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

- Held 3 EmbryoCellect™ training courses specifically designed for embryologists
- Commenced Pre-implantation Genetic Screening (PGS) service provision
- Commenced EmbryoCellect™ Kit sales
- Finalised DOPlify™ productisation and validated the performance of the kit using Next Generation Sequencing (NGS) in the lead up to launch
- Filed a patent to a method combining whole genome amplification for PGS with targeted amplification for Preimplantation Genetic Diagnosis (PGD), strengthening the IP portfolio of the Company
Financials – year to Dec 2015

- Initial EmbryoCellect™ sales of $65k were recognised in 2015
- Service provision commenced in the December 2015 quarter (initial sales $8k during start-up phase)
- Other income of $360k (R&D Tax Credit, Export Market Development Grant & interest)
Cash at bank 30\textsuperscript{th} April 2016 $0.9m

- + 2015 R&D Tax Refund being prepared (receipt expected July/August 2016)
- + EMDG 2\textsuperscript{nd} instalment expected June

Monthly operating cash requirements remain < $0.16m

Recent EmbryoCellect\textsuperscript{TM} sales in March of $12k & orders are expected to increase following completion of client evaluations

Services income was $6k in April, we expect services income to settle to a consistent base revenue with ongoing growth

New revenue opportunity with DOPlify\textsuperscript{TM} kit

Both the production and service businesses are readily scalable
EmbryoCellect™ update

Kit for the determination of chromosomal content from single or small numbers of cells, targeted at detecting aneuploidy in IVF embryo biopsies
Concerns with the accuracy and sensitivity of the 24sure PGS array from Illumina compared to their VeriSeq NGS kit have impacted on the market perception of arrays in general.

NGS approaches need large sample numbers (for example 24 samples with VeriSeq) to reduce the expense per sample. These volumes are not achievable by individual clinics unless they offer a service to other clinics.

Large global service providers are capturing the PGS NGS market; however, this impacts on time to result and price to patients. Currently PGS is not reimbursed.
Current status of PGS - clinical

- With the additional information provided by NGS comes more complicated data analysis, representing increased analysis complexity and time and exposure from uninterrogated genetic information.

- Embryos are not always made up of one population of cells. The ability to detect one in 5 cells being aneuploid (called low level mosaicism) creates the clinical dilemma of whether to transfer the embryo or not.
  - Some clinics are transferring mosaic embryos whilst others are calling them aneuploid and not transferring them. Current clinical data suggests that 40% of the mosaic embryos can result in a healthy live birth, the same frequency as untested embryos.

This demonstrates just one of the clinical
EmbryoCellect™ marketing strategy refinement

- EmbryoCellect™ was initially intended as a product to capitalise on the growing interest in PGS from clinics about to adopt PGS, offering them an uncomplicated, robust solution.

- The RHS PGS service is providing clinical confidence in EmbryoCellect™ and supporting the use of PGS in general.

- Those companies undertaking in-house evaluation of EmbryoCellect™ are using competing PGS products and are benchmarking protocols and relative performance.
  - This shift has significantly impacted on the rate of revenue generation.

- In summary, PGS is still in its early stage of adoption even by large clinics and clinicians are often hesitant to offer it to their patients due to the increased cost of IVF.
Competitive advantages of EmbryoCellect™

- Simple protocol intended for easy integration into IVF clinics with existing PCR expertise
- Optimised for and validated using large numbers of single cells
- Ideally suited to clinics requiring a fast, less expensive, small capacity kit for fresh embryo transfers
- Straightforward analysis and results offering clinics simplified decision making tools for PGS
- Array performance accuracy for aneuploidy detection is comparable to published data for competing array and NGS products
Comparison of array results

EmbryoCellect™ single cell, trisomy 15
Simple, robust chromosome aneuploidy detection

RHS provides a clearer result for whole chromosome aneuploidy

Illumina 24sure single cell, monosomy 2, 6, 7, 8, 9, 14, 18, 21, 22, trisomy 17

Agilent Genetisure single cell, Monosomy 2, 5, 9, trisomy 16
Extended marketing strategy

- **Training courses**
  - RHS held its third EmbryoCellect™ training course at our facilities in March 2016. The next training course for 2016 will be held in August
    - RHS is already receiving expressions of interest

- **Presentations**
  - Invited to present to key opinion leaders in the UK and Japan
  - Abstracts accepted for presentation at international conferences PGDIS and ESHRE
EmbryoCellect™ global marketing

- 2016 International conferences
  - Asia Pacific Initiative on Reproduction (ASPIRE)
    - Jakarta, April 2016, exhibitor
  - Pre-implantation Genetic Diagnosis International Symposium (PGDIS)
    - Bologna, May 2016, exhibitor and presenter
  - European Society Human Reproduction and Embryology (ESHRE)
    - Helsinki, July 2016, exhibitor and presenter
  - American Society for Reproduction Medicine (ASRM)
    - Salt Lake City, October 2016 exhibitor

- 2016 National conferences to attend
  - Scientists in Reproductive Technologies (SIRT) Adelaide, April/May 2016
  - Fertility Society of Australia (FSA) Perth September 2016
RHS PGS service business

- Established to meet customer needs
  - A substantial number of embryo biopsies from a broad range of patients with prior unsuccessful IVF outcomes have been completed
  - The healthy pregnancies reported by Flinders provide clinical validation of EmbryoCellect™
  - This positive outcome is anticipated to increased the use of PGS
  - In advanced discussions with other entities which include partnering opportunities to bring PGS to new emerging markets
The increasing use of PGS

- RHS market feedback suggests that 20% of US IVF cycles use PGS
- Virtus reported an increase in their number of PGS cycles by 54% in the last half year. Australia is an early adopter market with some centres reporting at least 30% PGS cycles and some of the larger providers are planning to commence PGS soon
- Illumina have estimated that globally more than 500,000 embryos have undergone PGS
- Genesis Genetics performs approximately 75,000 PGD, PGS and prenatal tests per annum (PGDIS 2016)
- RHS is confident that there will continue to be strong growth in the use of PGS, based on discussions held with clinics both locally and abroad and also recent acquisitions in the space
## The Opportunity: PGS Market

### Forecasts

<table>
<thead>
<tr>
<th></th>
<th>2013 data</th>
<th>Forecast 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global IVF cycles per annum</td>
<td>1.7m*</td>
<td>3m</td>
</tr>
<tr>
<td></td>
<td>(annual growth 10%)</td>
<td></td>
</tr>
<tr>
<td>Global PGS cycles per annum</td>
<td>51,000 (3% of IVF market)**</td>
<td>600,000 (20% of IVF market)***</td>
</tr>
<tr>
<td>Number of tests per IVF cycle (average, estimate)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Number of PGS tests per annum</td>
<td>204,000</td>
<td>2.4m</td>
</tr>
</tbody>
</table>

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

** Illumina estimate Jan 2014

*** RHS forecast based on market opportunity analysis
DOPlify™

Lysis and whole genome amplification kit for the amplification of DNA from limited starting material, including single cells
Captures RHS proprietary know-how for the lysis and whole genome amplification of single or small numbers of cells providing a solution for the amplification of limited DNA for a range of downstream applications, including:

- PGS and PGD
- Circulating tumour cells
- Stem cells
- Forensics
- Agricultural
- Disease surveillance
What is Whole Genome Amplification?

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1,000,000s of picograms of DNA from 1 cell
Copies of the whole genome
Whole Genome Amplification

- The most important determinant of accuracy for genetic analysis of single or small numbers of cells is the whole genome amplification. This is regardless of whether NGS or microarrays are used for the analysis.
- The upcoming launch of RHS’s lysis and whole genome amplification kit DOPlify™ will be the first Advanced DOP-PCR amplification kit on the market and represents a significant opportunity for RHS.
- RHS’s Advanced DOP-PCR is a unique method offering accuracy, robustness and flexibility to whole genome amplification not offered by competing methods.
WGA kit comparison

- Whilst there are a small number of WGA kits on the market, they are all different in the way that they copy the DNA template.
  - Different methods have different abilities to copy the DNA leading to differences in how much of the DNA is copied and biases in what is copied.

<table>
<thead>
<tr>
<th></th>
<th>GenomiPlex</th>
<th>PicoPlex/ SurePlex</th>
<th>Repli-G</th>
<th>MALBAC</th>
<th>DOPlify™</th>
</tr>
</thead>
<tbody>
<tr>
<td>From</td>
<td>Rubicon/ Sigma</td>
<td>Rubicon/ Illumina, Agilent</td>
<td>Qiagen/ Illumina</td>
<td>Yikon</td>
<td>RHS</td>
</tr>
<tr>
<td>Launched</td>
<td>Feb-06</td>
<td>Jun-09</td>
<td>Oct-12</td>
<td>Oct-14</td>
<td>Mid-16</td>
</tr>
<tr>
<td>Lysis</td>
<td>Proteinase K digestion</td>
<td>Enzyme</td>
<td>DTT-based</td>
<td>Enzyme</td>
<td>Enzyme</td>
</tr>
<tr>
<td>Amplification</td>
<td>Linker adapter PCR</td>
<td>Linker adapter PCR</td>
<td>Multiple displacement amplification</td>
<td>Linker adapter MDA hybrid</td>
<td>Advanced DOP PCR</td>
</tr>
<tr>
<td>Total incubation time (mins)</td>
<td>200</td>
<td>160</td>
<td>483</td>
<td>128</td>
<td>103</td>
</tr>
</tbody>
</table>
What is Next Generation Sequencing?

DOPlify™

Sequencing
1. Library preparation
   - Determining the DNA code

Bioinformatics
1. Checking the quality of the sequencing run
2. Working out where the >1 million DNA fragments match within the entire human genome
3. Looking for differences with the reference genome
4. Determining whether the differences are clinically significant or not using published databases

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## Comparison of NGS protocols for PGS

- The RHS protocol generated more than double the number of reads per sample as expected using the competing NGS protocols whilst also processing twice as many samples. This is expected to lead to a significant reduction in the cost per sample.

<table>
<thead>
<tr>
<th></th>
<th>RHS protocol</th>
<th>VeriSeq</th>
<th>Ion ReproSeq 318 chip</th>
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<tbody>
<tr>
<td>NGS platform</td>
<td>Illumina MiSeq</td>
<td>Illumina MiSeq</td>
<td>ThermoFisher Scientific Ion PGM</td>
</tr>
<tr>
<td>WGA method</td>
<td>DOPlify™</td>
<td>SurePlex</td>
<td>MDA</td>
</tr>
<tr>
<td>Library prep method</td>
<td>Nextera</td>
<td>Nextera</td>
<td>Ion SingleSeq™ Kit</td>
</tr>
<tr>
<td>Read length (bp)</td>
<td>300bp Paired-end</td>
<td>36bp</td>
<td>230-240bp</td>
</tr>
<tr>
<td>Total capacity of sequencer (reads)</td>
<td>30 million</td>
<td>30 million</td>
<td>4-5 million</td>
</tr>
<tr>
<td>Number of samples tested</td>
<td>48</td>
<td>24</td>
<td>2-24</td>
</tr>
<tr>
<td>Total aligned reads/sample</td>
<td>1.3 million</td>
<td>500,000</td>
<td>100,000</td>
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RHS’s strong IP portfolio

- RHS’s commitment to providing solutions to genetic analysis has led us to develop a protocol for the concurrent determination of chromosomal aneuploidy with the detection of genes of clinical significance.

- This is a mechanism to get more genetic information from a precious sample and provides unprecedented opportunity for the transfer of disease-free euploid IVF embryos.

- RHS has recently filed additional patents including to the combined use of PGD and PGS.
The correct aneuploidy result was maintained and the targeted gene was evident using both traditional PGD and NGS approaches.
Data of relevance – NGS and array

- RHS has demonstrated the ability to reliably determine aneuploidy using arrays or NGS and to detect chromosomal translocations down to 15Mb (smaller changes have not been tested yet).
- RHS has been able to detect a cancer-associated BRCA1 mutation from just 5 cells, the equivalent of a day 5 embryo biopsy.
Why RHS?

- RHS has amassed over 10 years of technical expertise in the genetic analysis of single cells including a strong IP portfolio.
- This has led to the development of cutting edge technologies that compete on performance with products from global multinationals.
- RHS has continued to strategically position its technology to stay relevant for PGS and to provide expansion opportunities into other valuable clinical and non-clinical markets.
- By keeping up with rapidly advancing genomics applications and using our advanced molecular biology expertise, RHS remains focussed on achieving profitability in 2017.
Reproductive Health Science

AT THE FOREFRONT OF SINGLE CELL GENETIC ANALYSIS

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