

## **FELIX DEVICE - VERIFICATION, VALIDATION AND KOL STUDY UPDATE**

### **Highlights**

- **Clinical testing of the engineering fix has been positive in validating its performance,**
- **Verification work for the upgraded device expected to be completed during quarter ending 30 June 2021,**
- **Validation work for the upgraded device expected to be completed during the quarter ending 30 September 2021, and**
- **Initial commercial sales discussions in early access markets anticipated to commence in the latter part of the quarter ending 30 September 2021, subject to study results and prevailing COVID conditions in country.**

Australian-based bio-separations company Memphasys Limited (ASX: MEM) (“Memphasys” or “the Company”) is pleased to provide a further update on the status of the remediation process for the Felix device following the identification of an engineering issue that constrained its performance<sup>1</sup>.

Further assessments by research and development partners using a modified device with the engineering modification have yielded positive results, further validating the science behind the Felix device as well as demonstrating an improvement in the sperm separation process compared with the prior Felix device.

As a result, Memphasys can now provide a more detailed, albeit extended, timeline on the path to market for the Felix device.

### **Verification & Validation Timeframe**

As previously announced, the majority of verification work was unaffected by this necessary modification to the design<sup>2</sup>. However, some Felix device verification tasks will need to be redone by our development partners. Memphasys anticipates this work will begin once sterilised upgraded cartridges are available with verification work to be completed during the quarter ending 30 June 2021.

In addition, some validation works previously performed by our development partners will need to be redone with the upgraded Felix device. Memphasys anticipates that this work will begin once sterilised upgraded cartridges are available, with this validation work anticipated to be completed during the quarter ending 30 September 2021.

### **Potential First Sales Timeframe**

Memphasys remains in regular contact with its Key Opinion Leader (KOL) partners and, in particular, those in early access markets where Memphasys has the opportunity to make the first sales of the Felix device.

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<sup>1</sup> Refer to ASX announcement dated 8<sup>th</sup> March 2021

<sup>2</sup> Refer to ASX announcement dated 30<sup>th</sup> March 2021

The Company anticipates distribution of the upgraded Felix products to KOL partners in the four early access markets ( Japan, NZ, India, and Canada ) by late June 2021 in order for them to complete their clinical assessment study on the upgraded Felix device.

Once clinical testing of the upgraded Felix device has been completed successfully, sales discussions with KOL partners and other prospects in early access markets will resume.

Based on this, the Company now anticipates initiating commercial sales discussions in early access markets in the latter part of the quarter ending 30 September 2021; however completion of the KOL studies and first sales will be subject to prevailing local Covid conditions, particularly in the four early access markets.

**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](http://www.memphasys.com)