EDISON

Regeneus

STEP clinical update

Potential Japan licence deal a STEP closer

Pharma & biotech

Regeneus reported that its STEP Phase I trial of Progenza in patients with knee osteoarthritis has completed recruitment and that a review of safety data did not identify any safety concerns. The study will complete in H117 when all patients have completed 12 months follow-up. We believe the positive safety review augurs well for the company's plan to secure a manufacturing and commercial partner for its Progenza mesenchymal stem cell therapy technology in Japan in the current quarter, which may prompt a re-rating of the stock. We leave our valuation unchanged at A$106m (A$0.51/share) ahead of this potential re-rating catalyst.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/14	2.0	(7.5)	(0.05)	0.00	N/A	N/A
06/15	1.9	(6.6)	(0.03)	0.00	N/A	N/A
06/16e	1.4	(3.9)	(0.02)	0.00	N/A	N/A
06/17e	1.7	(4.0)	(0.02)	0.00	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Positive safety outcome clears way for Japan deal

Progenza is Regeneus' lead product and contributes more than 60% of our valuation of the company. The Phase I STEP trial of the allogeneic stem cell treatment in patients with knee osteoarthritis has completed recruitment, and a review of cumulative safety data by the study safety oversight committee did not identify any safety concerns. Regeneus is in advanced discussions with a large Japanese company regarding licensing Progenza for the Japanese market. Guidance in the half-yearly report in February was for a deal to be signed by mid-year, and we would expect the clean safety outcome to help move the discussions forward. Directors expect to receive a significant upfront licensing fee on entering this agreement, which is also expected to include further milestone payments.

Costs trimmed to extend cash runway

Regeneus has successfully reduced operating costs after winding down the HiQCell business in FY15. The operating loss of A$3.1m in H116 was 46% less than the previous corresponding period, and the average quarterly cash burn (excluding an R&D tax incentive of A$3.4m received in October 2015) for the first three quarters of FY16 was A$1.5m compared to A$2.5m in FY15. Cash at 31 March 2016 (end Q316) was A$2.0m which, combined with an arrangement to forward-fund A$2m of the R&D rebate due in Q217, will fund operations into Q217.

Valuation: Unchanged at A$106m or A$0.51/share

Our valuation is unchanged at A$106m or A$0.51/share. The anticipated upfront fee from licensing Progenza for the Japanese market may extend the cash runway, but if that does not happen the company may need to raise additional capital this calendar year.

19 May 2016

Price	**A$0.16**
Market cap	**A$33m**
	US$0.7/A$
Net cash (A$m) at 31 March 2016	2.0
Shares in issue	208.9m
Free float	56%
Code	RGS
Primary exchange	ASX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(6.1)	93.8	24.0
Rel (local)	(9.8)	(80.4)	29.5
52-week high/low	A$0.21	A$0.07	

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

Partner or JV for Progenza in Japan	Q216
Kvax canine osteosarcoma trial results	Q216
CryoShot Canine pre-pivotal trial results	Q117

Analysts

Dennis Hulme +61 (0)2 9258 1161

Lala Gregorek +44 (0)20 3681 2527

healthcare@edisongroup.com

Edison profile page

First-in-man trial of Progenza completes recruitment and clears safety review

Regeneus reported that it has completed recruitment in its Phase I STEP (Safety, Tolerability and Efficacy of Progenza) trial of Progenza in patients with knee osteoarthritis. The trial recruited 20 patients in two dose cohorts. Sixteen of the 20 participants received ultrasound-guided injections of Progenza directly into their arthritic knee joint, while the other four participants received placebo injections.

A pre-specified review of the cumulative safety data on all 20 patients by the study safety oversight committee did not identify any safety concerns. The review included at least one month's safety data for all patients and substantially more data for the earlier Cohort 1 patients.

While safety and tolerability is the primary outcome of the STEP trial, patients will also be monitored for 12 months to assess the effect of Progenza on knee pain and function, quality of life, knee structures as assessed by MRI, and osteoarthritis biomarkers. We expect 12-month efficacy data from the second, high-dose cohort to be available in mid-2017.

Japan licence deal for Progenza a potential catalyst

In its FY16 interim report, Regeneus advised that it is in advanced discussions with a large Japanese company regarding licensing Progenza, its allogeneic off-the-shelf mesenchymal stem cell technology, for the Japanese market. Regeneus is seeking to capitalise on the fact that a number of large Japanese companies are seeking access to technology that will allow them entry into the regenerative medicine field to take advantage of the favourable regulatory environment, which includes a fast-track approval pathway. Regeneus anticipates finalising these discussions before the end of the current quarter and the positive safety review in the STEP trial is likely to be an important part of this process, in our view.

Upfront fees and milestone payments from the potential deal could offer a source of non-dilutive funding for the company's ongoing work on new product development. In addition, we would expect a partner to either fully or partly cover the costs of the planned Phase II trial of Progenza in patients with osteoarthritis of the knee.

Pipeline progresses on a number of fronts

Recruitment in human cancer vaccine trial expected to complete in the December quarter

The company's second product in development for human clinical applications is its RGSH4K human therapeutic cancer vaccine. Recruitment is expected to be completed in Q4 CY16 in the ACTIVATE Phase I trial, a single-centre, open label, dose-escalating study of the safety and preliminary efficacy of the vaccine. The trial will recruit 21 patients with a range of advanced cancers.

The RGSH4K therapy, which is produced from a patient's own cancer cells, is designed to activate the immune system against the cancer cells to initiate a systemic immune response.

The success of the immune checkpoint inhibitor (ICI) class of drugs at producing long-lasting responses to treatment in a range of cancers has led to renewed interest in cancer vaccines. The vaccines may provide a way to initiate an immune response while the ICI drugs effectively "take the handbrake off" immune responses and make them more potent. It is anticipated that combining

cancer vaccines with ICI drugs may lead to stronger responses to treatment than either therapy on its own.

Cosmetic cream for inflammatory conditions Q4 CY16

Regeneus expects to have a cosmetic cream containing cell secretions commercially available in Australia in the final quarter of 2016. The cream aims to capitalise on the anti-inflammatory properties of the secretions released by MSCs during cell culture. The company has partnered with the CSIRO on scale-up manufacturing and has demonstrated its capacity to produce cell secretions at commercial scale. Clinical testing is planned for the second half of the year. The cosmetic cream would be regulated in Australia under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

CryoShot Canine pre-pivotal trial results due Q1 CY17

Initial results from the randomised pre-pivotal study of CryoShot Canine in 80 client-owned dogs with arthritis are expected in Q1 CY17. The trial is being conducted at the University of Pennsylvania School of Veterinary Medicine under the leadership of Professor Dorothy Brown. The trial will assess the change in levels of pain and dysfunction in arthritic dogs by validated questionnaires and force-plate analysis following intra-articular injection of CryoShot or placebo.

The trial is being jointly funded by Regeneus and its unnamed top five veterinary pharma partner. On completion of the trial, the partner will have an option to exclusively license the CryoShot technology for canine applications; under the terms of the licence, Regeneus will receive an upfront fee, milestone payments and a royalty on sales. The results of the study will be used to finalise the design of a pivotal US FDA trial, which would be funded by the partner.

Kvax osteosarcoma results due Q2 CY16

Results are expected in Q2 CY16 in the trial of the company's Kvax cancer vaccine in dogs with osteosarcoma. The trial is being conducted with Dr Phil Bergman of VCA, which is the largest veterinary services group in the US.

Regeneus is currently recruiting subjects in a separate trial of Kvax in 45 dogs with lymphoma, which began in November 2015. The double-blind, placebo-controlled trial, being conducted by veterinary oncologists at the Small Animal Specialist Hospital in Sydney, Australia, will use Kvax together with chemotherapy to seek to extend remission times in dogs that initially respond to chemotherapy. Lymphoma is the most commonly treated cancer in dogs; remission typically lasts eight to 10 months with chemotherapy, with a median survival of about one year.

Research grant to explore treating chronic pain with stem cells

Regeneus is part of a research consortium that has been awarded a A$340,000 grant by the Australian Research Council (ARC) for research to better understand chronic pain and how stem cells specially selected for their cytokine profiles can be used to relieve chronic pain in animals and help lay the foundations for future human therapies. The consortium also includes researchers from Macquarie University and the University of Adelaide.

Regeneus has patents and patent applications on the use of stem cells for the treatment of neuropathic pain. The research project is expected to lead to the development of allogeneic stem cell products that have been specially selected for desirable cytokine profiles for the treatment of neuropathic pain in both veterinary and human markets. In our view, this project is consistent with the company's strategy of focusing on early-stage product development before licensing to partners for late-stage development and commercialisation.

Valuation

Our valuation of Regeneus is unchanged at A$106m, or A$0.51 per share, although individual product NPVs have changed as we have rolled the cash balance forward to end FY16e. Our sum-of-the-parts DCF valuation model is summarised in Exhibit 1, with key assumptions shown in Exhibit 2.

Our valuation model applies a standard 12.5% discount rate and includes estimated net cash of A$0.5m at end June 2016. We assume that product sales peak six years after market launch, plateau at that level for five years and decline at 10% per year. For simplicity, we do not include upfront and milestone payments from any future licensing deals 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.

Progenza is the key long-term value driver, with peak sales estimated at A$1.75bn. Therefore, clinical and regulatory progress over the next few years would significantly de-risk the product, which currently has a 15% probability of success.

Exhibit 1: 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	Australia/ Japan/EU/US	Phase I	2020 (Japan); 2024 (EU/US/Aus)	444.0	1,754	15%	Royalty (20%)	64.8	0.31
Human cancer vaccine	Solid tumours	WW	Phase I	2024	63.5	500	15%	13% net royalties	9.0	0.04
CryoShot	Animal - OA	Australia	Pre-registration field trials	2012	11.0	7	30-100%	Operating profit (40-60%)	2.4	0.01
CryoShot	Animal - OA	EU	Registration studies	2020	25.5	45	30%	30% effective royalty rate	7.0	0.03
CryoShot	Animal - OA	US	Registration studies	2020	32.7	54	30%	30% effective royalty rate	8.9	0.04
Kvax canine vaccine	Dog cancer	WW	Marketed (Aus) Marketing studies (US)	2016 (Aus); 2018	35.8	43	85%	30% effective royalty rate	13.8	0.07
Portfolio total					**619.3**				**105.9**	**0.51**
Net cash (FY16e - forecast for 30 June 2016)									0.5	0.00
Overall valuation									**106.4**	**0.51**

Source: Edison Investment Research

Exhibit 2: Regeneus valuation assumptions

Product	Setting	Region	Status	Key assumptions
Progenza	Human - OA	Australia/ Japan/EU/US	Phase I	Prevalence ~10% of >55yrs in all regions; 10% suitable candidates for treatment; 10% Progenza peak market share (2029 in US/EU); A$5,000 per procedure (A$3,750 in EU).
Human cancer vaccine	Solid tumours	WW	Phase I	$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 or probability (100% near-term to 30% post-2020).
CryoShot	Animal - OA	EU	Registration studies	~90,000 small animal vet practitioners; peak penetration in 2025, with 3% use CryoShot, 50x per year, at A$250 per dose; 30% probability with studies/partners to complete.
CryoShot	Animal - OA	US	Registration studies	~50,000 small animal vet practitioners; peak penetration in 2025, 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 2023 (=21,600 Kvax treatments); A$2,000 per treatment course; 40% probability with studies/partners to complete.

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 a manufacturing and commercial partner for Progenza in Japan would provide significant validation of the commercial value of the company's technology and represents near-term potential upside.

Financials

Regeneus reported an operating loss of A$3.1m in H116 (six-month period ending December 2015). The loss was 46% less than the pcp due to the reduction in operating costs following the closure of HiQCell operations in FY15. Cash burn in Q316 (three months ending 31 March) was A$1.4m. Average quarterly cash burn (excluding an R&D tax incentive of A$3.4m received in October 2015) for the first three quarters of FY16 was A$1.5m compared to A$2.5m/quarter in FY15, showing that the lower operating costs are reflected in the cash flow. The company intends to out-license its programmes for late-stage development to partners that would fund the majority of R&D expenses, which should allow it to maintain cash burn at around current levels. We have reduced our forecast capex for FY16 by A$230k to A$220k given the lower spend (A$183k) in the first nine months of FY16.

Cash at 31 March (end Q316) was A$2.0m. The company expects to receive a payment in excess of A$2.5m in Q217 under the Australian government's R&D tax incentive scheme. Regeneus has finalised in principle a loan arrangement that allows it to draw down up to A$2.0m, which would be repaid on receipt of the R&D incentive in Q217. The cash balance and loan arrangement will fund operations into Q217, by which time Regeneus expects to have finalised out-licensing its Progenza mesenchymal stem cell technology for the Japanese market.

The anticipated upfront fee from licensing Progenza for the Japanese market may extend the cash runway, but if that does not happen the company may need to raise additional capital this calendar year. In our forecasts, we assume this funding is provided by long-term debt, as per our standard policy, and we assign A$3.5m to long-term debt in FY17 and A$3m in FY18.

Exhibit 3: Financial summary

A$'000s	2014	2015	2016e	2017e	2018e
Year end 30 June	AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS					
Revenue	2,003	1,900	1,374	1,679	3,119
Cost of Sales	(621)	(915)	(155)	(224)	(468)
Gross Profit	1,381	985	1,219	1,454	2,652
R&D expenses	(5,758)	(4,945)	(3,956)	(4,154)	(3,946)
SG&A expenses	(6,756)	(6,250)	(3,672)	(3,772)	(3,972)
EBITDA	(10,800)	(9,805)	(6,130)	(6,218)	(5,035)
Operating Profit (before GW and except.)	(11,118)	(10,191)	(6,397)	(6,466)	(5,258)
Intangible Amortisation	(16)	(19)	(12)	(7)	(9)
Exceptionals	0	0	0	0	0
Other (includes R&D tax credit)	3,767	3,418	2,453	2,492	2,368
Operating Profit	(7,367)	(6,792)	(3,956)	(3,980)	(2,899)
Net Interest	(157)	186	(0)	(55)	(55)
Profit Before Tax (norm)	(7,507)	(6,588)	(3,945)	(4,029)	(2,946)
Profit Before Tax (IFRS)	(7,523)	(6,607)	(3,956)	(4,035)	(2,955)
Tax benefit	0	0	0	0	0
Profit After Tax (norm)	(7,507)	(6,588)	(3,945)	(4,029)	(2,946)
Profit After Tax (IFRS)	(7,523)	(6,607)	(3,956)	(4,035)	(2,955)
Average Number of Shares Outstanding (m)	166.5	208.9	209.4	210.4	211.4
EPS - normalised (A$)	(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	2,392	2,326	2,426
Intangible Assets	30	26	34	49	60
Tangible Assets	1,362	892	824	745	833
Investments	1,778	1,533	1,533	1,533	1,533
Current Assets	7,089	7,128	3,656	3,631	4,044
Stocks	206	99	72	105	218
Debtors	134	67	67	67	67
Cash	2,635	3,013	532	435	860
Other	4,114	3,950	2,985	3,025	2,900
Current Liabilities	(1,698)	(1,260)	(1,260)	(1,260)	(1,260)
Creditors	(921)	(781)	(781)	(781)	(781)
Short term borrowings	0	0	0	0	0
Other	(777)	(478)	(478)	(478)	(478)
Long Term Liabilities	(253)	(48)	(48)	(3,548)	(6,548)
Long term borrowings	0	0	0	(3,500)	(6,500)
Other long term liabilities	(253)	(48)	(48)	(48)	(48)
Net Assets	8,308	8,272	4,740	1,150	(1,337)
CASH FLOW					
Operating Cash Flow	(6,239)	(5,923)	(2,261)	(3,408)	(2,244)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,176)	(208)	(220)	(189)	(332)
Acquisitions/disposals	0	8	0	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	(2,481)	(3,597)	(2,575)
Opening net debt/(cash)	4,366	(2,635)	(3,013)	(532)	3,065
HP finance leases initiated	0	0	0	0	0
Other	(693)	333	0	0	0
Closing net debt/(cash)	(2,635)	(3,013)	(532)	3,065	5,640

Source: Regeneus accounts, Edison Investment Research

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand