#### AOM acquisition of:



"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 March 2014

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# Key Points

- Highly leveraged to growth segment within global IVF (In Vitro Fertilisation) market through lead product – "embryo select\*"
- □ First sales mid-2014, follows 10 years of R&D
- Board and Management team with experience and profile in the IVF market
- The proposed capital raising is forecast to see the company fully funded through to positive cash flow and self-sufficiency



# **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	
Exclusively out- licensed know-how	Protocols for the PCR amplification of multiple and single cells	
Primary value driver	Global product sales	

#### **Overview**

Current ASX Code:	AOM
Shares on issue:	153m*
To be Issued to Vendors:	191.2m
Proposed issued shares Capital Raising:	151m
Total Proposed	513.1m
Reconstruction:	1:10 (to 20c per share)
Shares on issue post- reconstruction	51.3m
Unlisted options:	Various \$0.25 to \$2.01
Market Capitalisation:	\$10.3
Cash:	\$3.0m

\*153m shares on issue is after proposals to issue to former directors has been approved



## **Board of Directors and Key Management**

Dr David Brookes <b>Non-Executive Chairman</b>	Current director of AOM and Atcor Medical Holdings Ltd (ACG:ASX); medical practitioner & biotechnology consultant; FAICD
Dr Michelle Fraser <i>Managing Director and CEO</i>	CEO and director of RHS, PhD (molecular biology); Grad Dip Science & Technology Commercialisation; GAICD
Mr Simon O'Loughlin <i>Non-Executive director</i>	Current Chairman of AOM, founding member of O'Loughlin's Lawyers; Director of a number of ASX-listed companies including Chairman of Kilbaran Resources Ltd (KNL:ASX).
Mr Donald Stephens Non-Executive Director	Current director and Company Secretary of AOM, over 25 years experience in accounting. Three current directorships with ASX- listed companies and company secretarial positions.
Mr Johnathon Matthews Non-Executive Director	Executive director of The Pipette Company; BEc, BComm, LLB; previously held positions at Australian Treasury, ASX and Commonwealth Bank
Emeritus Professor Colin Matthews AO <i>Alternate Non-Executive</i> <i>Director</i>	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



# **RHS** Overview



- Commenced single cell genomics R&D in 2004
- Initial venture capital investment Oct 2007
  - \$4.4m invested and \$1.3m grant funding leveraged
- 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



# What is RHS?

- Developer of novel products for the analysis of the genetic content of single cells
- Lead product "embryo select" will be launched 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 to improve the success rate of In-Vitro Fertilisation (IVF)



#### **IVF – A Clear Need For Improvement**

Over 80% of IVF embryos fail to implant due to **aneuploidy** (which means having the wrong number of chromosomes) resulting in:

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



#### Australian IVF Cycle Results 2011



# Chromosome imbalance is prevalent throughout reproductive years and increases with age

Pre-implantation GeneticScreening (PGS) increasespregnancy rates by enabling theselection of chromosomallynormal 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



*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

- 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"



#### **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 growth of IVF and PGS

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





# The RHS products



What are they?

How do they work?

What is their potential?

Lead product → *"embryo select"* for IVF PGS (Pre-implantation Genetic Screening)

## **Testing Single Cells**



### **RHS Products**



#### RHS Microarray "embryo screen"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



RHS/Kapa PCR System (DNA amplification)



- RHS has out-licensed its proprietary PCR (Polymerase Chain Reaction) know-how to Kapa Biosystems for commercialisation
- Co-branded product launches are anticipated by mid-2014
  - Kits for whole genome amplification, fluorescent labelling and single cell sequencing
- RHS will receive a royalty on sales and Kapa is providing product extension opportunities and access to target markets beyond IVF to which Kapa already has access



#### The RHS IVF Microarray Kit "embryo select"

- 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**

- 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
  - Late stage examination in Europe, 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**

Lead product "embryo select" 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



### Timetable

NOM despatched	6 Feb
Prospectus lodged	6 Mar
□ EGM	13 Mar
ASX trading halt	13 Mar
Close Prospectus	28 Mar
Re-quotation on ASX	24 Apr



#### Summary

- RHS is known to the IVF distributor and key opinion leader networks
- RHS has established alliances with existing and potential commercial partners
- Ease of scale-up of kit production
- Anticipated key appointments of an executive sales and marketing team to further the marketing strategy and oversee broad commercial roll-out of the products
- □ 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





**Reproductive Health Science** 

AT THE FOREFRONT OF SINGLE CELL GENETIC ANALYSIS

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