



## **MEM Chairman's report for AGM, 22 Nov 2018**

Dear Shareholders,

On behalf of the Directors of Memphasys, I would like to welcome you to our 2018 Annual General Meeting. My name is Alison Coutts and I am Executive Chairman of Memphasys.

I would like to introduce our two non-executive directors: Andrew Goodall, who is also a substantial shareholder, and Marjan Mikel, whose board appointment in June is to be ratified at this meeting.

I would also like to introduce our company secretary, Andrew Metcalfe and our auditor, Mark Godlewski from Pitcher Partners.

It has been a rewarding year for Memphasys and it is pleasing to report that the commercial development of our unique Felix device for male factor infertility continues to be on track and is anticipated to be available for commercial market release post the receipt of CE Mark approval, that indicates conformity with health, safety, and environmental protection standards, which is planned at the end of 2019.

When we look back over the past year, it is clear we have achieved many important milestones. Below is a summary of key events and milestones over the past year.

- In December 2017 the Company received funds from a non-renounceable rights issue and placement. This fund-raising provided approximately \$1,500,000 of fresh funds and the conversion of \$2,055,500 in director and other debts, which enabled the Company to focus on the development of its first commercial product, the Felix device for human IVF.
- Also, in December 2017, Memphasys received a special grant of \$400,000 from the NSW Medical Device Fund to advance the development of the Felix device.
- In March 2018, Memphasys settled the legal action with Platinum Road Pty Ltd. There is no remaining legal action within the Company.
- In May 2018 the Company received \$1 million through a private placement from Peters Investments Pty Ltd, an investment company headed by prominent Australian horse owner-breeder Bob Peters to advance work in fertility outcomes for both humans and horses.
- In June 2018, Memphasys appointed Marjan Mikel to the Board as a non-executive director replacing John Pereira who resigned on the same date.
- In August 2018, Memphasys consolidated its issued capital on a 15:1 basis after receiving approval for the consolidation at an EGM.
- In July and in October 2018, Memphasys senior executives attended two major international Human Reproduction & Embryology Conferences. The first, the European Society for Human Reproduction & Embryology, was in Barcelona, Spain and the second, the American Society for Reproductive Medicine, was in Denver. At each conference, executives met and progressed discussions with a range of European, Middle East and North American-based Key Opinion Leaders.

- In September 2018, Memphasys announced a collaborative agreement had been signed with Monash IVF Group (“Monash IVF”).
- In October 2018, Memphasys announced that it had appointed the first international Key Opinion Leader (“KOL”), ANOVA Karolinska in Sweden, to undertake clinical studies to assess the performance of the Felix device.

I will now provide a brief update on the Company’s activities over the past twelve months and the outlook for the Company.

## **The Felix program**

Memphasys’ lead program is the development of a unique medical device, Felix, to address male factor infertility, a factor in approximately 50% of all cases of infertility experienced by couples. Memphasys has been commercialising the device over many years in collaboration with world renowned fertility expert, Prof. John Aitken and his research team at the University of Newcastle.

The device efficiently separates the best quality, least DNA damaged sperm from a semen sample in preparation for human IVF and provides unique and critical advantages over current sperm processing methods.

The device gently and automatically processes semen samples in preparation for IVF procedures. It takes approximately 3 minutes, compared with the current, laborious and DNA-damaging 30-minute lab-based processes, “Density Gradient Centrifuging” and “Swim Up”. Most notably these current processes also do not reliably select the best sperm.

Over the past year, Memphasys has made excellent progress with Felix’s development, with market launch anticipated at end of 2019.

Newcastle University has continued to provide testing using student semen samples on the re-usable cartridge research device. Since early 2018, Monash IVF has also tested this device using semen samples from its IVF clinic and the device was shown to efficiently and reliably extract good quality sperm.

Monash IVF are also providing advice on the design of the final, clinical Felix device, which will have fully disposable cartridges. The cartridges will provide a large recurrent revenue stream for Memphasys; a new cartridge will be used each time the semen is processed for an IVF cycle.

Systems engineering work on the final clinical device is now well underway at Hydrix, Memphasys’ engineering development partners. Internal company CE Mark accreditation processes are also proceeding well, and the key global Key Opinion Leaders sought by Memphasys to provide *in vitro* testing of the device have all agreed to provide this service. The first international KOL to sign an MoU, ANOVA Karolinska Institute in Sweden, was announced in October and others will be announced shortly.

The device remains on track for first regulatory approval, CE Mark in Europe, by end of 2019.

## Depiction of final Felix console and single use, disposable cartridge



Over the next few months, we will commence building this device for *in-vitro* assessment by approximately 10 -15 Key opinion Leader (“KOL”) IVF/ andrology centres globally. We expect to be able to supply the device and cartridges to the KOLs at end March 2019. *In-vitro* testing and reporting of results should take around 6 months.

### Assisted Reproduction Applications for Animals

A scaled-up variant of the Felix device can also be used for animal artificial reproduction technology (“ART”). The first animal application is for horses.<sup>1</sup>

During the financial year, Memphasys continued its work with the University of Newcastle researchers in the further development of a device to separate equine sperm with the highest fertilising potential from the stallion’s semen. The current Felix prototype has reliably been able to extract good quality sperm, and this alone would be sufficient for use in ICSI procedures where only a small quantity of good sperm is required. However, Memphasys is also aiming to serve the far larger artificial insemination (“AI”) market

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<sup>1</sup> Artificial reproduction technologies (“ART”) are not legally allowed to be used on thoroughbreds but there is a sufficiently large market for ART in horses, apart from thoroughbreds. These horses include standard bred (trotters), show jumpers, dressage, eventers, polo ponies and Arab horses

and for that, much larger volumes of semen and quantities of sperm must be processed. This requires changes to the fluid dynamics of the current Felix device before it is scaled up to accommodate the large volume processing of equine semen for AI.

## **Conclusion**

We are excited about how well the commercial Felix device for human IVF is developing and we anticipate that in a years' time, we will be planning for commercial release of that product.

The equine application is also tracking well and although scale up presents some technical challenges, we have a plan to address these and envisage that the equine ART market will also become a valuable business in its own right.

We hope that shareholders will also be as excited as we are about the opportunities ahead. We thank them for their support.

Alison Coutts  
Executive Chair  
Memphasys Limited  
22 November 2018