

PROGRESS ACCELERATES FOR REPRODUCTIVE BIOTECHNOLOGY PORTFOLIO

Highlights

- **Memphasys continues to improve its portfolio of novel reproductive biotechnology products led by Prof. John Aitken and the team at University of Newcastle**
- **Stallion dismount fertility diagnostic prototype (SAMSON) approaching product finalisation**
- **SAMSON's diagnostic potential to be field tested during Sept-Nov 2021 Australian horse breeding season**
- **Semen long-life storage media, new sperm separation devices and sperm oxidative stress diagnostics also under development**

Australian-based bio-separations and reproductive biotechnology company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to provide a progress update on its portfolio of novel reproductive biotechnology products targeting high-value commercial applications.

Following the appointment of globally renowned andrology expert Professor John Aitken as Scientific Director (see ASX Announcement dated 5 July 2021) the Company has continued to accelerate its research activities across its human and animal artificial reproduction portfolio.

SAMSON Stallion fertility dismount

Memphasys' most advanced novel product is its SAMSON stallion fertility diagnostic, which continues to progress through the prototype development phase (see ASX Announcement dated 4 May 2021) and has been shown to perform effectively in laboratory trials.

SAMSON is targeted to be a rapid and easily applied in-vitro test, used by horse breeders initially, to assess the probability of the stallion's semen to fertilise a mare. The fertilising potential of semen from hooved animals (ungulates) like stallions, bulls, rams, etc needs different assessment methods from those employed to evaluate human semen due to their distinct pattern of metabolism.

A small ejaculate sample will be placed into a SAMSON cartridge and processed by the device, providing feedback in 15 minutes on the quality of the semen sample. Such a device would represent a major advancement over traditional diagnostic methods which are based on a labour-intensive cytological evaluation of the semen profile using laboratory-based tests by an expert in the field. By contrast, SAMSON is designed to provide rapid feedback on semen quality at the push of a button.

The Samson test can be used for both thoroughbreds and standard bred horses. For thoroughbreds, it is used immediately after the natural mating of the mare. For standardbreds, it is used to determine fertilising potential of semen collected for later AI procedures. There can be a high variability of semen quality, even within the same stallion, from day to day and even within the same day.

A SAMSON prototype product is to be field trialed during the Australian horse breeding season (September to December). A thoroughbred stud and standardbred stud farm for the assessment have been arranged and testing will begin as NSW COVID-19 lockdown constraints lift.

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Should researchers not be able to access the sites during the breeding season due to COVID-19 restrictions, Memphasys has proactively identified a potential field site in the USA where stallions could be assessed during the US breeding season (February – May) but this will also depend on lockdown constraints.

Semen Long-Life Storage Media

Memphasys, in conjunction with University of Newcastle (UoN), is currently developing a technology to enable human semen to be held at ambient temperature and shipped from the donor directly to andrology and IVF laboratories for sperm quality assessments. It is envisioned that a human long-life medium will allow these semen samples to remain intact for diagnostic purposes for about a week without the need for freezing, as opposed to a maximum of 24 hours currently. Access to fresh, rather than frozen, semen greatly increases the accuracy of diagnostic tests because it permits analysis of parameters such as sperm motility and some tests of DNA damage, which are seriously compromised when samples are frozen. This device would also eliminate the need for a man to travel to an IVF lab to donate his semen sample for assessment.

There is a growing demand, particularly from diagnostics companies, for a medium which will permit the safe storage and transport of semen from the donor to the laboratory and not increase the risk of DNA damage.

The development of long-life media may also unlock further potential products such as an improved cryostorage medium. Current cryostorage practices are sub-optimal and have not changed for more than half a century. Whilst this project is only just beginning, success to date with other media projects has provided insights on how such media may be developed.

New Sperm Separation Devices

Memphasys and UoN are researching new methods for selecting very high-quality sperm cells for use in Intracytoplasmic Sperm Injection (ICSI). In the ICSI process a single sperm is selected to be injected into the egg to fertilise it. It is important to select a cell with minimal DNA damage as one with high DNA damage can cause birth defects as well as longer term effects on the health/wellbeing of the child.

Sperm Oxidative Stress Diagnostic Test

Oxidative stress is the process by which key biological components (lipids, proteins and nucleic acids) become damaged by the presence of reactive oxygen species (ROS). Oxidative stress occurs when ROS production and the generation of free radicals outstrip the cell's antioxidant defenses.

Oxidative stress is not only linked to male infertility but also to a wide range of other human diseases such as Alzheimer's, diabetes and even heart disease.

Memphasys and the UoN team are researching the potential for developing a diagnostic test which will enable the measurement of the level of oxidative stress in biological fluids such as semen, blood and urine.

The test would give an assessment of the sample's oxidative stress levels and could be used in the IVF clinic or in the GP's office. The diagnostic could also be used to monitor the efficacy of the prescribed antioxidant therapy for those diagnosed with sperm that has oxidative stress.

There are many companies around the world selling antioxidant therapies for infertility, but there has never been a simple diagnostic test for oxidative stress that has been accepted by mainstream medicine. While in appropriate cases antioxidant therapy can prove beneficial, it also runs the risk of doing

considerable harm. Powerful antioxidants offered to people who do not need them may see the patient experience a decline in overall health resulting from 'reductive stress', the opposite of oxidative stress.

An appropriate course of antioxidant therapy would see the patient safely reduce their levels of oxidative stress and thereby improve the potential for conception.

Commenting on progress, Memphasys Executive Chair Alison Coutts said:

"We continue to be buoyed by the early successes we are seeing emanating from the developmental work on these projects being done by the University of Newcastle team, led by Distinguished Laureate Professor John Aitken. It is painstaking work requiring high levels of intellectual input and rigorous, laboratory trialling. So far it is showing great potential for the delivery of multiple innovative, high value products to address reproductive issues in humans and animal alike."

This announcement has been approved for release by the board of Memphasys Limited.

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About Memphasys:

Memphasys Limited (**ASX: MEM**) specialises in biological separations and reproductive biotechnology for high value commercial applications.

Reproductive biotechnology products in development include medical devices, in vitro diagnostics, and new proprietary media.

The Company's patented bio-separation technology, utilised by the Company's most advanced product, the Felix™ device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.

Website: www.memphasys.com

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