(26)
Profit Before Tax (norm)		(3,559)	3,276	(5,180)	2,189	(4,208)
Profit Before Tax (IFRS)		(3,574)	3,271	(5,185)	2,187	(4,208)
Tax benefit		0	0	0	0	0
Profit After Tax (norm)		(3,559)	3,276	(5,180)	2,189	(4,208)
Profit After Tax (IFRS)		(3,574)	3,271	(5,185)	2,187	(4,208)
Average Number of Shares Outstanding (m)		208.9	208.9	208.9	209.9	210.9
EPS - normalised (A\$)		(0.02)	0.02	(0.02)	0.01	(0.02)
EPS - IFRS (A\$)		(0.02)	0.02	(0.02)	0.01	(0.02)
Dividend per share (A\$)		0.00	0.00	0.00	0.00	0.00
BALANCE SHEET						
Fixed Assets		2,432	904	670	722	737
Intangible Assets		11	6	2	20	40
Tangible Assets		802	610	417	451	446
Investments		1,619	288	251	251	251
Current Assets		3,503	8,261	4,313	6,448	2,224
Stocks		30	22	15	8	7
Debtors		22	88	0	0	0
Cash		529	4,135	1,092	3,223	(1,088)
Other		2,922	4,016	3,206	3,218	3,305
Current Liabilities		(1,006)	(876)	(1,819)	(1,819)	(1,819)
Creditors		(906)	(743)	(707)	(707)	(707)
Short term borrowings		0	0	(1,000)	(1,000)	(1,000)
Other		(99)	(133)	(111)	(111)	(111)
Long Term Liabilities		(144)	(189)	(243)	(243)	(243)
Long term borrowings		0	0	0	0	0
Other long term liabilities		(144)	(189)	(243)	(243)	(243)
Net Assets		4,785	8,100	2,922	5,109	900
CASH FLOW						
Operating Cash Flow		(2,254)	3,588	(4,247)	2,310	(4,159)
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(250)	(150)	(151)	(178)	(151)
Acquisitions/disposals		19	(78)	0	0	0
Financing		0	0	0	0	0
Dividends		0	0	0	0	0
Other		0	247	354	0	0
Net Cash Flow		(2,485)	3,607	(4,044)	2,131	(4,310)
Opening net debt/(cash)		(3,013)	(529)	(4,135)	(92)	(2,223)
HP finance leases initiated		0	0	0	0	0
Other		0	(0)	(0)	0	0
Closing net debt/(cash)		(529)	(4,135)	(92)	(2,223)	2,088

Source: Regeneus accounts, Edison Investment Research

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