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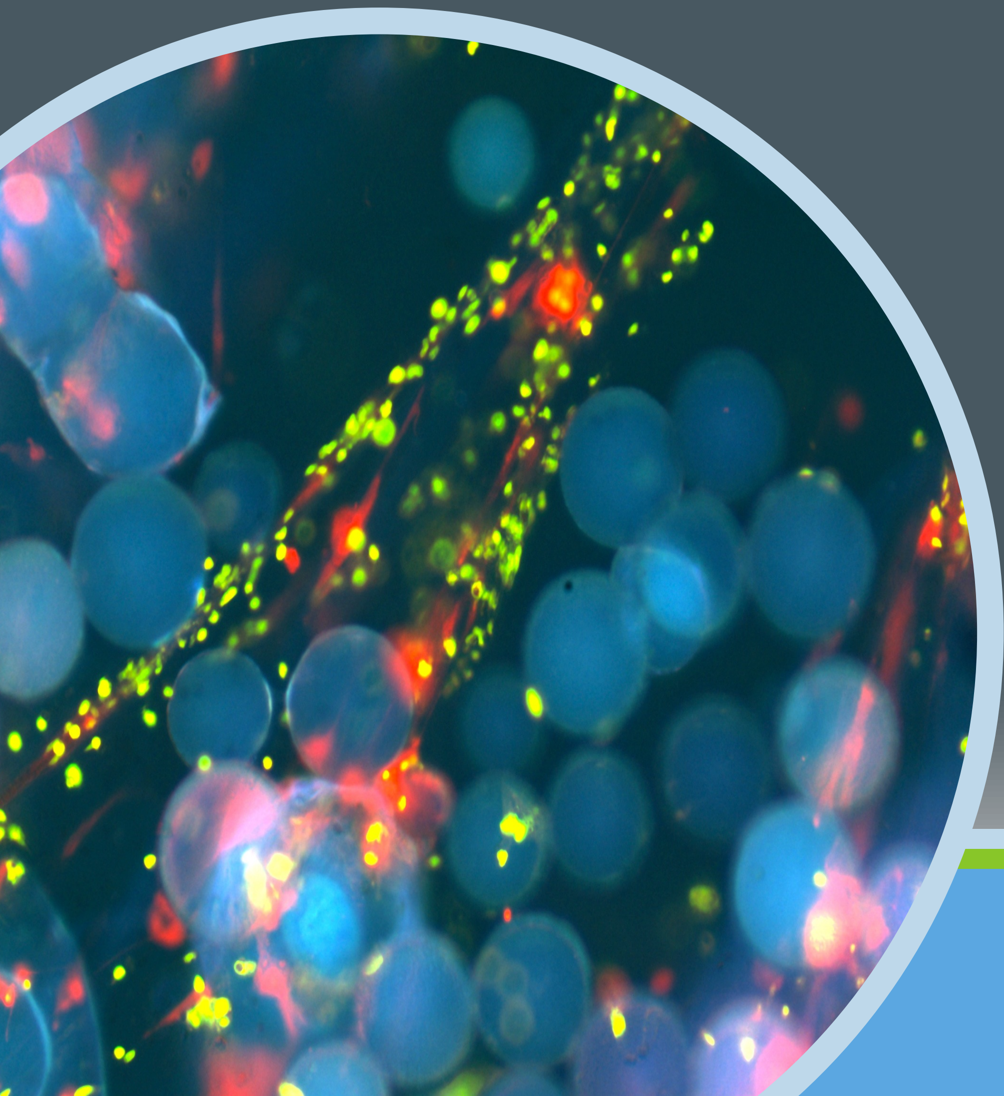

# Japan Update & Half-Year Results for FY17

Sydney
22 February 2017

# Agenda

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- Strategic strengths
- Key achievements for Half-Year FY17
- Japan update – AGC collaboration & licence
- Half-Year FY17 financial update
- FY17 / FY18 Milestones

# Strategic strengths

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| Multiple proprietary technology platforms | Diversified portfolio of clinical stage products | Innovation and collaboration |
| --- | --- | --- |
| • Allogeneic adult stem cells (MSCs) from adipose tissue for OA and other inflammatory conditions (Progenza, CryoShot)<br>• Immuno-therapy for oncology (RGSH4K, Kvax)<br>• Cell secretions from adipose MSCs for inflammatory skin conditions and wound healing | • Human and animal health markets<br>• All product platforms in clinical development<br>• Scalable manufacturing for allogeneic stem cells<br>• Strategic and growing IP portfolio to underpin technologies and products | • Commercially focussed<br>• Successful technology and clinical collaborative partnerships (AGC, University of Adelaide, Macquarie University, Kolling Institute)<br>• Strong and proven management team<br>• Experienced technical resources |

# Key achievements for H1 FY17

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**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

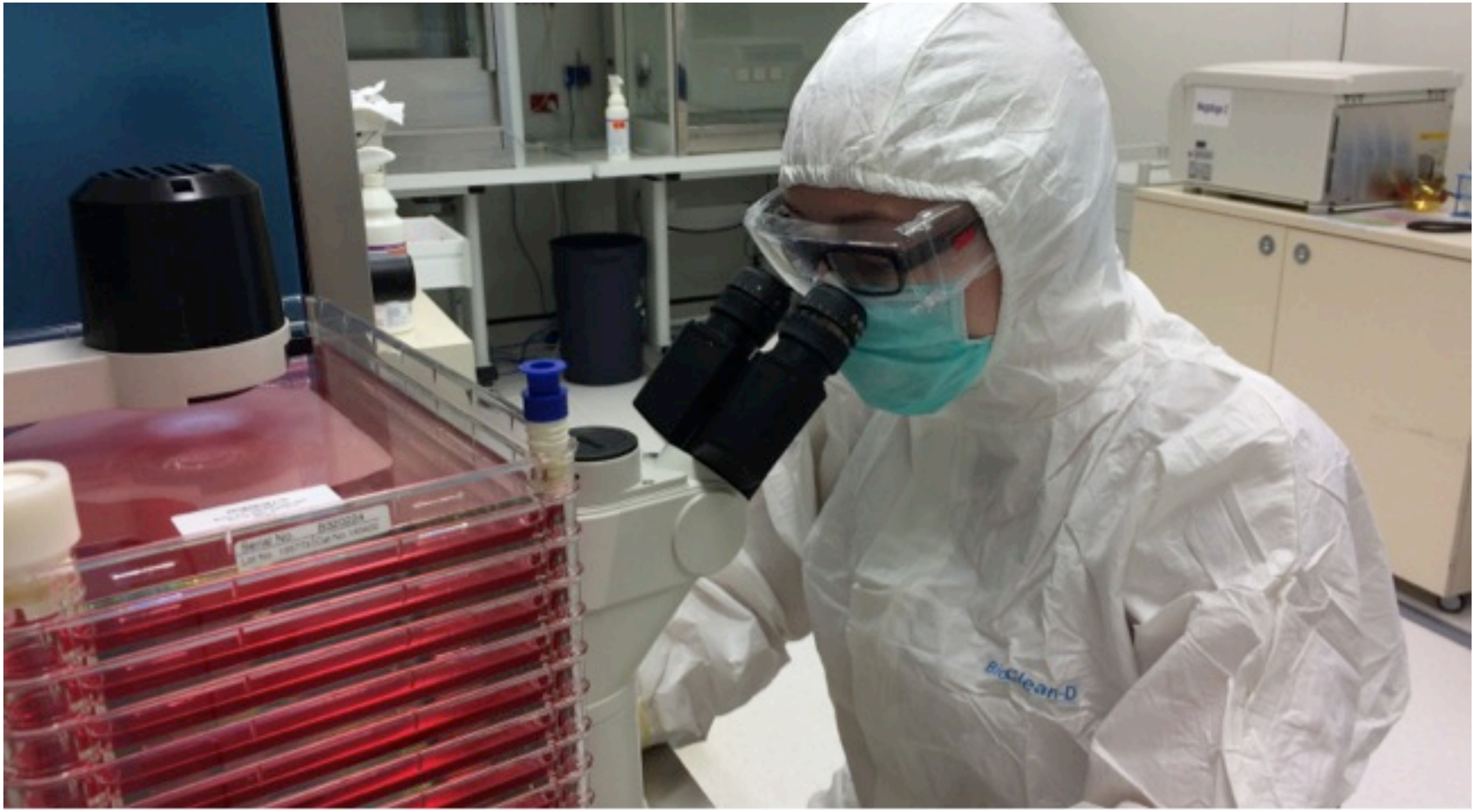
**Clinical trial progress**

- Progenza STEP trial in final stages of monitoring all participants – positive safety review
- RGSH4K 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

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**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**

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

# Collaboration benefits

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- **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

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- **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:

**$13B**
5-yr Budget*

**$10B**
For R&D

**$3B**
For M&A

AGC
AGC plus

BIOMEVA MANUFACTURING — Acquired (Sep. 2016)

CMC biologics — Acquired (Dec. 2016)



*Incl. mobility, electronics & life sciences
http://www.agc.com/english/ir/pdf/c_overview.pdf

# Japan is at the forefront of regenerative medicine

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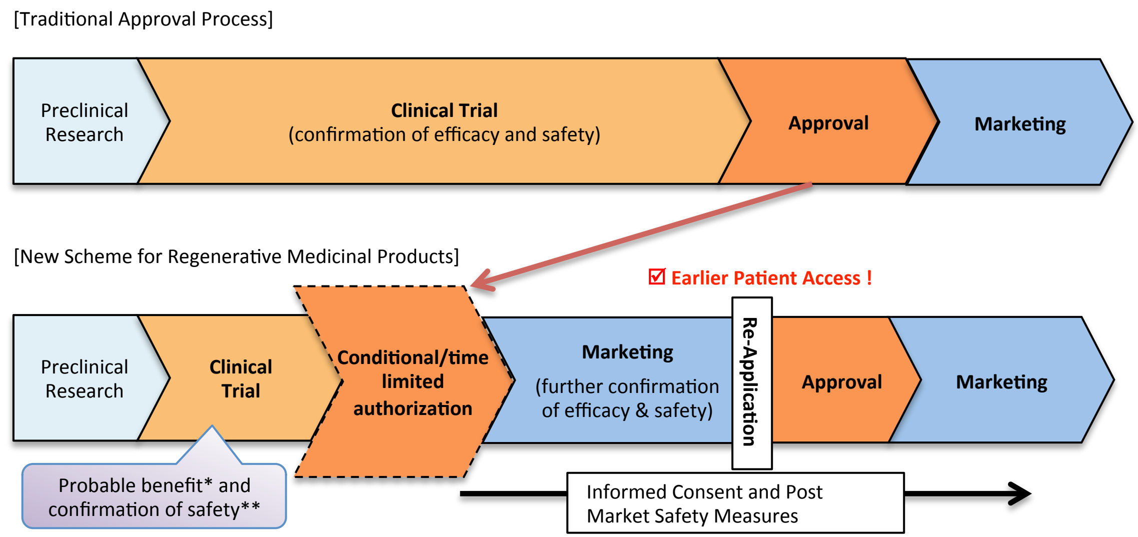
- Prime Minister Abe made Regenerative Medicine a key part of its strategy for revitalising the economy
  - **New laws** passed in Nov 2013 (took effect in Nov '14) positioned Japan at the forefront for regenerative products and services
  - New **accelerated pathway** for industry sponsored clinical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




*Probable benefit*: Confirmation of efficacy with small population
**Safety: Evaluation of acute adverse events etc.

https://www.jetro.go.jp/ext_images/australia/JVBFPresentations/FIRM.pdf

# Increasing Japanese regenerative medicine dealflow

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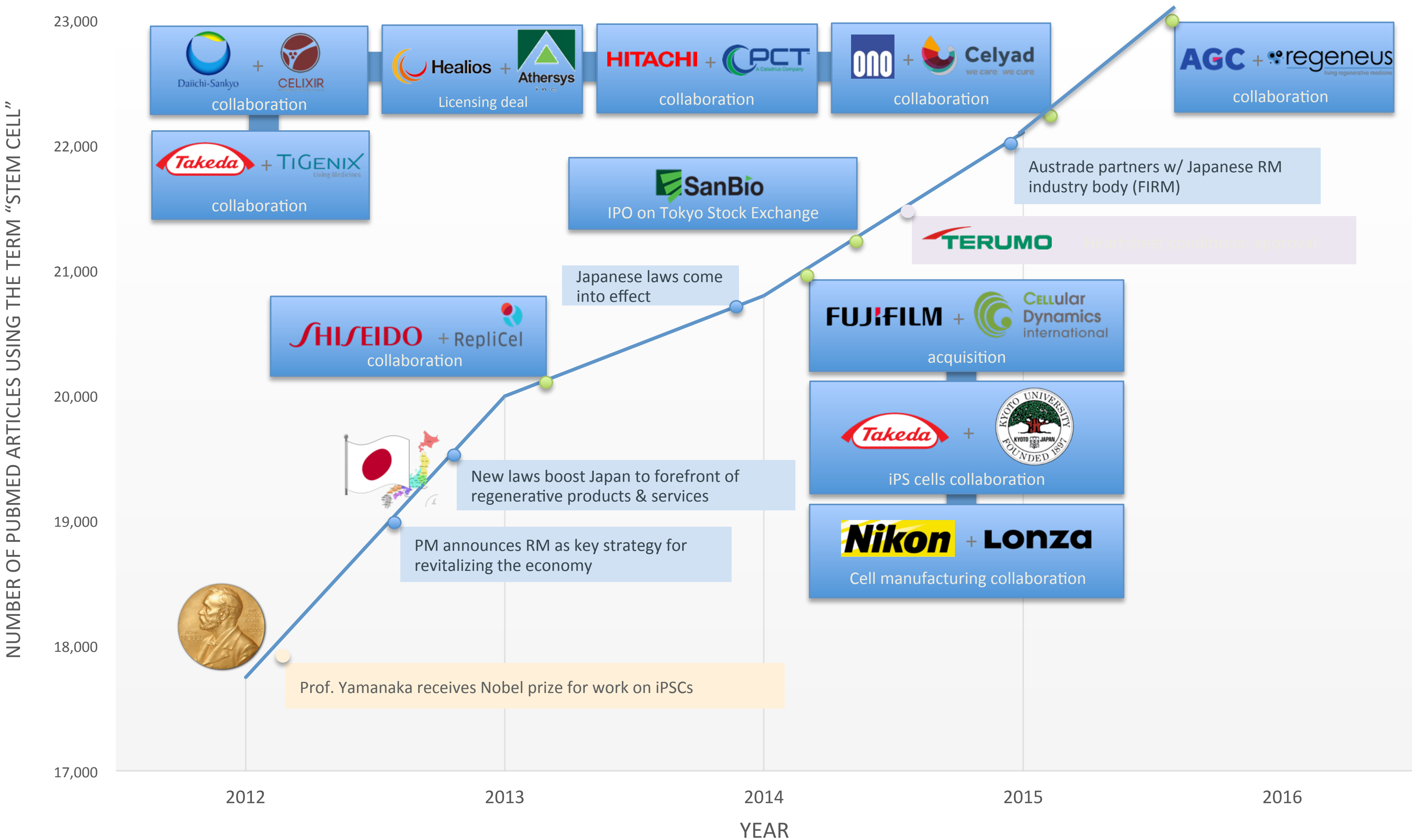

# Half-Year FY17 financial update

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# H1 FY17 financial results overview

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| $'000's | 2016 | 2015 | Change |
|---|---|---|---|
| Revenue | **8,189** | 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 |
| **Profit**/(Loss) for half year | **3,757** | (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<br>• Japan up-front licence fee net receipt Jan'17<br>• Shareholder loan repayment Aug'17<br>• R&D tax incentive receipt Oct '17 | <br>6,700<br>1,297<br>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

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| | |
|---|---|
| **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

**ASX: RGS**

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