ASX Release
ASX Code: MEM

28 November 2022

CHAIRMAN'S AGM ADDRESS

Memphasys Limited (ASX: MEM) ('the Company' or 'Memphasys' provides the following address to shareholders at the Company's Annual General Meeting on 28 November 2022.

Good morning shareholders and thank you for joining us today at this year's Annual General Meeting.

My name is Robert Cooke. For those of you I have not had the pleasure of meeting before, I assumed the role of Chairman of the board of Memphasys in April 2022, replacing Ms. Alison Coutts who held the dual role of Managing Director and Executive Chairman prior to that date.

In terms of my background, I have more than 40 years' experience in healthcare, spanning executive leadership of publicly listed and privately-owned healthcare companies, overseeing numerous M&A transactions, and management of private and public hospitals in Australia, Asia and the United Kingdom.

I was the Managing Director and Chief Executive Officer of Healthscope from 2010-2017 and am currently the Non-Executive Chairman of OptiScan Imaging. I also hold other directorships in private companies.

The reason for the change of chairperson is two-fold. It allows Ms. Coutts more time and opportunity to focus on business development and the day-to-day operations of the Company. The appointment of a dedicated chair also expands the board's capabilities as Memphasys continues to progress its strategy further into the commercialisation phase of its products.

I would also like to thank Mr Shane Hartwig who resigned as Non-Executive Director on the Memphasys board in April this year to focus on other business interests.

Memphasys delivered solid progress for shareholders in 2022.

Our progress is a result of the efforts of our talented and dedicated people and your Board would like to thank them for their commitment to developing Memphasys as an emerging reproductive biotechnology company.

I would especially like to thank Dr John Aitken, Distinguished Emeritus Laureate Professor of Biological Sciences. Dr Aitken stepped down from his role at the University of Newcastle in 2022 and appointed Scientific Director at Memphasys. He heads a team of seven biotechnology experts located at University of Newcastle who are exclusively dedicated to the development our product pipeline.

I would also like to thank Ms. Coutts for her vision of Memphasys and acknowledge the tireless dedication she has shown to building the Company from the bottom up.

Our ability to progress the business has been particularly important as we faced a continued period of challenges in the past two years with the COVID-19 pandemic.

The operating environment has a defining influence on the performance of our business, and it was not immune to the impact the pandemic had on market forces across the globe in the past financial year. Our access to target markets was heavily restricted and this has limited our ability to readily engage potential stakeholders at the rate we would have hoped. The delivery of some timelines in our tactical plan were pushed back as a result.

We are pleased to note that since the reopening of markets in mid-2022, Memphasys has been able to engage with its offshore stakeholders in person for the first time in almost three years. The simple fact of being able to travel has very positively influenced our interaction with medical institutions and stakeholders in global target markets in the past few months.

Memphasys has a compelling investor narrative. We operate in a sector with strong and growing market demand. We have globally recognised research and development capabilities. We have a diversified portfolio of company-making products. We have a strong, stable, and experienced team in developing and commercialising human and animal health products. Most importantly, we have an effective strategy to deliver long-term value for our shareholders.

Your Board remains focused on Memphasys vision of becoming Australia's leading provider of reproductive biotechnology products.

The fundamentals of our business are strong, our faith in Memphasys is resolute. We will continue to advance our strategy and to effectively manage the challenges of our operating environment as we progress our business into 2023.

On behalf of the Memphasys board, I would like to thank you for your valuable support of Memphasys over the past year. I would also like to take this opportunity to thank my fellow board members for their contribution to Memphasys in 2022.

I will now hand you over to Ms. Coutts, who will take you through the Chief Executive Officer and Managing Director's 'Review of Operations' for the past financial year.

MANAGING DIRECTOR'S AGM ADDRESS

Memphasys Limited (ASX: MEM) ('the Company' or 'Memphasys' provides the following address to shareholders at the Company's Annual General Meeting on 28 November 2022.

Thank you, Robert,

Good morning and welcome to Memphasys 2022 Annual General Meeting. Thank you for being here with us today.

The past twelve months have been a period of important strategic growth at Memphasys. The Company has successfully transitioned from the product development phase of its Felix™ system to the launch of its commercial clinical sales in India and preparation to launch in Japan and Canada.

We were able make this transition in the difficult operating environment caused by COVID-19, which subsequently impacted our supply chains, and slowed trials and temporarily closed IVF clinics globally.

Felix™ System

I would now like to provide progress report on the Memphasys product suite, starting with an update on commercial sales of the Felix™ System in a number of early markets.

India

In 2022, Memphasys completed the first clinical sale of the Felix™ System, comprising a desktop console and sterile Felix™ System single-use cartridges to process semen samples, to the Coimbatore Women's Hospital Centre in India. The hospital followed up its initial order with repeat purchases of cartridges.

In August, the Indian regulator, the Central Drugs Standard Control Organisation (CDSCO), introduced changes to the regulation of all medical devices sold in India and to all Assisted Reproductive Technology (ART) clinical processes undertaken in India. These changes have had a short-term impact on our sales schedule for the Felix™ system in that market.

We have been actively consulting with our Indian-based regulatory adviser on the changes and taken significant steps to comply with the amendments by submitting a voluntary product registration with CDSCO.

Very recently, I returned from India where I engaged directly with our Indian Key Opinion Leader ("KOL") partners on their approach to the new regulations. I also spoke with consultants, Indian medical device manufacturers and distributors who are all working their way through these new regulations.

The new regulations have sought to improve IVF processes throughout India, which is a much-needed change. The government now recognises the World Health Organisation's definition of infertility as a disease and is actively seeking to reduce the high infertility load in India. Medical colleges are now introducing IVF as a subject in the curriculum and all IVF clinics must now be registered and audited. Commercial surrogacy – a previously common practice in India – has been banned and private surrogacy has been limited to one donor, one recipient, once only per life, per married couple. The couple must also insure the donor.

Greater regulation on medical devices has also been implemented, but the rules are still opaque. For example, the regulations do not specify the classification for a novel device such as the Felix™ system.

At this point, we cannot confirm how long CDSCO will take to issue us a license to sell the Felix™ system in India nor whether the CDSCO will agree with the classification we have nominated. There is a backlog of applications and the timeframe for registration is uncertain.

One alternative under consideration is to manufacture in India. This could significantly reduce the Felix™ System production costs, which is an important consideration in the price sensitive Indian market. In addition, there would be no import duty or import agent fees. Of note, in-country manufacturing is given priority by CDSCO for granting licenses to sell domestically. There are also potential inducements by the Indian government and various state governments to establish manufacturing in India.

Japan

Due to changes to Japan's IVF insurance market, MEM has chosen to initially work with clinics only treating self-funded patients.

We are currently working with our KOL partner in Japan, a major clinic in Tokyo and Osaka, which deals with difficult infertility cases. This clinic will commence a small *in vivo* clinical trial to assess the Felix™ System, which is expected to be completed in the next few months. The clinic has indicated they may buy the Felix™ System based on the outcome of the trials.

Canada

Memphasys is also in the process of undertaking an *in vivo* clinical trial of Felix™ System with a large Canadian KOL site, which has also indicated a potential willingness to purchase the Felix™ System based on the clinical trial results.

China

In conjunction with our Chinese distribution partner, Memphasys has completed and translated the Felix™ System's regulatory documentation for submission to China's regulatory authority, the National Medical Products Administration (NMPA).

Memphasys is preparing two applications to NMPA: the first requesting a device classification for the Felix™ System; the second seeking eligibility for the fast-tracked 'Green Channel' regulatory pathway for innovative medical products. The Company anticipates the NMPA will review these applications concurrently over the next couple of months and we will keep investors informed of further progress.

United States of America

A pre-submission meeting request has been submitted to the Food and Drug Administration (FDA). Memphasys expects to receive feedback from the FDA in early 2023.

I would like to quickly discuss why regulation is so important and why it can sometimes influence the timing of our business development schedule.

We own a world-class reproductive device in the Felix™ System and our aim is to sell it globally. Effectively managing regulations in any jurisdiction is an essential component of the development and commercialisation of any product. Regulatory improvements are positive for the development of our business. They improve market stability and clarity, and provides more certainty around the opportunities for MEM in these markets.

Australia

Memphasys is currently conducting a clinical trial in collaboration with leading Australian reproductive and fertility services company, Monash IVF Group Ltd (MVF). The trial seeks to assess the safety and performance of the Felix™ System versus the traditional sperm preparation techniques: Swim-up and Density Gradient Centrifugation (DGC).

The results of the clinical study will be filed in a conformity assessment application to the Australian Therapeutic Goods Administration (TGA). This is required for the commercial sale of the Felix™ System in Australia and to support its registration in other jurisdictions.

The trial's overall initial (blinded) results have been encouraging with respect to fertilisation rates and embryo utilisation rates. To date, the combined data from the Felix™ System and the alternative sperm preparation techniques (Swim-up or DGC) have exceeded clinical performance expectations, with no reported adverse effects.

Mobius Medical Pty Ltd (Mobius), the clinical research organisation project managing the trial, has noted participation rates have been lower than expected across their various clinical trial sites post-COVID. This is mainly due to patients failing to meet the trial's stringent entry criteria. We anticipate the trial's completion will be pushed back into 2023.

Memphasys is working with MVF and Mobius on initiatives to improve trial participation rates. This includes working with MVF technical and marketing personnel to increase awareness of the trial among fertility specialists, increasing the number of participating sites, and broadening patient inclusion criteria.

Additionally, we are in the process of recruiting international clinics into the MVF trial to boost the pool of potential patients. I will continue to keep investors abreast of any updates as the clinical trial progresses.

Samson device for stallion fertility prediction

MEM has completed its 2022 field trials for the novel prototype Samson stallion fertility diagnostic device in conjunction with University of Newcastle (the University).

The new trials have generated data from new samples. The University's researchers returned to a stud farm participating in the previous year's trials to validate Samsons pregnancy prediction on a new set of mares using the same stallions as was used in the trial last year.

The field trial data will be combined with pregnancy outcomes and previous individual mare and stallion breeding statistics and analysed by the University researchers to further refine the accuracy of the diagnostic to predict mare pregnancy.

Other MEM novel reproductive biotechnology products

MEM continues to develop a strong pipeline of company-making products.

The Rapid Oxidative Stress Assay (ROSA) assesses the presence of oxidative stress, which is an imbalance between reactive oxygen species and antioxidant protection within the body. Oxidative stress is linked to important issues like male infertility, Alzheimer's, diabetes and heart disease. There are currently no rapid, point of care tests available to assess the presence of oxidative stress.

MEM research director, Laureate Professor John Aitken, has discovered a method to assess the level of antioxidants in semen and blood. MEM is in the process of securing patents for this finding and commencing with the development of a device prototype.

AI-Port stores and transports animal semen for artificial insemination without the harmful effects of freezing.

MEM has developed a prototype which allows the transport of semen at room temperature for up to four days. MEM will establish rapid *in vivo* field trials to compare the prototype device and medium with the standard AI procedure, which involves the destructive process of freezing sperm.

Semport is a human semen transport system. We have developed a means to store semen for three hours at ambient temperature, which is sufficient time for the semen sample to be produced at home and then transported, intact, for full semen analysis to an andrology laboratory. The current practice is for the man to provide the sample at the andrology centre/ IVF clinic, which for many men is an uncomfortable experience.

Development of competing products

I would like address concerns raised by some of our investors about the potential development of a rival product to the Felix™ System. The concerns were raised because of recent press regarding a microfluidic swim up device for sorting sperm from semen, which is being developed by Monash University.

Firstly, this technique is being developed by Monash University researchers, not by Monash IVF, as some investors mistakenly believed.

Also, it is the nature of universities is to undertake research as that is what they do. The device is yet to be commercialised.

Secondly, various microfluidic devices using the Swim-Up method of separating sperm are already available on the market. All microfluidic devices are reliant on the sperm's intrinsic ability to swim and are therefore subject to the same core strengths and weaknesses of the Swim-Up technique. Swim-Up has limited ability to deal efficiently with samples of low sperm count, high viscosity and of course, poor motility. These are the common factors arising in males suffering from infertility.

The Felix™ System takes a completely different approach to separating sperm from semen. It is not reliant on the sperm's motility but instead relies upon sperm's net surface negative charge – the higher the charge, the healthier the sperm. The Felix™ System process takes six minutes vs Swim-Up's much longer process. It is this different approach that is why our researchers saw the opportunity presented by the Felix™ System and have dedicated themselves to developing the product.

Memphasys recently submitted a paper for publication on the Felix™ System *in vitro* results versus DGC. The work was undertaken by a number of our partner KOL sites, who are co-authors on the paper, together with our Scientific Director, Laureate Professor John Aitken, and our Clinical Applications Executive, Dr Farnaz Shapouri.

In finishing today, I would ask our shareholders to stay focused on the long-term value Memphasys is building with the development of its world class portfolio of unique reproductive biology products. We are an emerging research-based biotechnology company and bringing products to market is a process. It is inevitable that we will be limited in realizing the full benefit of our investor offering until a number of milestones in that process are successfully completed. I can say that your board and management are committed to delivering on our vision for Memphasys and we are buoyed by the progress we have made to date.

Finally, I would like to thank my board, our management and research team and our shareholders for their ongoing support. I look forward to updating investors on our progress during the coming year.

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

ENDS

For further information, please contact:

Alison Coutts
Managing Director / Chief Executive Officer
Memphasys Limited
Tel: +61 2 8415 7300
E: alison.coutts@memphasys.com

David Tasker
Managing Director
Chapter One Advisors
Tel: +61 433 112 936
E: dtasker@chapteroneadvisors.com.au

About Memphasys
Memphasys Limited (ASX: MEM) specialises in 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™ System device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.
Website: www.memphasys.com