*ASX Release*
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# Felix Product Development and Commercialisation in 2019 On Track

**Highlights**

- **Global IVF Key Opinion Leaders express strong interest to conduct their own clinical studies on Felix device;**
- **Device functionality and ergonomics improved by testing and advice from leading Australian IVF company;**
- **Pre-production Felix device to be completed in December 2018 quarter; final Felix device completed in March quarter 2019;**
- **First Felix devices to be distributed to selected global IVF Key Opinion Leaders ("KOLs") to start clinical studies in March quarter 2019;**
- **Regulatory plan for CE/TGA and FDA approval developed; initial meetings with EU regulatory authority held in the UK;**
- **Initial sales of Felix device in Europe are on track for Q4 2019; anticipated additional and substantial recurrent revenue from sale of single use disposable cartridges; and**
- **Studies at University of Newcastle on equine semen progressing well for application of core technology to horses.**

Memphasys **(ASX: MEM)** ("Memphasys" or "The Company") remains on track with the product development and commercialisation strategy for its Felix device, a unique device for separating the most viable sperm in a semen sample for use in human IVF, with The Company reconfirming it plans to commence initial sales of the Felix device in Europe during Q4 2019.

The technology was developed in conjunction with world renowned fertility expert, Prof John Aitken from the University of Newcastle and provides crucial advantages over current sperm processing methods. It was proven to work in a prior clinical study at Westmead IVF using an early prototype device, which resulted in numerous live births. The Company is now developing a commercial device, Felix, to be used by IVF clinics globally.

**Key Opinion Leader facilities to commence using the Felix Device in Q1 2019**

Memphasys is in advanced discussions with a number of IVF KOLs in the United States, Europe and Australia with a view to having these IVF clinics undertake *in-vitro* assessments using the Felix device, currently in development, and to assess its ability to select the most viable sperm for human IVF treatments.

It is expected agreements for clinical assessment by selected KOL clinics will be entered into during the current quarter, with those clinics to commence testing of the Felix device when the production device is available at the end of Q1 2019.

The studies will assess and confirm Felix's performance in preparing sperm from diverse semen types for IVF when compared with the current lab-based methods which are labor intensive, costly and contribute to sperm DNA damage.

The outcomes of these studies will provide further evidence as to the technical capabilities and clinical benefits of the Felix device, provide significant user examples of range of use and further define the commercialisation strategy of the Company. Initial results from the *in-vitro* study will be used to complete the technical file for seeking regulatory approval of the device, starting with the EU.

**Key operating parameters optimised/ verified as functionality/ergonomics improved**

The company has also been working closely with a leading Australian IVF company to improve the functionality and ergonomics of the Felix device. This has led to a number of improvements to be incorporated into the final commercial device.

Key operating parameters for the Felix device have been optimised and verified. A wide range of semen types, including clinical samples from a large commercial IVF clinic, have been tested using the current prototype. "Voice of customer studies" conducted with IVF clinicians on the design and operation of the final device have also been completed. Memphasys, together with its engineering development partner Hydrix, is now commencing development of the final Felix production device to be marketed.

Initially, a fully functional pre-production device will be made and thoroughly tested and then the final injection-moulded production device will be manufactured at scale, ready for *in-vitro* testing by selected KOL IVF clinics globally.

**Regulatory plan completed**

The regulatory plan for obtaining CE Mark, TGA and FDA approval of the Felix system has been developed. The plan includes definition of the target markets, which are initially Europe, Australia and the USA (in that order), with the potential for other markets, such as Japan and emerging markets including China and India, to be added. It also includes identification of the class of the device (Class IIb in Europe and Australia; Class II, with a De Novo submission pathway in the USA) and the relevant regulatory requirements and proposed strategy for obtaining approvals in each of the key target markets.

Memphasys senior management has had initial meetings in Europe with the EU Notified Body which will be responsible for assessing the Felix device for CE Mark approval. The meetings clarified the assessment process and confirmed that the Felix device is truly novel and that it would be a Class IIb for CE Mark and also for TGA approvals.

With all key milestones related to the product development and commercialisation of the Felix device having been met to date, the Company reconfirms initial sales of Felix device in Europe are on track for Q4 2019 (refer Appendix 1: Key Milestones to Felix Product Launch).

**Studies at Uni of Newcastle on equine semen progressing well for application of core technology to horses**

With respect to the equine application of the core technology, studies at the University of Newcastle on processing equine semen with the current Felix prototype device are ongoing and are proceeding well. These studies consistently show that the quality of the harvested sperm is vastly better than the average

quality in the raw semen. The harvested sperm have statistically significant improvement in viability, motility and, most importantly, DNA intactness. Further study results will be reported as they become available.

ENDS

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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.

## Appendix 1: Key Milestones to Felix Product Launch