EDISON

Regeneus

FY16 results

Japan licence deal close to finalisation

Pharma & biotech

Regeneus anticipates entering a binding arrangement with a manufacturing and commercialisation partner for its Progenza mesenchymal stem cell therapy technology in Japan by the end of the current quarter. Following on from the positive safety review of its STEP Phase I trial of Progenza in patients with knee osteoarthritis, it has already begun procuring donor material in preparation for manufacturing Progenza for a Phase II trial in Japan. Our valuation is virtually unchanged at A$108m (A$0.52/share) ahead of this potential re-rating catalyst.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/15	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	2.0	(3.6)	(0.02)	0.00	N/A	N/A
06/18e	2.6	(3.2)	(0.02)	0.00	N/A	N/A

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

Advanced discussions with potential Japan partner

Regeneus is in advanced discussions with a large Japanese company regarding manufacturing and commercialisation of Progenza for the Japanese market, and anticipates converting these discussions into binding arrangements by the end of September. Directors expect the company to receive upfront funding and milestone payments on entering this agreement.

Six months' cash runway to secure Japan deal

Regeneus has successfully reduced operating costs after winding down the HiQCell business in FY15. The operating loss of A$3.6m in FY16 was 45% 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) in FY16 was A$1.48m compared to A$2.35m in FY15. Cash at 30 June 2016 (end FY16) was A$0.5m which, combined with the A$2.7m R&D rebate received in September, will fund operations to the end of H1FY17, allowing time to finalise the licensing deal in Japan.

Preparations underway to support a Phase II in Japan

Regeneus has already commenced manufacturing activities that will support a Japan-based Phase II trial of Progenza in osteoarthritis. Procurement of donor adipose tissue has commenced, with ethics approval to procure up to 20 donors to proceed into cell bank manufacture in preparation for the trial.

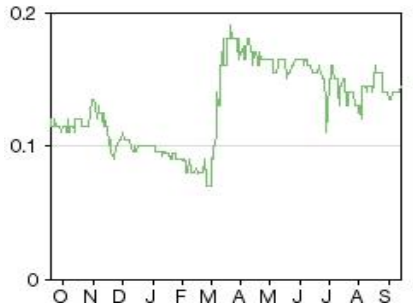
Valuation: Little changed at A$108m or A$0.52/share

Our valuation of Regeneus increases slightly to A$108m, or A$0.52 per share (previously A$106m or A$0.51/share) with the impact of a later (2019) commercial launch of Kvax in the US more than offset by rolling forward our DCF model to FY17. 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.

14 September 2016

Price	**A$0.15**
Market cap	**A$31m**
	US$0.76/A$
Net cash (A$m) at 30 June 2016	0.5
Shares in issue	208.9m
Free float	67.7%
Code	RGS
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	0.0	9.4	26.1
Rel (local)	6.0	8	21.0
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.

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Japan licence deal for Progenza a potential catalyst

Regeneus is in advanced discussions with a large Japanese company regarding licensing Progenza for the Japanese market, and anticipates converting these discussions into a binding arrangement by the end of the current quarter. Progenza is an allogeneic (off-the-shelf) mesenchymal stem cell technology and Regeneus has encountered significant interest as it seeks 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. These companies are seeking to take advantage of the favourable regulatory environment in Japan, which includes a fast-track approval pathway specifically designed for regenerative medicine products like Progenza.

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.

Preparations underway to support a Progenza Phase II in Japan

Regeneus has commenced manufacturing activities that will support a Japan-based Phase II trial of Progenza in patients with knee osteoarthritis, following on from the positive safety review of the Phase I STEP trial in May. Procurement of donor adipose tissue has commenced, with ethics approval to procure up to 20 donors which will then proceed into cell bank manufacture in preparation for the Phase II trial.

The recent Phase I STEP (Safety, Tolerability and Efficacy of Progenza) trial recruited 20 patients with knee osteoarthritis 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 in May 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. Patients will continue to 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 the June quarter of 2017.

Human cancer vaccine trial to fully recruit by December

The company's second product in development for human clinical applications is its RGSH4K human therapeutic cancer vaccine. Recruitment is anticipated 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.

In FY17 Regeneus will explore the opportunity to combine RGSH4K with the immune checkpoint inhibitor (ICI) class of drugs. RGSH4K is designed to initiate an immune response, while the ICI drugs effectively "take the handbrake off" immune responses making them more potent, so the combination of the two approaches could potentially stimulate highly effective immune responses against cancer cells.

CryoShot Canine pre-pivotal trial results due Q2 CY17

CryoShot is an allogeneic (off-the-shelf) product containing mesenchymal stem cells (MSCs) derived from the fat tissue of donor animals and expanded in cell culture. Regeneus has partnered with an unnamed top five veterinary pharma company to develop CryoShot Canine. Regeneus and the partner are jointly funding a randomised pre-pivotal study in 80 client-owned dogs with arthritis at the University of Pennsylvania School of Veterinary Medicine. The trial was more than 30% recruited at the date of the annual report in August; recruitment is anticipated to be completed by the end of the calendar year, with results anticipated in Q2 CY17.

At the 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 in the December quarter

In addition to the RGSH4K human product, Regeneus is also developing a therapeutic cancer vaccine for use in dogs, known as Kvax. The company is conducting a marketing study of Kvax in conjunction with Dr Phil Bergman of VCA, the largest veterinary services group in the US, to generate real-world clinical study results in osteosarcoma. Results in this study are expected to be announced in Q4 CY16.

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.

Cell secretions for inflammatory conditions

Regeneus has developed products for topical application for the treatment of inflammatory skin conditions such as acne and wound healing. The products harness the anti-inflammatory properties of the secretions released by MSCs during cell culture. The company has partnered with CSIRO on scale-up manufacturing and developing the capability to produce cell secretions at commercial scale. The company plans to conduct further preclinical and clinical testing of the latest secretions-based products in FY17.

Valuation

We have delayed the commencement of significant commercial sales of Kvax in the US by one year to 2019 as we allow more time to generate compelling efficacy data to support substantial commercial uptake. The negative effect of this change on valuation is more than offset by rolling forward our DCF model to FY17. The net result of these changes is that our valuation of Regeneus increases slightly to A$108m, or A$0.52 per share (previously A$106m or A$0.51/share).

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 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)	498.2	1,754	15%	Royalty (20%)	69.6	0.33
Human cancer vaccine	Solid tumours	WW	Phase I	2024	71.5	500	15%	13% net royalties	9.4	0.05
CryoShot	Animal - OA	Australia	Pre-registration field trials	2012	12.4	7	30-100%	Operating profit (40-60%)	2.6	0.01
CryoShot	Animal - OA	EU	Registration studies	2020	28.4	45	30%	30% effective royalty rate	7.3	0.03
CryoShot	Animal - OA	US	Registration studies	2020	36.2	54	30%	30% effective royalty rate	9.2	0.04
Kvax canine vaccine	Dog cancer	WW	Marketed (Aus) Marketing studies (US)	2016 (Aus); 2019	27.5	35	85%	30% effective royalty rate	9.8	0.05
Portfolio total					**681.9**				**107.8**	**0.52**
Net cash (at 30 June 2016)									0.5	
Overall valuation									**108.3**	**0.52**

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$3.6m in FY16 (year ending June 2016). The loss was 45% less than the previous corresponding period due to the reduction in operating costs following the closure of HiQCell operations in FY15. Average quarterly cash burn in FY16 (excluding an R&D tax incentive of A$3.4m received in October 2015) was A$1.48m compared to A$2.35m 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 made only minor changes to our FY17 forecasts, with the operating cash outflow unchanged at A$3.4m. The later forecast commercial launch of Kvax in the US reduces forecast FY18 revenue by A$0.5m to A$2.6m, with FY18 operating cash outflow A$0.7m higher at A$2.9m.

Cash at 30 June (end FY16) was A$0.5m. The company received a payment of A$2.7m in September under the Australian government's R&D tax incentive scheme, taking pro forma cash to A$3.2m. The cash should be sufficient to fund operations to the end of the calendar year, whereas Regeneus expects to finalise out-licensing its Progenza mesenchymal stem cell technology for the Japanese market within the next few weeks.

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 both FY17 and FY18.

Exhibit 3: Financial summary

A$'000s	2014	2015	2016	2017e	2018e
Year end 30 June	AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS					
Revenue	2,003	1,900	1,735	1,998	2,598
Cost of Sales	(621)	(915)	(292)	(240)	(484)
Gross Profit	1,381	985	1,444	1,757	2,115
R&D expenses	(5,758)	(4,945)	(4,309)	(4,525)	(4,299)
SG&A expenses	(6,756)	(6,250)	(3,578)	(3,564)	(3,600)
EBITDA	(10,800)	(9,805)	(6,092)	(6,085)	(5,553)
Operating Profit (before GW and except.)	(11,118)	(10,191)	(6,428)	(6,325)	(5,781)
Intangible Amortisation	(16)	(19)	(15)	(7)	(3)
Exceptionals	0	0	0	0	0
Other (includes R&D tax credit)	3,767	3,418	2,747	2,715	2,579
Operating Profit	(7,367)	(6,792)	(3,696)	(3,617)	(3,205)
Net Interest	(157)	186	122	(20)	(20)
Profit Before Tax (norm)	(7,507)	(6,588)	(3,559)	(3,630)	(3,222)
Profit Before Tax (IFRS)	(7,523)	(6,607)	(3,574)	(3,637)	(3,224)
Tax benefit	0	0	0	0	0
Profit After Tax (norm)	(7,507)	(6,588)	(3,559)	(3,630)	(3,222)
Profit After Tax (IFRS)	(7,523)	(6,607)	(3,574)	(3,637)	(3,224)
Average Number of Shares Outstanding (m)	166.5	208.9	208.9	209.9	210.9
EPS - normalised (A$)	(0.05)	(0.03)	(0.02)	(0.02)	(0.02)
EPS - IFRS (A$)	(0.05)	(0.03)	(0.02)	(0.02)	(0.02)
Dividend per share (A$)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets	3,170	2,451	2,432	2,408	2,458
Intangible Assets	30	26	11	27	46
Tangible Assets	1,362	892	802	761	792
Investments	1,778	1,533	1,619	1,619	1,619
Current Assets	7,089	7,128	3,503	3,482	3,802
Stocks	206	99	30	46	79
Debtors	134	67	22	22	22
Cash	2,635	3,013	529	509	932
Other	4,114	3,950	2,922	2,905	2,769
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)	(3,644)	(7,144)
Long term borrowings	0	0	0	(3,500)	(7,000)
Other long term liabilities	(253)	(48)	(144)	(144)	(144)
Net Assets	8,308	8,272	4,785	1,239	(1,890)
CASH FLOW					
Operating Cash Flow	(6,239)	(5,923)	(2,253)	(3,298)	(2,796)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,176)	(208)	(250)	(222)	(281)
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)	(3,520)	(3,077)
Opening net debt/(cash)	4,366	(2,635)	(3,013)	(529)	2,991
HP finance leases initiated	0	0	0	0	0
Other	(693)	333	0	0	(0)
Closing net debt/(cash)	(2,635)	(3,013)	(529)	2,991	6,068

Source: Regeneus accounts, Edison Investment Research

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