EDISON

Regeneus

FY15 results

Potentially two partnering deals in H215

Pharma & biotech

Regeneus has sharpened its focus on its area of expertise in early-stage development of regenerative medicine products and cancer vaccines. This strategy appears to be bearing fruit, with partnering arrangements for both its human and veterinary off-the-shelf stem cell therapies expected to be finalised before the end of CY15. A partnering deal for Progenza in Japan is likely to be a re-rating catalyst. Our valuation is A$106m (A$0.51/share).

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/14	2.0	(7.5)	(0.05)	0.0	N/A	N/A
06/15	1.9	(6.6)	(0.03)	0.0	N/A	N/A
06/16e	1.4	(4.6)	(0.02)	0.0	N/A	N/A
06/17e	1.9	(4.5)	(0.02)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation & exceptional items.

Focus on early product development, then partner

Regeneus has firmed up its strategy to partner its product opportunities for development and commercialisation, which it outlined in its strategic review in late 2014. We have a positive view of this strategy, which allows the company to focus on its expertise in early-stage product development. For example, it has indicated that it will seek to identify wider applications of its off-the-shelf Progenza stem cells, beyond the initial development for osteoarthritis. As part of this re-orientation it has wound down its autologous HiQCell cell therapy operations.

Two partnering deals expected before year end

Regeneus has been actively involved in discussions with potential partners across its product portfolio, and these discussions are starting to bear fruit. The FY15 annual report indicated that it expects to finalise partnering discussions for both its human (Progenza) and veterinary (CryoShot) off-the-shelf stem cell products in the current half year. Most significantly, it expects to finalise one or more deals with potential manufacturing, clinical and marketing partners for Progenza in Japan.

First Progenza patient treated, cancer vaccine next

The sentinel patient has been treated in the first-in-human trial of Progenza, with no safety concerns. Dosing of the first cohort of 10 patients with knee osteoarthritis should occur in H215, followed by the second cohort in Q116. Separately, the first patient is expected to be treated in Q315 in the Phase I trial of the RGSH4K human cancer vaccine. Patient tumour samples continue to be banked to allow treatment with the vaccine once other treatment options have been exhausted.

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

Our valuation is unchanged at A$106m or A$0.51/share, with the removal of HiQCell offset by the roll-forward of the DCF model. The company had A$3.0m cash at 30 June, and expects to receive a A$3.4m R&D incentive rebate in October, giving it a cash runway to Q416 at an underlying burn rate of A$1.7m/quarter. We estimate the company needs additional funds of A$2m for working capital in FY16 and A$4m in FY17. These funds could come from pending partnering deals, or potentially a capital raise.

Regeneus is a research client of Edison Investment Research Limited

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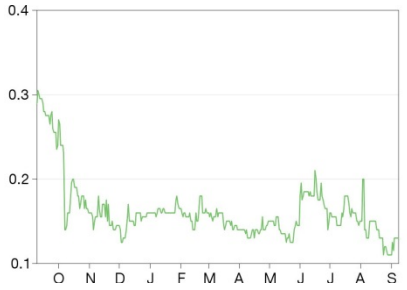
Price	**A$0.13**
Market cap	**A$27m**
	US$0.70/A$
Net cash (A$m) at 30 June 2015	3.0
Shares in issue	208.9
Free float	56%
Code	RGS
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	0.0	(29.7)	(53.6)
Rel (local)	6.6	(24.6)	(49.5)
52-week high/low	A$0.31		A$0.13

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 patient treated with human cancer vaccine	Q315
Partner or JV for Progenza in Japan	H215
Partner canine CryoShot	H215

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Adipose-derived stem cells and cancer vaccines

Regeneus is developing and commercialising its portfolio of proprietary, adipose (fat) derived stem cell therapies and its cancer vaccines, which is summarised in Exhibit 1. Its key product, Progenza, comprises human allogeneic (donor) stem cells that have been expanded in a proprietary manufacturing process. Progenza will initially be developed as an off-the-shelf treatment for knee osteoarthritis that will target a potential fast-track approval in Japan. The company is also developing human and veterinary therapeutic cancer vaccines (RGSH4K and Kvax), an off-the-shelf veterinary stem cell therapeutic (CryoShot), and a cell secretions product for topical dermatology applications.

Exhibit 1: Regeneus product portfolio

	Progenza	CryoShot	RGSH4K human cancer vaccine	Kvax canine cancer vaccine	Secretions (topical)
Market	Human	Veterinary	Human	Veterinary	Human
Cell source/type	Allogeneic, adipose-derived	Allogeneic, adipose-derived	Autologous	Autologous	Allogeneic, adipose-derived
Cell production/ product manufacture	Expanded cells, off-the-shelf	Expanded cells, off the shelf	Soluble proteins from patient's own tumour	Soluble proteins from patient's own tumour	Cell secretions from expanded cells.
Mode of admin	Intra-articular	Intra-articular	Intradermal injection	sc injection	Topical
Primary indication	Osteoarthritis	Osteoarthritis	Solid tumours	Solid tumours, Osteosarcoma (dogs)	Acne
Regulatory status	Biologic requiring safety and efficacy clinical studies for approval. Phase I trial underway under CTN* scheme	Trial product availability (limited). Safety and efficacy studies required for full registration/ approval	Biologic requiring safety and efficacy clinical studies for approval in most markets. Phase I trial underway	US, Aus – exempt biological not requiring approval. Other markets may require safety and efficacy clinical studies for approval	Varies, depends on therapeutic claim. Approval not required for cosmetic claims.
Key target markets	Initial target Japan; then Australia, US, EU	US, EU, Australia	US, EU, Australia, Japan	Australia, US, EU	Australia, US EU, Japan
Partner(s)		Provet – distribution partner; Lonza – manufacturing partner	Kolling Institute of Medical Research	Kolling Institute of Medical Research. VCA for US clinical trial	

Source: Company documents, Edison Investment Research. * Note CTN = clinical trial notification scheme in Australia

Potential for two deals this calendar year

1. Progenza

Regeneus has treated the sentinel patient in its first-in-human trial of Progenza in patients with knee osteoarthritis. The study safety oversight committee reported that there were no safety concerns with the sentinel patient. Dosing of the first cohort of 10 patients with knee osteoarthritis should occur in H215, followed by the second cohort of 10 patients in Q116. In each cohort eight patients will be treated with Progenza and two will receive a placebo injection.

Importantly, Regeneus demonstrated earlier this year that its proprietary and scalable manufacturing process has the capacity to produce millions of doses of Progenza from a single donor, which has attracted the interest of potential manufacturing partners.

The company is in discussions to establish a joint venture or other partnering arrangement to conduct a Phase II trial in osteoarthritis patients in Japan. Management has observed that a number of large Japanese companies are interested in entering the regenerative medicine space to take advantage of the favourable regulatory environment, which includes a fast-track approval pathway. Regeneus has encountered genuine interest from a number of potential partners, and anticipates finalising these discussions in H215.

The licence and partnership agreement between Athersys and Chugai in March 2015 illustrates the high level of interest in regenerative medicine products in Japan. The deal covers the development and commercialisation of Athersys' MultiStem allogeneic cell therapy for ischemic stroke in Japan, which is in Phase II development. The deal terms include US$10m upfront, US$45m in development and regulatory milestones, and US$150m sales milestones, plus a tiered double-digit royalty on sales and payments for product supplied to Chugai by Athersys.

Regeneus is also seeking to identify partners for Progenza for Europe and the US. The commentary in the 2015 annual report appears to suggest that discussions for those regions are less advanced than for Japan.

2. CryoShot

Regeneus is well advanced in its preparations to initiate a pre-pivotal US clinical trial of canine CryoShot in Q315. The company is looking to finalise arrangements in H215 with a marketing partner who would also support the final stages of development of canine CryoShot, including GMP manufacture and a pivotal clinical trial in dogs with osteoarthritis.

We expect the pre-pivotal trial that will be conducted at the University of Pennsylvania to recruit around 60 dogs and include groups treated with CryoShot or placebo. This pre-pivotal trial will use CryoShot product manufactured by Regeneus in its facilities in Sydney, whereas the final pivotal trial would use product manufactured to GMP standards.

A small efficacy trial conducted in Australia identified new potential IP for optimising success of treatment by predicting which animals are most likely to have a positive response. The pre-pivotal trial will gather additional information regarding this potential IP.

HiQCell operations wound down

Regeneus has previously commercialised its HiQCell autologous cell therapy under a model whereby it charged a service fee for processing adipose tissue samples to extract a cell preparation that could be administered into patients with joint disease. Over 600 patients have been treated with HiQCell since it was launched in 2012, but the business model did not prove profitable at achieved volumes.

As an autologous human cell therapy, obtained during a medical procedure by medical practitioners, HiQCell is currently exempt from standard regulation by Australia's regulatory agency, the Therapeutic Goods Administration (TGA). The TGA is currently undertaking a review of the regulation of autologous cell therapies in Australia, with submissions to the review having closed in March 2015.

In view of the regulatory uncertainty created by the TGA review, and the lack of profitability to date, Regeneus has wound down its HiQCell processing operations and will not be proceeding with the planned launch in Singapore. Instead, it will focus its resources on the development of its allogeneic, off-the-shelf stem cell product, Progenza, which offers more attractive commercial opportunities.

First patient to be treated with RGSH4K cancer vaccine Q315

Regeneus received ethics approval in May for a Phase I trial of its RGSH4K human cancer vaccine. Patient tumour samples continue to be banked to allow treatment with the vaccine once other treatment options have been exhausted. The company expects the first patient to be treated in the trial in Q315, and expects to complete the enrolment of 21 patients with advanced cancers in H116.

The trial will evaluate the safety, tolerability and preliminary efficacy of the vaccine to identify a biologically active dose for further studies.

Kvax clinical trial ongoing

Recruitment has finished in the marketing study of Kvax conducted with Dr Phil Bergman of VCA, the largest veterinary services group in the US, to generate real-world clinical study results in osteosarcoma. Regeneus is planning a new trial in FY16 in another (undisclosed) major canine cancer type.

As Kvax is an autologous vaccine it can be made commercially available in Australia and the US without specific regulatory approval. 26 commercial Kvax treatments were initiated in FY15, giving rise to A$26k of revenue. However, widespread commercial uptake will depend on positive efficacy data in clinical trials. Regeneus continues to explore global commercial partnering opportunities for Kvax.

Valuation

Our valuation of Regeneus is unchanged at A$106m, or A$0.51 per share, with the impact of the removal of HiQCell from our forecasts offset by the roll-forward of the risked DCF model. HiQCell previously contributed A$3m to our valuation. Our sum-of-the-parts DCF valuation model is summarised in Exhibit 2, with key assumptions displayed in Exhibit 3.

Exhibit 2: 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)	443.1	1,754	15%	Royalty (20%)	62.4	0.30
Human cancer vaccine	Solid tumours	WW	Phase I	2024	62.1	500	15%	13% net royalties	8.3	0.04
CryoShot	Animal - OA	Australia	Pre-registration field trials	2012	10.8	7	30%-100%	Operating profit (40%-60%)	2.0	0.01
CryoShot	Animal - OA	EU	Registration studies	2020	24.9	45	30%	30% effective royalty rate	6.8	0.03
CryoShot	Animal - OA	USA	Registration studies	2020	31.3	54	30%	30% effective royalty rate	8.4	0.04
Kvax canine vaccine	Dog cancer	WW	Marketed (Aus) Marketing studies (US)	2016 (Aus); 2018	36.6	43	40%	30% effective royalty rate	14.6	0.07
Portfolio total					**615.7**				**102.5**	**0.49**
Net cash (FY15 – as of 30 June 2015)									3.0	0.01
Overall valuation									**105.5**	**0.51**

Source: Edison Investment Research

Our valuation model applies a standard 12.5% discount rate and includes H215 (30 June 2015) net cash of A$3.0m. 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, and our valuation is not a price target but a fair value for the stock today. Risk adjustments would unwind as programmes advance through clinical studies, gain regulatory approvals, 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 3: 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. A commercialisation deal for the secretions technology represents potential upside, as we do not currently include secretions products in our valuation model. The decision to wind-down the self-commercialisation of HiQCell in Australia and reduce overall expenditure helps to reduce the execution risk in that area.

Financials

Regeneus reported a loss of A$6.6m for FY15 (ended 30 June 2015). The result included one-off costs totalling A$1.6m incurred in winding-down the HiQCell business. Net cash used in operating activities was A$5.9m. The company had A$3.0m cash and equivalents at 30 June 2015, and expects to receive a A$3.4m R&D incentive payment in October. Under the Australian government's R&D tax incentive scheme approximately 45% of eligible R&D costs can be reimbursed. The combined total of A$6.4m gives it a cash runway to Q416 at an underlying burn rate of A$1.7m/qtr. We estimate that an additional A$2m funds would provide sufficient working capital to fund operations until the FY16 R&D rebate payment (our estimate A$2.7m) is received in October 2016, with a further A$4m required in FY17. These funds could come from pending partnering deals, or potentially a capital raise. In our forecasts we assume that this funding is provided by long-term debt, as per our standard policy, and we assign A$2m to long-term debt in FY16, A$4m in FY17, and A$3m in FY18.

Exhibit 4: Financial summary

A$'000s	2014	2015	2016e	2017e	2018e
Year end 30 June	AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS					
Revenue	2,003	1,900	1,374	1,878	3,486
Cost of Sales	(621)	(915)	(128)	(287)	(471)
Gross Profit	1,381	985	1,246	1,591	3,015
R&D expenses	(5,758)	(4,945)	(4,550)	(4,641)	(4,177)
SG&A expenses	(6,756)	(6,250)	(4,020)	(4,203)	(4,426)
EBITDA	(10,800)	(9,805)	(7,044)	(6,924)	(5,296)
Operating Profit (before GW and except.)	(11,118)	(10,191)	(7,312)	(7,246)	(5,578)
Intangible Amortisation	(16)	(19)	(12)	(7)	(9)
Exceptionals	0	0	0	0	0
Other (includes R&D tax credit)	3,767	3,418	2,730	2,784	2,506
Operating Profit	(7,367)	(6,792)	(4,594)	(4,468)	(3,081)
Net Interest	(157)	186	(0)	(55)	(55)
Profit Before Tax (norm)	(7,507)	(6,588)	(4,582)	(4,517)	(3,127)
Profit Before Tax (IFRS)	(7,523)	(6,607)	(4,594)	(4,524)	(3,137)
Tax benefit	0	0	0	0	0
Profit After Tax (norm)	(7,507)	(6,588)	(4,582)	(4,517)	(3,127)
Profit After Tax (IFRS)	(7,523)	(6,607)	(4,594)	(4,524)	(3,137)
Average Number of Shares Outstanding (m)	166.5	208.9	209.4	210.4	211.4
EPS - normalised (A$)	(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	2,645	2,527	2,605
Intangible Assets	30	26	37	54	66
Tangible Assets	1,362	892	1,074	940	1,007
Investments	1,778	1,533	1,533	1,533	1,533
Current Assets	7,089	7,128	4,765	4,804	5,057
Stocks	206	99	59	134	219
Debtors	134	67	67	67	67
Cash	2,635	3,013	1,377	1,287	1,732
Other	4,114	3,950	3,262	3,317	3,038
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)	(2,048)	(6,048)	(9,048)
Long term borrowings	0	0	(2,000)	(6,000)	(9,000)
Other long term liabilities	(253)	(48)	(48)	(48)	(48)
Net Assets	8,308	8,272	4,102	24	(2,646)
CASH FLOW					
Operating Cash Flow	(6,239)	(5,923)	(3,163)	(3,879)	(2,185)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,176)	(208)	(473)	(211)	(370)
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	(3,636)	(4,090)	(2,555)
Opening net debt/(cash)	4,366	(2,635)	(3,013)	623	4,713
HP finance leases initiated	0	0	0	0	0
Other	(693)	333	0	0	0
Closing net debt/(cash)	(2,635)	(3,013)	623	4,713	7,268

Source: Regeneus accounts, Edison Investment Research

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