EDISON

Regeneus

Clinical and IP update

Positive STEP data and Japan patent grant

Pharma & biotech

Regeneus announced that its Phase I STEP knee osteoarthritis (OA) trial met its primary safety endpoint at 12 months and produced promising signs of efficacy, including clinically meaningful reductions in pain for the majority of patients and improvement in knee cartilage volume. Separately, it has also been granted a key patent that protects Progenza in Japan until 2032. The positive data and patent grant will be helpful as the company seeks to advance licensing discussions for Progenza for OA and other indications in Japan (in conjunction with JV partner AGC). We increase our valuation to A$145m or A$0.70/share.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/15	1.9	(6.6)	(0.03)	0.00	N/A	N/A
06/16	1.7	(3.6)	(0.02)	0.00	N/A	N/A
06/17e	10.2	4.6	0.02	0.00	N/A	N/A
06/18e	8.4	1.9	0.01	0.00	N/A	N/A

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

Primary safety endpoint met, evidence of efficacy

The Phase I Progenza safety trial met its primary endpoint, with a single injection of 3.9m or 6.7m cells into the knee joint shown to be safe and well tolerated, with no serious adverse events observed. The Principal Investigator, Dr Donald Kuah, commented that the majority of Progenza-treated patients experienced clinically meaningful reductions in pain, whereas the same pain reduction was not seen in the placebo group. In addition, there was significant improvement in lateral tibial knee cartilage volume in patients treated with 3.9m cells, compared to a worsening in the placebo group. We understand that detailed analysis of exploratory efficacy endpoints will be presented in a future scientific publication.

Patent protection to 2032 in Japan

Regeneus has been granted a patent covering the composition, manufacture and use of the company's allogeneic Progenza stem cell technology in Japan. The patent will provide IP protection in Japan through to 2032.

Patent and trial results should help partnering

The positive safety data, early indications of efficacy and granted patent should all aid the Regeneus Japan JV as it negotiates with potential partners to progress the clinical development of Progenza for OA and other indications in Japan.

Valuation: Lifted to A$145m, A$0.70 per share

We increase our valuation to A$145m (vs A$120m) or A$0.70/share (vs A$0.57/share) following the successful completion of the Phase I trial and grant of additional IP protection in Japan. The A$4.9m cash at 31 March 2017, combined with A$1.2m of loans to shareholders that mature in July 2017 and estimated A$2.5m R&D tax incentive payment receivable in H1 FY18 would fund operations to end Q3 FY18 at the current burn rate of A$2.1m/quarter. The company expects additional licencing and milestone payments to extend the funding runway beyond the end of FY18 (we model US$6m of AGC milestones earned by end FY18).

31 May 2017

Price	**A$0.13**
Market cap	**A$27m**
	US$0.75/A$
Net cash (A$m) at 31 March 2017	4.9
Shares in issue	208.9m
Free float	67%
Code	RGS
Primary exchange	ASX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(10.7)	(13.8)	(24.2)
Rel (local)	(7.7)	(13.7)	(28.0)
52-week high/low	A$0.19		A$0.11

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

First AGC milestone payments	Q2 CY17
Commence process development for Progenza manufacture in Japan	Q2 CY17
JV sublicenses clinical development partner in Japan	TBA

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Edison profile page

Safe with signs of efficacy – further detail to be published later

The Phase I STEP (Safety, Tolerability and Efficacy of Progenza) placebo-controlled trial randomised 20 patients to receive either 3.9m or 6.7m Progenza cells or placebo via a single injection into the knee. Eight patients were treated with each dose of Progenza and four received placebo injections. Twelve months of follow-up showed that Progenza was both safe and well tolerated. There were no serious adverse events and the incidence and nature of adverse events were similar in the Progenza and placebo groups.

While safety and tolerability was the primary outcome of the trial, patients were also monitored to assess the effect of Progenza on knee pain and function, quality of life, knee structures as assessed by MRI, and osteoarthritis biomarkers.

The Principal Investigator on the STEP study, Dr Donald Kuah, commented that the majority of Progenza-treated patients experienced clinically meaningful reductions in pain, whereas the same pain reduction was not seen in the placebo group. The 16 Progenza-treated patients showed a statistically significant reduction in pain from baseline (measured on the WOMAC pain subscale, p<0.001), whereas for the smaller group of four patients treated with placebo there was no statistically significant reduction in pain (Exhibit 1). Regeneus commented that pain measured on the widely used visual analogue scale (VAS) revealed very similar findings, but no details were disclosed.

MRI examination showed that there was a significant improvement in lateral tibial knee cartilage volume in patients treated with the 3.9m cell dose of Progenza, compared with a worsening in the placebo group (p=0.028), as shown in Exhibit 2.

Exhibit 1: Change in WOMAC pain subscale scores from baseline

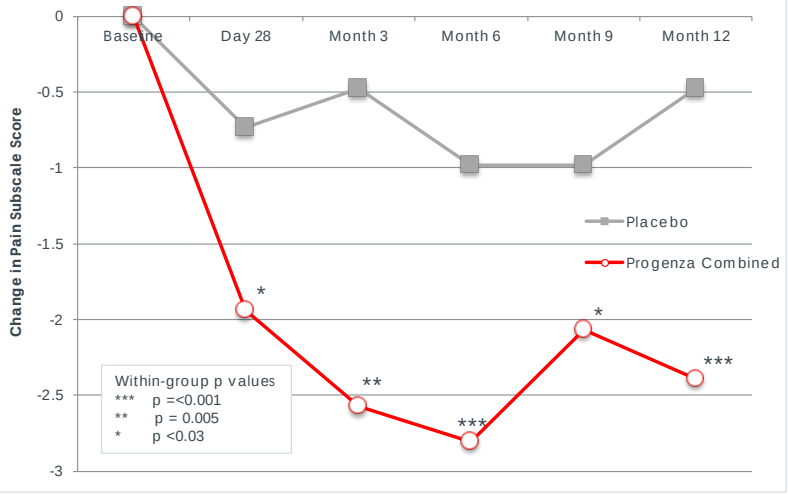
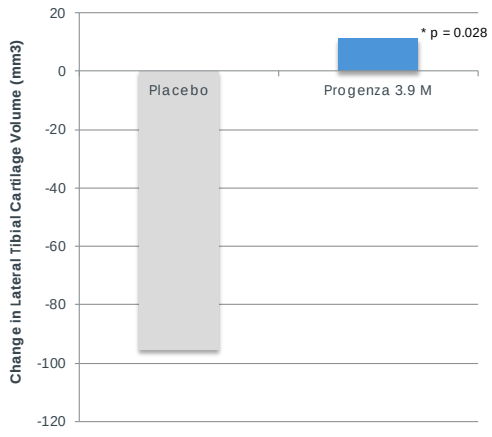


Exhibit 2: Change in lateral tibial cartilage volume at 12 months post treatment



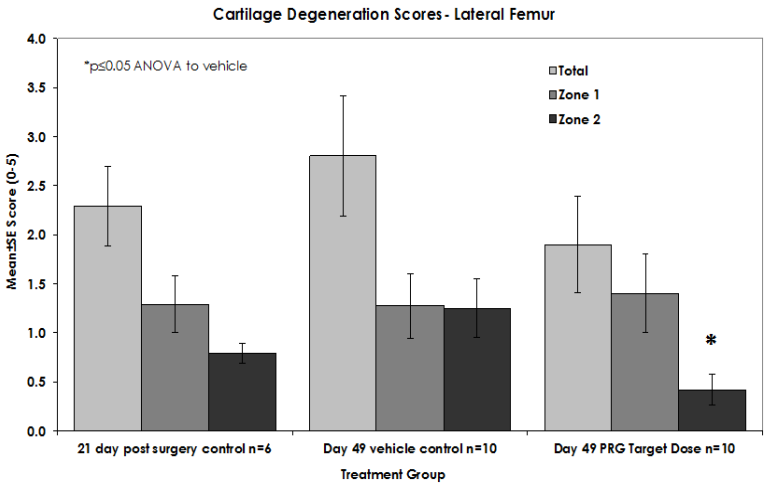
Source: Regeneus presentation to China BIO partnering forum, May 2017

We understand that detailed analysis of exploratory efficacy endpoints will be presented in a future scientific publication. The publication of these data in a peer-reviewed scientific publication will aid the assessment of the implications of the study for the probability of success in future clinical trials.

STEP outcome consistent with preclinical studies in knee OA

Regeneus highlighted that the reduction in cartilage degeneration seen in the STEP trial following Progenza treatment was consistent with results seen in a rabbit osteoarthritis model. In the rabbit model osteoarthritis was induced by partial meniscectomy (removal of knee cartilage), and the knees were injected with Progenza cells 21 days after the surgery. At day 49, four weeks after Progenza treatment, there was a significant reduction in cartilage degeneration scores in the middle load-bearing zone of the femur (zone 2) compared to the control group, as shown in Exhibit 3.

Exhibit 3: Progenza reduced Cartilage degeneration scores in rabbit knee OA model



Source: Regeneus presentation to China BIO partnering forum, May 2017. Note: PRG = Progenza

Patent protection and trial results should help partnering discussions

In December 2016 Regeneus entered a strategic collaboration and licensing agreement with AGC of Japan, granting AGC exclusive rights to manufacture Progenza in Japan and a 50% interest in Regeneus Japan, which holds the rights to develop and commercialise Progenza for OA and all other indications in Japan. Regeneus received US$5.5m upfront and is eligible for up to US$11m of development and approval milestone payments.

The Regeneus Japan JV is seeking clinical development partners to progress the development of Progenza for OA and other indications in Japan. Japan is a most attractive market for regenerative medicines because of laws that took effect in November 2014, which allow for expedited conditional approval of regenerative medicine products on the basis of safety and early evidence that is predictive of efficacy.

The positive safety data, early indications of efficacy and recently granted patent should all aid the Regeneus Japan JV as it negotiates with potential partners to progress the clinical development of Progenza for OA and other indications in Japan.

Progenza timeline on track

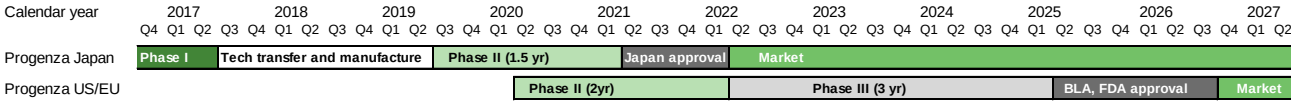
The successful completion of the STEP trial on schedule means that our forecast development timelines for Progenza are intact.

The next step in the clinical development of Progenza is likely to be a Phase II efficacy trial in Japan in patients with knee osteoarthritis; Regeneus' preference is for this trial to be conducted by a clinical development partner. Before this trial can commence the Progenza technology will need to be transferred to AGC, which will undertake GMP manufacture of Progenza for the trial. We assume that the technology transfer and validation of Progenza manufacture by AGC would be

completed in H1 CY19, enabling a Phase II trial in Japan to commence in Q3 CY19 and report results in Q1 CY21, allowing a potential market launch in early 2022.

We assume that a separate Phase IIb trial will be conducted outside Japan to support Phase III efficacy studies in the US and Europe, with the Phase IIb study commencing in 2020 leading to a potential market launch in 2026, as shown in Exhibit 4.

Exhibit 4: Edison's assumed Progenza development timeline



Source: Edison Investment Research

Upcoming catalysts in 2017

The ongoing discussions with potential clinical development partners for Progenza in Japan represent the most important potential catalysts in 2017. Securing a clinical partner for one or more indications would provide further validation of the commercial potential of Progenza, as well as providing additional non-dilutive funding.

Other anticipated milestones in 2017 include:

- Progress donor procurement and process development for manufacturing Progenza in Japan by AGC;
- Report on the ARC funded Progenza chronic pain study; and
- Complete preclinical trials for human secretions technology for inflammatory skin conditions.

Valuation

Our valuation of Regeneus has increased to A$145m (vs A$120m), or A$0.70/share (vs A$0.57/share). Following the successful completion of the Phase I STEP trial we have increased the likelihood of success for Progenza from 30% to 35% in Japan and from 15 to 20% in other markets. With the grant of patent in Japan we have extended market exclusivity for Progenza in Japan by one year to 2032.

With the end of FY17 approaching we have rolled forward the DCF model and are now using the end FY17e cash balance vs end FY16 cash balance previously. Our sum-of-the-parts DCF valuation model is summarised in Exhibit 5, with key assumptions shown in Exhibit 6.

Exhibit 5: Regeneus valuation model

Product	Setting	Region	Status	Launch	NPV (A$m)	Peak sales (A$m)	Probability of success	Economic interest	rNPV (A$m)	rNPV per share (A$)
Progenza	Human – OA	Japan	Phase II ready	2022	116.2	504	35%	Royalty (10%)	38.9	0.19
Progenza	Human – OA	Australia/ EU/US	Phase I complete	2026	298.9	1,558	20%	Royalty (20%)	54.2	0.26
Human cancer vaccine	Solid tumours	WW	Phase I	2024	94.9	500	15%	13% net royalties	13.8	0.07
CryoShot	Animal – OA	Australia	Pre-registration field trials	2012	15.5	7	30-100%	Operating profit (40-60%)	4.5	0.02
CryoShot	Animal – OA	EU	Pre-pivotal studies	2021	19.3	46	30%	Royalty (20%)	5.5	0.03
CryoShot	Animal – OA	US	Pre-pivotal studies	2021	25.7	55	30%	Royalty (20%)	7.4	0.04
Kvax canine vaccine	Dog cancer	WW	Marketing studies	2019	23.7	43	40%	Royalty (20%)	9.3	0.04
AGC milestones		Japan			10.2		30-90%		7.5	0.04
Portfolio total					604.4				141.2	0.68
End FY17e net cash (at 30 June 2017)									4.3	0.02
Overall valuation									145.5	0.70

Source: Edison Investment Research

Our valuation model applies a standard 12.5% discount rate and includes estimated net cash of A$4.3m at end June 2017. We assume that product sales reach peak market share six years after launch, grow in line with the market for the next four years (five years for Progenza in Japan) and then decline at 10% per year. For simplicity, we do not include upfront and milestone payments from any potential future licensing deals that have not yet been signed and instead assume that the full value of the product will be paid as a royalty. We note that there is a risk adjustment applied to each programme, appropriate to the status of development. Risk adjustments would unwind as programmes advance through clinical studies, gain regulatory approvals and secure commercial partners, etc.

Exhibit 6: Regeneus valuation assumptions

Product	Setting	Region	Status	Key assumptions
Progenza	Human – OA	Japan	Phase I	Prevalence ~18% of >55 yrs; 10% suitable candidates for treatment; 10% Progenza peak market share (2028; 6 yrs to peak); A$5,000 per procedure; 50:50 JV with AGC for Japan.
Progenza	Human – OA	Australia/EU/US	Phase I	Prevalence ~10% of >55 yrs in all regions; 10% suitable candidates for treatment; 10% PRG peak market share (2031; 6 yrs to peak); A$5,000 per procedure (A$3,750 in EU).
Human cancer vaccine	Solid tumours	WW	Phase I	A$500m peak sales indicative potential (non-cancer specific); 13% net royalty rate after 4-7% pay-away to Northern Sydney Local Health District (NSLHD).
CryoShot	Animal – OA	Australia	Pre-registration field trials	~4,500 small animal vet practitioners; 5% peak penetration in 2023, 75x per year, at A$250 per dose; sliding scale of probability (100% near-term to 30% post-2020).
CryoShot	Animal – OA	EU	Pre-pivotal studies	~90,000 small animal vet practitioners; peak penetration in 2026, with 3% use CryoShot, 50x per year, at A$250 per dose; 30% probability with studies/partners to complete.
CryoShot	Animal – OA	USA	Pre-pivotal studies	~50,000 small animal vet practitioners; peak penetration in 2026, with 5% use CryoShot, 75x per year, at A$250 per dose; 30% probability with studies/partners to complete.
Kvax canine vaccine	Dog cancer	WW	Marketed (Aus), marketing studies (US)	~540/100,000 annual incidence of dog cancers; ~860,000 cancers US/EU/Japan/Aus; assume 10% get drug/vaccine treatment; 25% peak Kvax penetration of treated dogs by 2024 (=21,600 Kvax treatments); A$2,000 per treatment course; 40% probability with studies/partners to complete.
AGC upfront & milestones		Japan		US$5.5m upfront; plus US$11m milestones, assume payable over FY17-FY22, risked at 30-90%.

Source: Edison Investment Research

Sensitivities

With regard to Progenza, CryoShot, Kvax and the human cancer vaccine – the key long-term valuation drivers – we have assumed timely clinical and commercial progress in multiple regions, which should be achievable, but any delays/setbacks would have a negative impact on our valuation. Signing up AGC as a manufacturing partner for Progenza in Japan has provided significant validation of the commercial value of the company's technology; this should make it easier to sign clinical development partners, which represents near-term potential upside.

Progenza could potentially be developed for a range of disease indications. At present we include only the single osteoarthritis indication in our valuation model, so progress in developing additional indications or licensing deals that include additional indications for Progenza represent potential sources of upside to our valuation.

Financials

We have made modest revisions to our financial forecasts, including pushing back receipt of US$1m of AGC milestone payments from FY17 to FY18. We now assume that US$1m of AGC milestone payments will be received in FY17 and US$5m in FY18.

The latest quarterly cash flow statement for the three months ending 31 March 2017 showed that operating cash payments in Q3 FY17 totalled A$2.1m (adjusted for AGC transaction costs and exchange rate impact), an increase over the A$1.8m average over the preceding two quarters due to planned acceleration in R&D activities. The cash balance at 31 March 2017 was A$4.9m, which,

combined with A$1.2m of loans to shareholders that mature in July 2017 (provided at time of IPO in 2013 to fund exercise of employee options), and an estimated ~A$2.5 R&D tax incentive payment that will be receivable in H1 FY18, would fund operations to end Q3 FY18 at the current burn rate. The company expects additional licencing and milestone payments to extend the funding runway beyond the end of FY18 (we estimate an additional ~A$1-2m would be required from these sources). Up to US$11m in milestone payments could be received under the agreement with AGC on the achievement of specific development and approval milestones – we model US$6m (A$7.9m) milestones being received by end FY18, which would extend the funding runway into H2 FY19 (if received). We forecast Regeneus to have A$5.9m of net cash at the end of FY18.

Exhibit 7: Financial summary

A$'000s	2014	2015	2016	2017e	2018e
Year end 30 June	AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS					
Revenue	2,003	1,900	1,735	10,200	8,383
Cost of Sales	(621)	(915)	(292)	(214)	(297)
Gross Profit	1,381	985	1,444	9,986	8,087
R&D expenses	(5,758)	(4,945)	(4,309)	(4,525)	(5,430)
SG&A expenses	(6,756)	(6,250)	(3,578)	(3,564)	(3,738)
EBITDA	(10,800)	(9,805)	(6,092)	2,144	(849)
Operating Profit (before GW and except.)	(11,118)	(10,191)	(6,428)	1,904	(1,078)
Intangible Amortisation	(16)	(19)	(15)	(7)	(3)
Exceptionals	0	0	0	0	0
Other (includes R&D tax credit)	3,767	3,418	2,747	2,715	2,986
Operating Profit	(7,367)	(6,792)	(3,696)	4,612	1,906
Net Interest	(157)	186	122	(20)	(20)
Profit Before Tax (norm)	(7,507)	(6,588)	(3,559)	4,599	1,889
Profit Before Tax (IFRS)	(7,523)	(6,607)	(3,574)	4,592	1,886
Tax benefit	0	0	0	0	0
Profit After Tax (norm)	(7,507)	(6,588)	(3,559)	4,599	1,889
Profit After Tax (IFRS)	(7,523)	(6,607)	(3,574)	4,592	1,886
Average Number of Shares Outstanding (m)	166.5	208.9	208.9	209.9	210.9
EPS - normalised (A$)	(0.05)	(0.03)	(0.02)	0.02	0.01
EPS - IFRS (A$)	(0.05)	(0.03)	(0.02)	0.02	0.01
Dividend per share (A$)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets	3,170	2,451	2,432	2,408	2,404
Intangible Assets	30	26	11	27	52
Tangible Assets	1,362	892	802	761	733
Investments	1,778	1,533	1,619	1,619	1,619
Current Assets	7,089	7,128	3,503	7,910	9,895
Stocks	206	99	30	25	138
Debtors	134	67	22	672	672
Cash	2,635	3,013	529	4,308	5,909
Other	4,114	3,950	2,922	2,905	3,176
Current Liabilities	(1,698)	(1,260)	(1,006)	(1,006)	(1,006)
Creditors	(921)	(781)	(906)	(906)	(906)
Short term borrowings	0	0	0	0	0
Other	(777)	(478)	(99)	(99)	(99)
Long Term Liabilities	(253)	(48)	(144)	(144)	(144)
Long term borrowings	0	0	0	0	0
Other long term liabilities	(253)	(48)	(144)	(144)	(144)
Net Assets	8,308	8,272	4,785	9,168	11,149
CASH FLOW					
Operating Cash Flow	(6,239)	(5,923)	(2,253)	4,302	1,828
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,176)	(208)	(250)	(223)	(227)
Acquisitions/disposals	0	8	19	0	0
Financing	10,209	6,168	0	0	0
Dividends	0	0	0	0	0
Other	4,900	0	0	0	0
Net Cash Flow	7,694	45	(2,484)	4,079	1,601
Opening net debt/(cash)	4,366	(2,635)	(3,013)	(529)	(4,308)
HP finance leases initiated	0	0	0	0	0
Other	(693)	333	0	(300)	0
Closing net debt/(cash)	(2,635)	(3,013)	(529)	(4,308)	(5,909)

Source: Regeneus accounts, Edison Investment Research

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