ACN 010 126 708

ASX Release
27 November 2017

RHS demonstrates advanced performance for NGS product PG-Seq™

Highlights from ASRM 2017

- Repromed releases validation data for non-invasive embryo testing being co-developed with RHS
- Validation results for new RHS product PG-Seq™ released confirming test accuracy
- Ability to detect BRCA1 mutation from 5 cells demonstrated, providing option of screening IVF embryo biopsies for cancer risk

Highlights subsequent

- Throughput of PG-Seq™ quadrupled compared to competitor kits, a product that can significantly expand RHS' revenue streams and of interest to large global service labs
- RHS validates PG-Seq™ on significantly cheaper Illumina sequencer & targets clinics considering bringing embryo testing in-house
- Progression in commercial relationships for genomic solutions using RHS products

Adelaide, 27 November 2017 :RHS Limited (ASX:RHS) ("RHS" or the "Company") is pleased to report high levels of commercial interest in its products and capabilities following the recent American Society of Reproductive Medicine (ASRM) conference held in San Antonio, USA.

In particular, the use of embryo culture medium for non-invasive Preimplantation Genetic Testing for Aneuploidy (PGT-A, previously called PGS) has been received very positively and is creating opportunities for DOPlify™ and PG-Seq™ with a number of clinics globally.

The strong interest follows the presentation of results from the co-development of non-invasive PGT-A by Repromed (Monash IVF Group) and RHS, which showed a 93% concordance between culture media and biopsy. The ability to use spent embryo culture media makes sample collection low tech and simple and makes PGT-A more accessible to clinics. Embryo biopsy for the current PGT-A requires considerable operator skill and specialised biopsy equipment. Non-invasive PGT-A is anticipated to significantly increase the uptake of this testing from its current use in approximately 10% of the estimated 2 million global annual IVF cycles. Analysis of the culture media can be performed in-house or the media can be sent to a service provider. RHS will continue to update the market on the progress of this exciting technology and the relationship with Monash IVF Group as it progresses.

The new RHS product PG-Seq™ incorporates our WGA (Whole Genome Amplification) product DOPlify™ followed by sample preparation for NGS (Next Generation Sequencing) and software for analysis and reporting. Similar competitor kits for PGT-A typically cost approximately USD$100 per sample. PG-Seq™ has been validated as highly accurate, with sensitivity of 98.4% and specificity of 100% for samples of 5 cells. A summary of the PG-Seq™ validation study is available on the RHS website (http://www.rhsc.com.au/uploads/general/PG-Seq_full_validation_data.pdf).

The main competitor NGS product, VeriSeq from Illumina is capable of analysing 24 embryo biopsies using the MiSeq sequencer. RHS' PG-Seq™ has been validated for the analysis of 48 samples on the same MiSeq sequencer and has now been further validated for analysing 96 samples on the same sequencer. This very high throughput workflow offers additional lab efficiencies and has received positive feedback from the large capacity labs and clinics. Additionally, RHS has just completed validation of PG-Seq™ on the Illumina MiniSeq sequencer, an instrument which is sold for less than half the price of the MiSeq. This represents a significant cost saving to clinics and labs that are considering starting PGT-A and have not purchased their sequencer equipment yet. These parallel advances provide advantages for the full range of end users.

RHS commercial and scientific teams are readying for full commercial launch of PG-Seq™ with external clinical validation already underway and progressing well, as expected.

RHS has also developed a unique embryo signature using the mitochondrial DNA that can be used to confirm embryo identity. This is specific to RHS and will be included in the second generation software for PG-Seq™.

Recently it was announced that Medicare will subsidise genetic screens for BRCA1 and 2 mutations in patients diagnosed with breast or ovarian cancer and their families (http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt113.htm and http://www.msac.gov.au/internet/msac/publishing.nsf/content/D3E96917F7B2253BCA25801000123C2E/$File/PSD_1411.1.pdf). It is feasible that individuals diagnosed as being positive for mutations in these genes may choose IVF to screen their embryos in the future. This screening called PGT-M (Preimplantation Genetic Testing for Monogenic Disorders, previously known as PGD) can be used to identify unaffected embryos that can be transferred and provides the ability to remove the mutation from future generations. RHS has already released proof of principle for the detection of BRCA1 mutations from samples of 5 cells using its proprietary Target Sequence Enrichment protocol.

RHS is also co-developing the use of DOPlify™ in a number of commercially available products and services with commercial partners to improve sensitivity for single cell analysis. These products and services span Pre-implantation Genetic Testing, Non-invasive Prenatal Testing and cancer "liquid biopsy" applications.

RHS' CEO, Dr. Michelle Fraser, will be providing an updated Company presentation for investors next week as part of a series of planned investor meetings to be held in early December.

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About RHS

RHS is a developer of advanced single cell genomic technologies focussed on improving health and research outcomes, based on deep technical experience in the field. DOPlify™ is a platform product for whole genome amplification (WGA) of single or small numbers of cells. DOPlify™ is applicable to the global Next Generation Sequencing (NGS) market. PG-Seq™, RHS' NGS workflow and EmbryoCellect®, RHS' microarray workflow, both incorporate DOPlify™ and have been specifically designed for the genetic screening of IVF embryos.

About PG-Seq™

RHS' validation of PG-Seq™ for Pre-implantation Genetic Testing for Aneuploidy (PGT-A) is by far the most extensive dataset released for any equivalent product. The release of RHS' cell line validation data coincides with the commencement of clinical validation at 2 selected independent clinical sites, each of which will generate comparative data from rebiopsied embryos that have previously been tested with VeriSeq.

PG-Seq™ includes all of the specific reagents needed for PGT-A and is sold under the Research Use Only product label. RHS is now finalising supplier agreements in preparation for full commercial launch and will supply PG-Seq™ under a targeted early access program prior to the official product launch in early 2018.

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Issued Capital
89.9 million shares
7.05 million options

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