



**ASX Release  
19 November 2020**

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## **2020 Annual Meeting | Chair's address | 19 November 2020**

### **Chairman's Speech**

It is with great pleasure that I provide shareholders with an update on the achievements of your company over the past year, and importantly our plans for the coming 12 months.

The past twelve months have seen Memphasys significantly advance the commercialisation activities of the Felix device, a novel automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures. We have also progressed other complementary research activities led by global fertility expert Professor John Aitken and his team at University of Newcastle and those activities are all proceeding well.

Despite the challenges this year has presented, the resilience we have created within our Company over many years, together with our research and commercial partners, has enabled us to remain focused on the delivery of our strategy.

In late 2019 we identified and secured as key opinion leaders ("KOLs"), who are renowned leaders of international IVF laboratories and andrology centres. They have been selected for their technical and academic expertise, geographic market positioning and their value to Memphasys' commercialisation strategy.

The KOL assessment program is designed to provide further evidence of the technical capabilities and clinical benefits of the Felix device in commercial IVF centres, provide significant examples of the range of use (semen quality) and to further define the commercialisation strategy of the Company. The KOL sites are anticipated to be some of the first to purchase the Felix device.

The majority of IVF centres to receive these first Felix devices for the KOL assessment program are in countries believed to have a regulatory framework that aligns to the Company's commercialisation objectives of seeking early commercial sales timeframes. These include sites in Japan, New Zealand, Canada and India.

Apart from the New Zealand clinic, which was more recently selected, KOL sites in these countries received the Felix devices and consumable cartridges earlier in the year. While some of the sites commenced testing soon after receiving the devices, they were severely impacted during COVID-19 lockdown as they needed to focus all their attention on their core IVF activities.

The Felix device must pass a set of Verification and Validation ("V&V") activities before it can be commercially used in IVF clinics. The V&V process requires the full design and manufacturing process of the device to have been satisfactorily completed, including (but not limited to) the following key activities:

- The setting up of a biologically controlled manufacturing environment (i.e a cleanroom) at MEM's cartridge manufacturer, W&S Plastics ("W&S")
- Cartridge gamma sterilisation, post final manufacturing at W&S
- Traceability demonstration of all key components used in the manufacturing process and demonstration of final product packaging and labelling
- Full electrical safety testing, and various biological testing of the device e.g. cytotoxicity and Mouse Embryo Assay testing ("MEAs") to verify that the device is biologically safe to use
- Requisite shelf-life testing of cartridges and consoles
- Clinical testing, independently performed by Monash IVF, to show the device meets its intended use.

Pleasingly, I am happy to report that the V&V process, for sales into these early markets has largely occurred and so too has recommencement of Felix device testing at a number of the KOL sites, although some are still being heavily adversely impacted by Covid-19.

In addition to our defined sales strategy into the key early markets we are continuing to advance our regulatory program in Australia and the US, noting this will likely take 2-3 years to complete.

As we progressed the commercialisation of the Felix device we also identified a group of product opportunities focussed on innovative fertility diagnostics and improvements in assisted reproduction technologies, initially developed for animal use, some with potential application for humans.

Technical feasibility studies on these projects are progressing to establish these products' operational and economic viability. The goal is to complete these feasibility studies by the end of Q4 CY2020, at which time the board will determine which will be progressed into the product development phase into 2021 and beyond.

While these research initiatives have the potential to be exciting and valuable to Memphasys and our shareholders, we are focused on and committed to the commercialisation of the Felix device, with first sales orders possible before year end.

So, as we look forward to 2021, I want to reassure you, our shareholders, that we have a clear plan on how we are going to build value.

We believe in our technology and the positive role it can play in the global IVF industry. We have assembled an outstanding team to achieve our goals, both within Memphasys and extending beyond. Our technical and operational partners include the research team at Newcastle University, led by Professor John Aitken, a global leader in reproductive biology, Hydrix, our engineering design collaborators, W&S, our cartridge manufacturers and Monash IVF who have assisted us throughout to help optimise the design and operation of Felix and to test it with clinical samples.

We have confidence we will achieve sales of the Felix device in our early target markets into 2021 and beyond – and that Memphasys will transition from product developer to product manufacturer, growing its sales and brand in global markets.

I would like to thank each and every one of you for your support of the company and for putting your faith in the Memphasys board and executives.

We look forward to rewarding that support into 2021 and beyond.

Thank you

**ENDS**

**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 for high value commercial applications. The Company's patented membrane processes in combination with electrophoresis, the application of an electrical potential difference across a fluid, enable the separation of high value substances or contaminants from the fluid in which they are contained.

The main application of the technology is the separation of the most viable sperm cells for artificial reproduction, most particularly for human IVF.

Website: [www.memphasys.com](http://www.memphasys.com)