



ASX Release
3 November 2021

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Verification and Validation Assessments Complete

Highlights

- **Verification and validation (V&V) assessments for the Felix™ device now complete for early-access markets with low regulatory requirements**
- **Initial KOL assessment data with updated Felix™ device received**
- **Results positive and in-line with expectations, demonstrating successful selection of sperm with low DNA damage**
- **Commercial discussions underway with Key Opinion Leaders (KOLs) in early-access markets who have finished in vitro testing of the Felix™ device**

Australian-based bio-separations and reproductive biotechnology company, Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company"), is pleased to announce completion of V&V assessments for early-access markets. Verification is undertaken to confirm the specified design requirements have been fulfilled. Validation is undertaken to confirm requirements for specific intended use can be consistently fulfilled. Passing V&V assessments is a prerequisite before commercial sales may begin.

Despite the adverse impact of Covid-19 on the operation of many IVF clinics which has substantially slowed the KOL testing, the Company has also received preliminary in vitro KOL assessments on the Felix™ device's performance and more data is expected shortly. Pleasingly, initial results, which consist of 25 in vitro samples per KOL, have been positive and in-line with Memphasys' expectations. Most importantly, preliminary results have demonstrated the Felix device's consistent ability to rapidly select cells with low levels of DNA fragmentation. The results also show that it can be used with a wide range of semen samples, including viscous samples and samples with low sperm counts, poor motility and high DNA fragmentation levels.

Commercial discussions are underway with some of the Company's Key Opinion Leaders (KOLs) in early-access markets who have completed the in vitro testing of the performance of the Felix™ device.

Commenting on the commercialisation progress of the Felix™ device, Memphasys Executive Chairman, Alison Coutts said:

"Memphasys is very pleased with the in vitro testing results reported from KOLs to date, especially the DNA fragmentation results, and the consistent feedback about the Felix™ device's ease of use and rapid operation."

"We continue to believe that a maiden commercial sale can be made prior to the end of the calendar year."

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

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.

Website: www.memphasys.com