

# Japan Update & Half-Year Results for FY17

Sydney  
22 February 2017

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- FY17 / FY18 Milestones

# Strategic strengths

## Multiple proprietary technology platforms

- Allogeneic adult stem cells (MSCs) from adipose tissue for OA and other inflammatory conditions (Progenza, CryoShot)
- Immuno-therapy for oncology (RGSH4K, Kvax)
- Cell secretions from adipose MSCs for inflammatory skin conditions and wound healing

## Diversified portfolio of clinical stage products

- Human and animal health markets
- All product platforms in clinical development
- Scalable manufacturing for allogeneic stem cells
- Strategic and growing IP portfolio to underpin technologies and products

## Innovation and collaboration

- Commercially focussed
- Successful technology and clinical collaborative partnerships (AGC, University of Adelaide, Macquarie University, Kolling Institute)
- Strong and proven management team
- Experienced technical resources

# Key achievements for H1 FY17



## **Partnering and licensing**

- Secured manufacturing and commercial partner for Progenza in Japan (AGC)
- Agreed to establish 50/50 JV with AGC for licensing of clinical development rights for Progenza in Japan
- Advanced clinical partnering discussions for Progenza for OA and other indications in Japan
- Entered into Australian Research Council linkage grant funded collaborative research project exploring use of Progenza in treatment of chronic pain

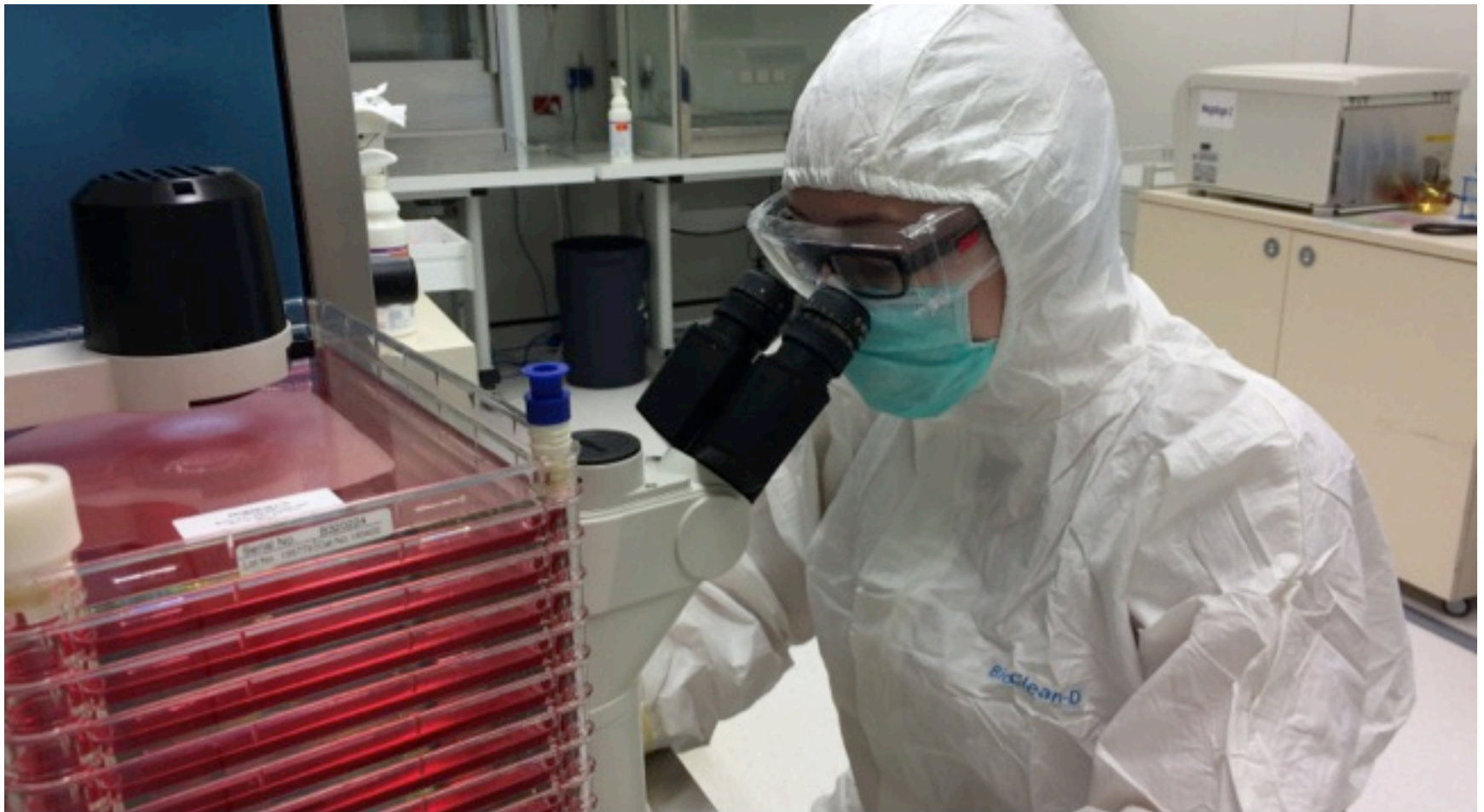
## **Clinical trial progress**

- Progenza STEP trial in final stages of monitoring all participants – positive safety review
- RGS4K ACTIVATE trial progressing with patients treated safely in all 3 dose cohorts
- CryoShot pre-pivotal OA trial at University of Pennsylvania 50% recruited – 40 dogs

## **Financial imperatives**



- Maintained cash burn at \$1.5m per quarter (target \$1.7 million)
- Secured 18 month funding runway

# Japan update



# Overview of AGC transaction

**Regeneus and AGC, the leading Japanese manufacturer of biopharmaceutical products, enter into collaboration and licence agreement for the manufacture and joint licensing of the clinical development of its off-the-shelf stem cell therapy platform, Progenza, in Japan**

 living regenerative medicine	Received <b>US\$5.5M</b> Upfront licence fee	Entitled to <b>US\$11.0M</b> Specific milestone payments	Established 50/50 JV for licensing clinical development and marketing rights of Progenza for OA and all other indications in Japan	Entitled to 50% of Progenza clinical licensing, milestone payments and sales royalties
	Exclusive manufacturer of Progenza in Japan	Funds product development for GMP manufacture for Phase 2 Progenza trial		

# Collaboration benefits



- **Large Japanese/global partner with aligned goals**
  - Dominant biopharmaceutical contract manufacturing organisation in Japan leading to accelerated entry into cell-based therapeutics manufacture
  - Ambition and resources dedicated to supply global market
- **Increased impetus of Progenza development**
  - OA development
  - Other inflammatory indication areas
- **Existing and ongoing relationships with**
  - Regulators in biopharmaceuticals manufacturing
  - Other major pharmaceutical businesses

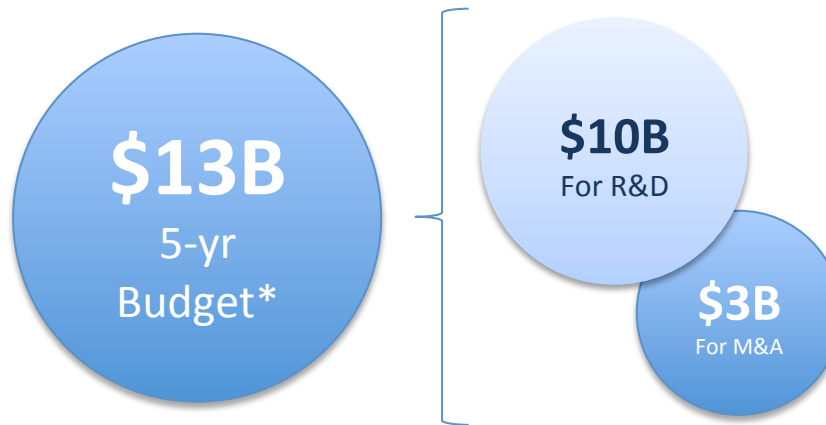




# Japan's leading bio-CMO with global ambition

- **AGC** is Japan's leading biopharmaceutical contract manufacturing organization
  - 2015 Group sales of JPY1,326 billion (US\$13 billion)
  - Existing CMO relationships with many major pharmaceutical businesses
- In **AGC's** recent "Vision 2025", **Life Sciences** was designated a **strategic business**

Strategic  
business  
funding  
plan:



**AGC**  
**AGC plus**



Acquired (Sep. 2016)



Acquired (Dec. 2016)





# Japan is at the forefront of regenerative medicine

- Prime Minister Abe made Regenerative Medicine a key part of its strategy for revitalising the economy
  - **New laws** passed in Nov 2013 (took effect in Nov '14) positioned Japan at the forefront for regenerative products and services
  - New **accelerated pathway** for industry sponsored clinical trials



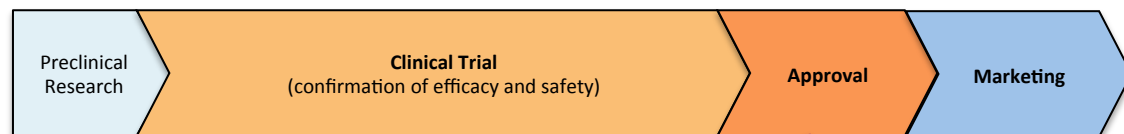
**Second largest  
healthcare market  
in the world**



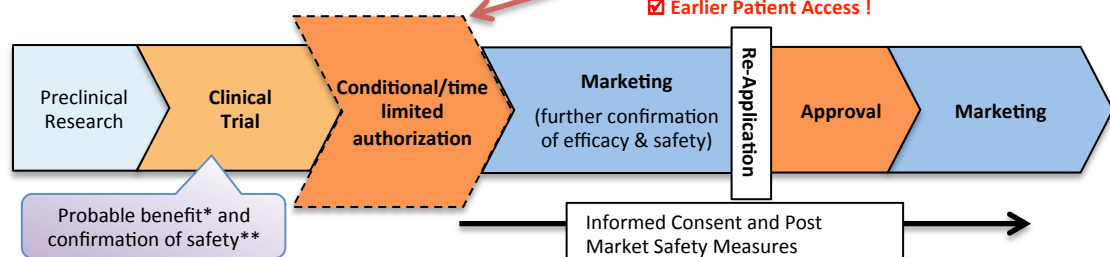
**Regen Med sector  
projected to grow  
to US\$5.5b by 2030**

- allows for **conditional approval** of new cell therapy after confirmation of safety and “predicted efficacy”
- **5-7 years** to gain clinical data
- **70% Government reimbursement**

[Traditional Approval Process]



[New Scheme for Regenerative Medicinal Products]

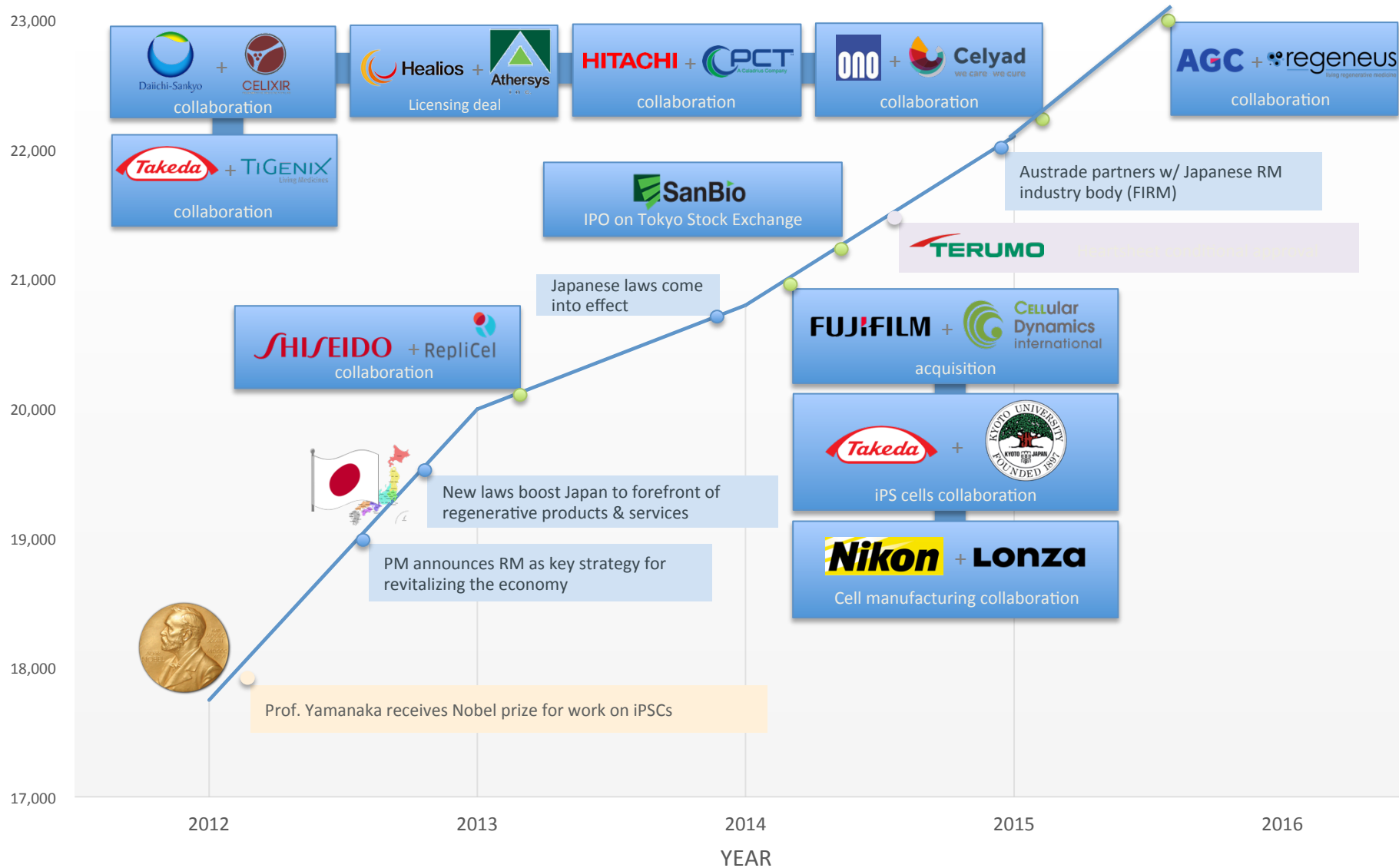


\*Probable benefit\*: Confirmation of efficacy with small population

\*\*Safety: Evaluation of acute adverse events etc.

# Increasing Japanese regenerative medicine dealflow

NUMBER OF PUBMED ARTICLES USING THE TERM "STEM CELL"



# Half-Year FY17 financial update



# H1 FY17 financial results overview

	\$'000's	2016	2015	Change
Revenue		<b>8,189</b>	881	7,308
Cost of Sales		(54)	(118)	64
Gross Profit		8,135	763	7,372
R & D expenses		(1,843)	(1,932)	89
Selling expenses		(111)	(249)	138
Occupancy expenses		(192)	(247)	55
Corporate expenses		(1,410)	(1,420)	10
Finance Costs		(12)	(10)	(2)
One-off transaction costs		(810)	-	(810)
Net Expenses		(4,378)	(3,858)	520
<b>Profit/(Loss) for half year</b>		<b>3,757</b>	(3,095)	6,852

- Revenue includes \$7.6m from AGC licence fee
- R&D tax incentive, not recognised in half year results. Full year claim is expected to be similar to 2016 - \$2.7m
- One-off transaction costs incurred in securing licence to AGC - includes withholding tax, consulting fees and legal costs

# Forecast operating cash burn

	\$'000's
Cash at 31/12/2016	396
Material cash inflows	
• Japan up-front licence fee net receipt Jan'17	6,700
• Shareholder loan repayment Aug'17	1,297
• R&D tax incentive receipt Oct '17	2,700
Cash available ending FY18	11,093
Monthly cash burn	550 to 650
Cash available	18+ months

- Material cash receipts are reasonably certain
- Quarterly cash burn has been held at \$1.5 million
- Future quarterly cash burn to progressively increase to ~\$2 million
- Incremental cash receipts not in forecast include:
  - AGC milestone payments
  - Share of licence fees from licensing clinical development and marketing rights of Progenza for OA and other indications in Japan
  - Licences of other clinical assets
- Sustainable 18 month cashflow

# FY17 / FY18 Milestones

## Progenza

- Advance clinical partnering discussions for Progenza in Japan Ongoing
- Commence donor procurement and process development for manufacturing Progenza for Phase 2 trial in Japan Q4 FY17
- Report on Progenza osteoarthritis STEP trial Q4 FY17
- Commence chronic pain preclinical study Q4 FY17

## RGSH4K

- Further recruitment on ACTIVATE clinical trial Ongoing
- Complete recruitment and report on ACTIVATE trial H2 FY18

## Secretions

- Undertake preclinical trials for human secretions technology for inflammatory skin conditions Q4 FY17

## CryoShot

- Complete recruitment and report on CryoShot Canine pre-pivotal OA trial H2 FY18



# Further information

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