



***“IMPROVING HEALTH AND RESEARCH OUTCOMES THROUGH THE  
APPLICATION OF OUR FRONTIER TECHNOLOGIES WITH A LEAD FOCUS  
BEING EMBRYO SCREENING TO IMPROVE IVF SUCCESS”***

**Reproductive Health Science  
Michelle Fraser, Chief Executive Officer  
August 2014**

# Forward Looking Statements

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# RHS & PGS (Pre-Implantation Genetic Screening)

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- Developer of novel products for the analysis of the genetic content of single cells
- Lead product EmbryoCollect™ launched in July 2014 as:
  - DNA amplification and fluorescent labelling kits
  - A microarray for counting the number of chromosomes in a single human cell

**This two component system has immediate application for PGS which improves the success rate of IVF (In-Vitro Fertilisation)**

# Background RHS



- Commenced single cell genomics R&D in 2004
- Initial venture capital investment Oct 2007
  - \$4.4m invested and \$1.3m grant funding leveraged
- Listed on ASX at \$0.20 in April 2014
- Located within the BioSA Incubator at Thebarton, South Australia
  - Dedicated laboratory and office space
  - Manufacturing capability with scope for scale-up
- Established network of commercial partners

# EmbryoCollect™ for PGS Launch

- Trademarked and soft-launched EmbryoCollect™ at ESHRE, Munich in July 2014
  - Set key messaging for PGS market
  - Released product brochure
  - Finalising kit design and Technical Data Sheet for end users
  - Introductory pricing established and received positive market feedback
- Scaled up microarray manufacturing capacity
- Initial key markets and distributors identified based on their interest in the product
- Negotiating with a number of clinics and distributors; ethics approvals for clinical use in progress
- Currently focussed on preparation for training provision and in-market support, distributor agreements and clinical utility testing agreements



# Pathway to EmbryoCollect™ Sales

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- Ethics approvals at selected IVF clinics in Australia and overseas
- Training plan will be rolled out
  - On-site at clinic
  - At RHS premises
  - Online web-based
  - RHS service provision to limited number of clinics
- Clinical feedback
  - Test ease of use
  - Pricing
- Publication of data; clinic testimonials
- Driving towards sales end 2014



# Continued Industry Interest in the PGS Market

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- Rubicon, suppliers of PicoPlex used in Illumina's 24Sure kit, increased revenues by 85% in 2013
- Established companies are still improving products for this market
  - Illumina demonstrated ongoing commitment to arrays and launched single cell sequencing kit for PGS called VeriSeq
  - Agilent announced a shortened single cell PGS protocol at ESHRE that is undergoing internal improvement and validation

# IVF and PGS market growth

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## □ IVF market potential

- **Local:** Monash IVF and Virtus Health successfully listed on the ASX; Primary Health entered the IVF market
- **International:** In 2010 it was estimated that there were 48.5m couples experiencing fertility issues globally. The global IVF market is approximately 1.7m cycles per annum and was valued at \$9.3bn in 2012. The global IVF market is forecast to grow to \$21.6bn by 2020.

- Illumina estimates that 3% of IVF cycles currently include PGS
  - Equates to 51,000 IVF cycles, average 4 embryos tested per cycle, estimated 204,000 tests per annum
  - Australian IVF clinics offer PGS for approximately \$650 per embryo



# RHS Product Extension

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- A next generation sequencing kit has been developed using existing RHS single cell PCR know-how
  - Currently undergoing internal evaluation prior to external benchmarking
- The applications for this kit extend well beyond PGS to other single cell and limited DNA applications including;
  - Tumour diagnosis
  - Stem cell monitoring
  - Forensics
  - Infectious disease surveillance
  - Veterinary applications
- Revenues from this kit have not been included in the RHS forecasts

# Corporate Overview

## Key assets

Exclusively in-licensed patent family	Granted patent family in most key territories to method for detecting chromosomal abnormalities
Primary value driver	Clinical impact in the IVF market
Single cell genetic analysis know-how	Kits developed for the PCR amplification of multiple and single cells for microarrays and sequencing
Primary value driver	Global product sales and key partnerships

ASX Code	RHS
Shares on Issue	51.3m <sub>(1)</sub>
Share Price	20c
Options	5.7m
Market Capitalisation	\$10.3
Cash at 30 June 2014	\$2.58m

## Corporate Highlights 1H 2014

- Board and Senior Management transition in line with corporate plan
  - New Director – Ms Sue MacLeman
  - Commercial Manager and Finance and Administration Officer appointed
  - Internal appointment of Chief Scientific Officer
- European patent notice of allowance
- Connors Arch sale

# Board of Directors & Key Management

Dr David Brookes <b>Non-Executive Chairman</b>	Director of Atcor Medical Holdings Ltd (ACG:ASX); medical practitioner & biotechnology consultant. MBBS;FACRRM;FAICD
Dr Michelle Fraser <b>Managing Director and CEO</b>	PhD (molecular biology); Grad Dip Science & Technology Commercialisation; GAICD
Ms Sue MacLeman <b>Non-Executive Director</b>	Distinguished career in biotechnology with wealth of industry experience; has been CEO and a Board member of a number of publicly-listed companies in both the USA & Australia; BPharm;MMktg:MLaw;FACPP;FAICD
Mr Donald Stephens <b>Executive Director</b>	Chief Financial Officer and Company Secretary of RHS, over 25 years experience in accounting. Three current directorships with ASX-listed companies and company secretarial positions. BAcc;FCA
Mr Johnathon Matthews <b>Non-Executive Director</b>	Executive director of The Pipette Company; previously held positions at Australian Treasury, ASX and Commonwealth Bank. BEc;BComm;LLB
Emeritus Professor Colin Matthews AO <b>Alternate Non-Executive Director</b>	Inaugural director of RHS, Single Cell Pty Ltd, Flinders IVF; co-founder and director of The Pipette Company; former Director ReproMed; Chairman of Research Committee and Board member of Channel 7 Research Foundation

# Summary

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- ❑ RHS has established alliances with existing and potential commercial partners in the IVF and genetic analysis industries
- ❑ Ease of scale-up of kit production for lead product EmbryoCollect™ for PGS use in IVF
- ❑ Processes for commercial roll-out this quarter with sales expected 2014
- ❑ RHS has the intention of achieving profitability in 2017
- ❑ Strong corporate potential in the investment proposition as demonstrated by the sale of BlueGnome to Illumina
- ❑ Potential for product extensions using existing know-how

# Appendix

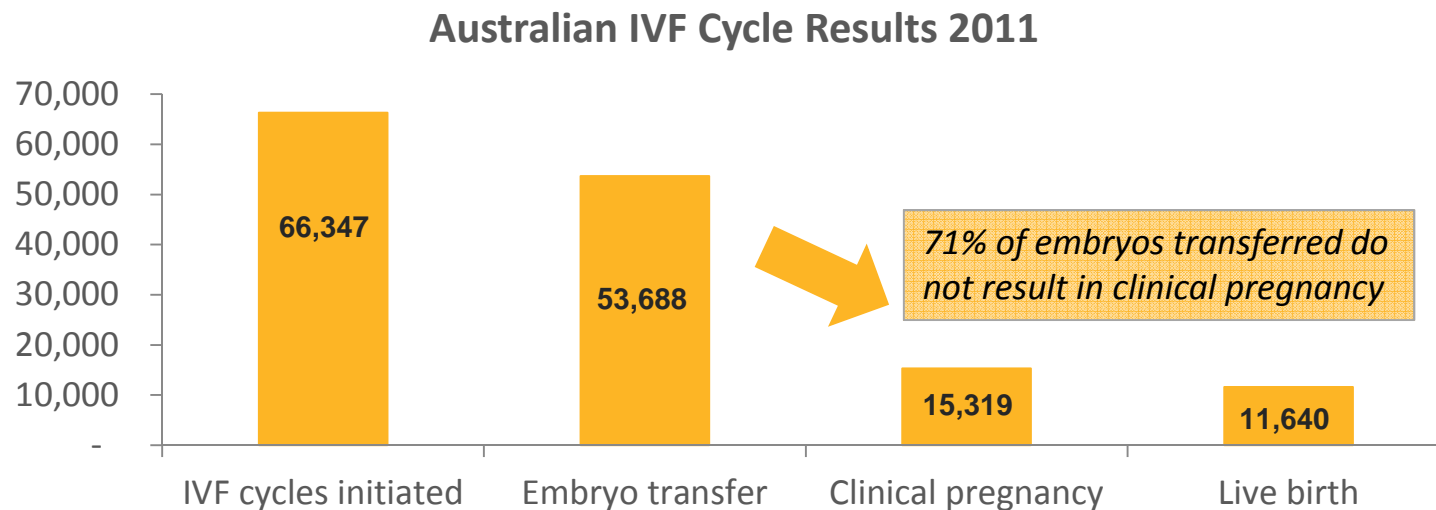
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- IVF – A clear need for improvement
- Modern IVF and PGS (Screening Embryos Pre-Transfer)
- Factors driving increased PGS use
- IVF and PGS Market Forecasts
- The RHS products
- RHS Competitive Advantages
- Intellectual Property
- Key Competitors

# IVF – A Clear Need For Improvement

Over 96% of IVF embryos that are aneuploid (which means having the wrong number of chromosomes) fail to implant resulting in:

- IVF failure or miscarriage
- Emotional trauma
- Significant financial cost to patients, insurers and Government

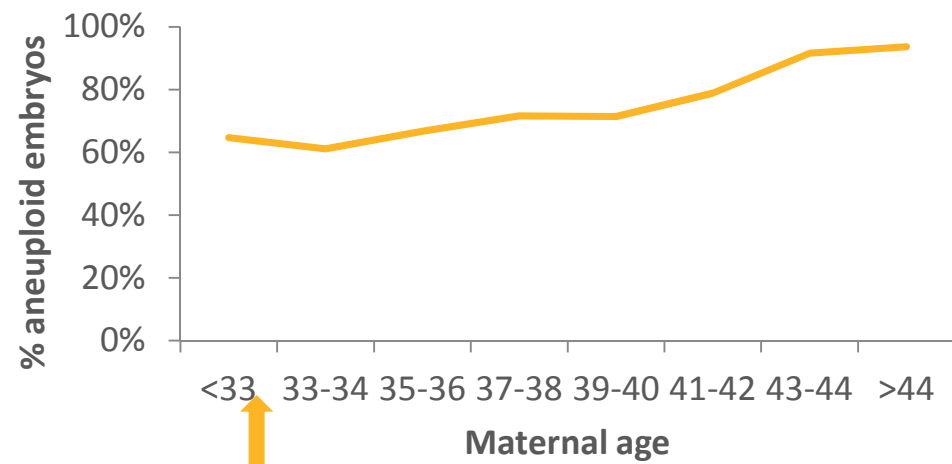


# Chromosome number errors are prevalent throughout reproductive years and increase with age

Pre-implantation Genetic Screening (PGS) increases pregnancy rates by enabling the selection of chromosomally normal embryos

Recently recognised clinical advance with 24 chromosome screening using microarrays first introduced in 2009. This technology advance provides breakthrough potential to improve IVF success

**Aneuploidy in embryos increases with maternal age**

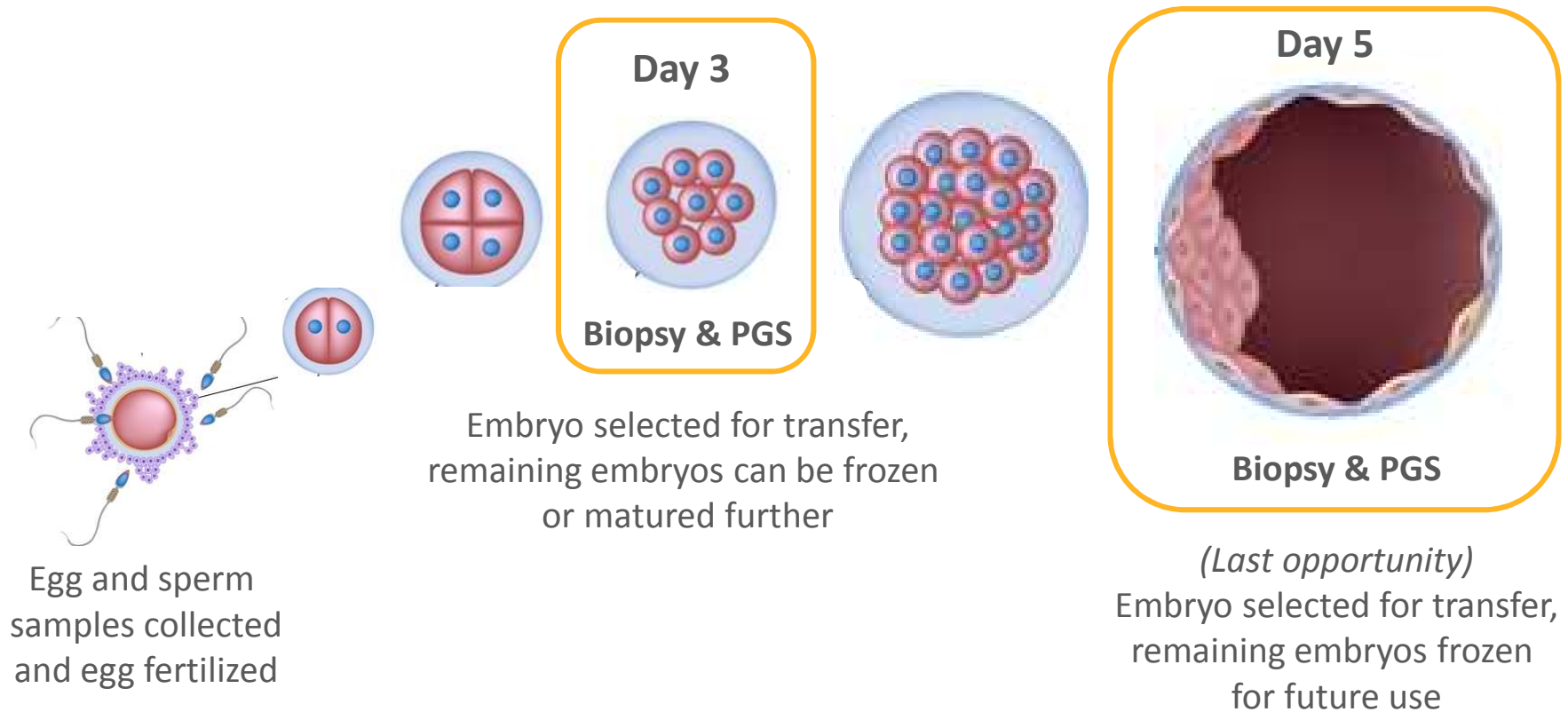


*Even younger IVF patients have significant numbers of aneuploid embryos*

Fiorentino, 2012

# Modern IVF and PGS (Screening Embryos Pre-Transfer)

## Process for obtaining cells for analysis





# Factors driving increased PGS use

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- **Pre-implantation Genetic Screening (PGS)** screens embryos before transfer during IVF to determine whether they have the correct number of chromosomes
- PGS increases the implantation rate and hence reduces the time to achieve pregnancy; even in younger women, with good prognosis, success increased >50%\*
  - Reduced risk of miscarriage
  - Allows single embryo transfer, avoiding risks of multiple pregnancies (twins, triplets, etc.)
  - Allows the selection of healthy embryos for freezing for future use
    - Estimated that there are over 1 million embryos already in storage
  - Overcomes the adverse impact of maternal age on IVF success
    - Embryos derived from “older mothers” commonly fail to implant, PGS can attain similar implantation rates as “younger mothers”

# The growth of IVF and PGS

The IVF market itself is growing globally, which generates significant untapped potential for PGS



*Patients lining up for fertility and prenatal treatment at a Hospital in Beijing, China*

# IVF and PGS Market Forecasts

	2013	Forecast 2019
Global IVF cycles per annum	1.7m*	3m (annual growth 10%)
Global PGS cycles per annum	51,000 (3% of IVF market)**	600,000 (20% of IVF market)
Number of tests per IVF cycle (average, estimate)	4	4
Number of PGS tests per annum	204,000	2.4m

\*Estimated based on there being a reported 1.5m IVF cycles in 2010 and 10% growth per annum

\*\* Illumina estimates Jan 2014

# The RHS products



What are they?

How do they work?

What is their potential?

Lead product → EmbryoCollect™ for IVF PGS  
(**P**re-implantation **G**enetic **S**creening)

# Testing Single Cells



Start with a single cell

**RHS PCR System**

Polymerase Chain Reaction (PCR)

Generate lots of copies of the cell's DNA using PCR to create enough test material

**RHS Microarray**

Interrogate the cell to gain information on the entire entity

Count the number of chromosomes in the cell

# RHS Products

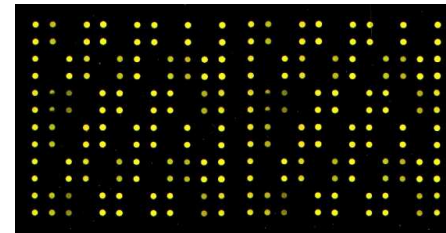
**Lead product** EmbryoCollect™  
IVF kit

**RHS microarray**

**RHS PCR kits**

Cell lysis and DNA amplification

Fluorescent labelling

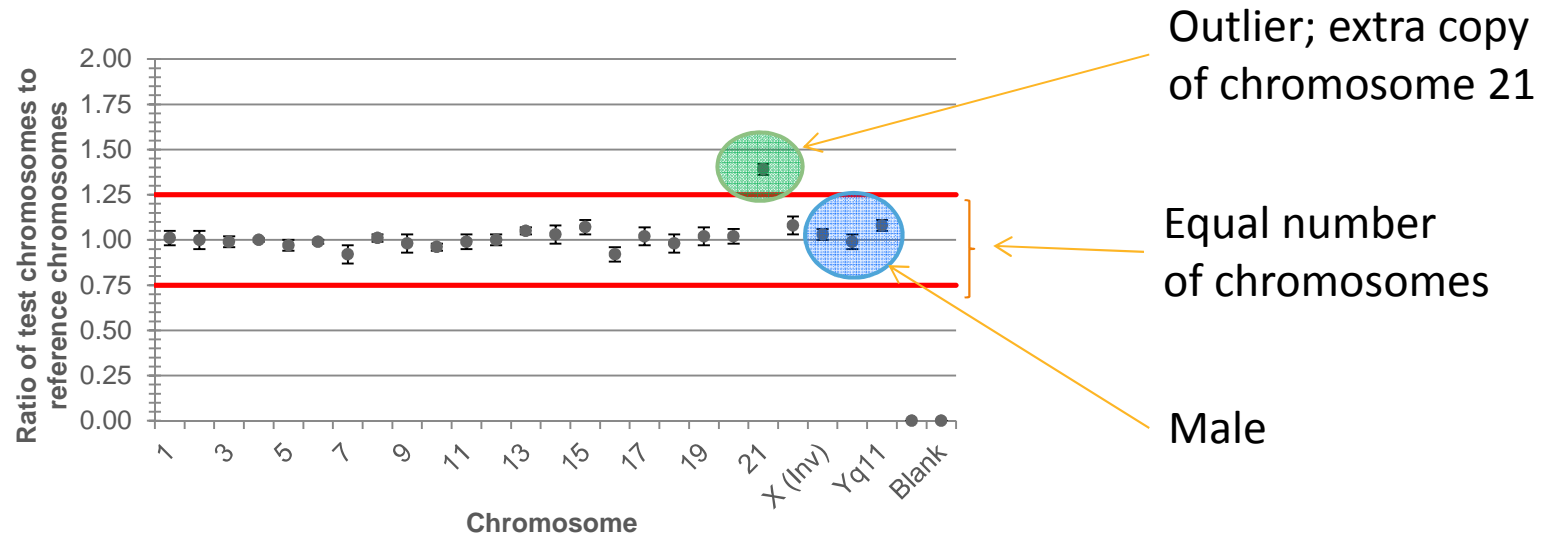


**Additional product**

Next Generation Sequencing



# RHS Microarray EmbryoCollect™ - improved, simpler PGS



RHS microarray results generated from a single blood lymphocyte from a male with Down Syndrome (47,XY+21)

The RHS microarray is able to generate visually simple results requiring minimal interpretation and limited genetic counselling.

RHS has validated that its microarray is >90% accurate for single cell chromosome analysis

# The RHS IVF Microarray Kit EmbryoCollect™

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- The end user product will comprise the PCR and Labelling Kit and the microarray
  - Manufacturing scale-up of the RHS microarray is uncomplicated and inexpensive
- Cost competitive pricing
- The kits are able to be sold as *research use only* products, not requiring regulatory approval





# Intellectual Property

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- Microarray patent family;
  - RHS has exclusively in-licensed a patent family from The University of Adelaide
  - Patent has been granted in the United States of America, Australia, New Zealand and China and allowed in Europe
  - Late stage examination in Canada, Hong Kong
- RHS has 10 years of know-how, providing significant expertise in the genetic analysis of low copy number DNA and single cells
- These technologies have broader applications

# Key Competitors in Single Cell Analysis

Technology	Company
DNA amplification	Rubicon Genomics Inc, Sigma-Aldrich Co. LLC, Qiagen N.V.
Microarrays	BlueGnome Ltd*, Agilent Technologies Inc, Natera Inc
Sequencing	Life Technologies Corp, Illumina Inc, Fluidigm Corp

*\*In September 2012, BlueGnome was acquired by Illumina for USD \$95.5m including USD \$88m in initial cash payments. At that time, Bluegnome were generating USD\$17m in revenues and \$1m in profits*

RHS products will compete across the DNA amplification, microarray and sequencing markets

# RHS Competitive Advantages

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Lead product EmbryoCollect™ offers:

- Robust single cell validation prior to clinical use
- Ease of use
- Simple interpretation not reliant on complicated algorithms
- No complex genetic counselling, thus limited ethical, legal risks
- Cost competitive pricing through relationship with Kapa Biosystems and in-house microarray development and manufacture
- The IVF market is poised to incorporate PGS widely



***AT THE FOREFRONT OF SINGLE CELL  
GENETIC ANALYSIS***

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