EDISON

Regeneus

Cryoshot partner

Partner for CryoShot a vote of confidence

Pharma & biotech

The agreement with one of the top five veterinary pharma companies to collaborate on the development of CryoShot Canine is recognition of the good progress that Regeneus has made developing its regenerative medicine products and cancer vaccines. At its recent AGM, Regeneus confirmed that it anticipates winning the much bigger prize of a manufacturing and development partner in Japan for its Progenza off-the-shelf human stem cell product by Q116. We maintain our valuation of 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)	0.0	N/A	N/A
06/15	1.9	(6.6)	(0.03)	0.0	N/A	N/A
06/16e	1.4	(3.9)	(0.02)	0.0	N/A	N/A
06/17e	1.7	(4.0)	(0.02)	0.0	N/A	N/A

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

Top five vet pharma partners CryoShot development

Regeneus has partnered with an un-named top five veterinary pharma company to develop CryoShot Canine. Regeneus and the partner will jointly fund a randomised pre-pivotal study in 80 client-owned dogs with arthritis, with results anticipated in Q316. The partner has an option to exclusively license the CryoShot technology at the completion of the study in exchange for an upfront fee, development milestone payments and a royalty on all CryoShot sales. The results of the study will be used to design a pivotal US FDA trial, which would be funded by the partner.

Progenza: Partnering discussions and clinical trial

Dosing of the first cohort of 10 patients with knee osteoarthritis in the first-in-human trial of Progenza is currently underway. A review of safety data from cohort 1 is expected before the end of CY15, with enrolment of the final cohort to start in Q116. Positive safety data would be an important milestone towards the company's goal to finalise one or more deals with potential manufacturing, clinical and marketing partners for Progenza in Japan before the end of Q116.

Human cancer vaccine trial underway

The first patient in the ACTIVATE trial of the RGSH4K human cancer vaccine was safely dosed in October. Enrolment in the 21-person trial is expected to be completed in Q316.

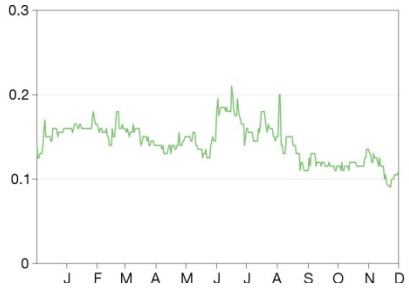
Valuation: Unchanged at A$106m or A$0.51/share

Our valuation is unchanged at A$106m or A$0.51/share. The company had A$1.5m cash at 30 September and received an A$3.4m R&D incentive payment in October, giving it a cash runway to Q3 CY16 at an average burn rate of A$1.7m/quarter. We estimate the company needs additional funds of A$2m for working capital in FY16 and A$3m in FY17. These funds could come from partnering deals, or potentially a capital raise. With the company continuing to trim costs, we have reduced forecast operating losses by 13%, 11% and 6% in FY16, FY17 and FY18 respectively.

2 December 2015

Price	**A$0.11**
Market cap	**A$23m**
	US$0.7/A$
Net cash (A$m) at 30 June 2015	3.0
Shares in issue	208.9m
Free float	56%
Code	RGS
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(15.4)	0.0	(24.1)
Rel (local)	(16.8)	(3.7)	(25.9)

52-week high/low	A$0.21	A$0.09

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

Progenza cohort 1 safety data	Q415
Partner or JV for Progenza in Japan	Q116
Kvax canine osteosarcoma trial results	Q116

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Japan licence deal for Progenza a potential catalyst

Regeneus is in advanced discussions to secure a manufacturing and development partner for Progenza in Japan. 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 has encountered genuine interest from a number of potential partners, and anticipates finalising these discussions before the end of Q116.

Upfront fees and milestone payments from the potential deal could offer a source of non-dilutive funding for its 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.

Regeneus has treated the first cohort of 10 patients in its Phase I trial of Progenza, with the second of the two dose cohorts expected to begin enrolling subjects in Q116. Trial participants receive ultrasound-guided injections of either Progenza or placebo directly into their arthritic knee joint. In each cohort eight patients will be treated with Progenza and two will receive a placebo injection.

High potency cell identification technology adds to product development capability

Regeneus has in-licensed technology from Macquarie University that may allow it to develop more potent cell products that secrete higher levels of desired cytokines and growth factors. Acquiring this technology fits neatly with the company's strategy to focus on its expertise in early-stage product development.

The technology for the first time enables researchers to identify as well as select individual live stem cells that are able to secrete high levels of cytokines. The technology could potentially allow Regeneus to develop designer stem cell products where the cytokine production profile has been matched to the disease being treated.

Importantly, the technology is applicable to a wide range of cell types and is not restricted to mesenchymal stem cells or cells derived from adipose tissue. There are near-term applications of the technology for developing analysis kits for research and diagnostic markets.

While the development team has shown that high-secreting cells selected using the technology maintain that profile through several cell culture passages, there would still be plenty of challenges remaining in ensuring that the cells maintained the desirable cytokine secretion profile when scaled up for commercial manufacture. The in-licensed technology provides a useful tool that could be used in this process to help identify the cell culture conditions that best maintain the cytokine-secreting capacity of the selected cells.

Pre-pivotal trial of CryoShot Canine underway

A randomised pre-pivotal study of CryoShot Canine in 80 client-owned dogs with arthritis began on 2 November 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 intraarticular injection of CryoShot or placebo.

The trial will be jointly funded by Regeneus and its un-named top five veterinary pharma partner. At the completion of the trial (results expected in Q316), the partner will have an option to exclusively license the CryoShot technology. The results of the study will inform the design of a pivotal US FDA

trial, which would be funded by the partner, and may also provide additional validation for new IP developed by Regeneus that could improve the likelihood of success when using CryoShot.

Trial of Kvax in dogs with lymphoma to support commercial uptake

Regeneus began recruiting subjects in a trial of its Kvax cancer vaccine in 45 dogs with lymphoma in November. The double-blind, placebo-controlled trial, to be 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 8-10 months with chemotherapy, with a median survival of about one year.

The trial of Kvax in dogs with osteosarcoma conducted with Dr Phil Bergman of VCA, the largest veterinary services group in the US, has competed recruitment and is expected to report results in Q116.

As Kvax is an autologous vaccine it can be made commercially available in Australia and the US without specific regulatory approval. Over 100 dogs with more than 14 different cancers have been treated with Kvax in Australia. However, while there are no further regulatory hurdles to be cleared, widespread commercial uptake will depend on positive efficacy data in clinical trials such as those currently underway in osteosarcoma and lymphoma. 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. Our sum-of-the-parts DCF valuation model is summarised in Exhibit 1, with key assumptions displayed in Exhibit 2.

Our valuation model applies a standard 12.5% discount rate and includes 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 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)	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%)	1.9	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 (as of 30 June 2015)									3.0	0.01
Overall valuation									**105.5**	**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. A commercialisation deal for the secretions technology represents potential upside, as we do not currently include secretions products in our valuation model.

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 in the first quarter of FY16 was A$1.6m. With the company continuing to trim costs, we have reduced forecast operating expenses, reducing forecast losses by 13%, 11% and 6% in FY16, FY17 and FY18 respectively. Regeneus had A$1.5m cash at 30 September, and received an A$3.4m R&D incentive rebate 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$4.9m gives it a cash runway to Q416 at an average 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$2.5m) 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 and A$3m in both FY17 and FY18.

Exhibit 3: Financial summary

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)	(3,632)	(3,773)	(3,973)
EBITDA	(10,800)	(9,805)	(6,090)	(6,144)	(4,983)
Operating Profit (before GW and except.)	(11,118)	(10,191)	(6,357)	(6,466)	(5,259)
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)	(3,916)	(3,980)	(2,900)
Net Interest	(157)	186	(0)	(55)	(55)
Profit Before Tax (norm)	(7,507)	(6,588)	(3,905)	(4,029)	(2,946)
Profit Before Tax (IFRS)	(7,523)	(6,607)	(3,916)	(4,036)	(2,955)
Tax benefit	0	0	0	0	0
Profit After Tax (norm)	(7,507)	(6,588)	(3,905)	(4,029)	(2,946)
Profit After Tax (IFRS)	(7,523)	(6,607)	(3,916)	(4,036)	(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	2,642	2,501	2,548
Intangible Assets	30	26	34	49	60
Tangible Assets	1,362	892	1,074	920	956
Investments	1,778	1,533	1,533	1,533	1,533
Current Assets	7,089	7,128	5,446	4,995	5,461
Stocks	206	99	72	105	218
Debtors	134	67	67	67	67
Cash	2,635	3,013	2,322	1,800	2,276
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)	(2,048)	(5,048)	(8,048)
Long term borrowings	0	0	(2,000)	(5,000)	(8,000)
Other long term liabilities	(253)	(48)	(48)	(48)	(48)
Net Assets	8,308	8,272	4,780	1,190	(1,298)
CASH FLOW					
Operating Cash Flow	(6,239)	(5,923)	(2,221)	(3,333)	(2,192)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,176)	(208)	(470)	(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	(2,691)	(3,522)	(2,523)
Opening net debt/(cash)	4,366	(2,635)	(3,013)	(322)	3,200
HP finance leases initiated	0	0	0	0	0
Other	(693)	333	0	0	0
Closing net debt/(cash)	(2,635)	(3,013)	(322)	3,200	5,724

Source: Regeneus accounts, Edison Investment Research

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