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Completion of Felix Device Validation Process to be delayed.

During the latter stages of the Validation process on the Felix Device, Memphasys has identified an engineering flaw that is likely to have reduced the effectiveness of the Felix system currently in use.

As previously advised, Memphasys is required to undertake a verification and validation (V&V) process on the Felix Console and Cartridges (Felix Device). The V&V process is an internal testing process seeking to ensure the proposed final production units pass an array of design, safety, QA and QC tests prior to the production units being available for commercial sale. Specifically, Validation is designed to identify any issues in the design or final build and operation of the Felix Device.

As reported in its 31 December 2020 Half Year Report, Memphasys expected the Validation process to be completed by end of March 2021, however this schedule will now need to be extended. Furthermore, commercial sales of the device will be delayed. For such sales to occur, the Validation process must be completed and passed, which will include additional validation testing by University of Newcastle and Monash IVF. A further set of testing on the final validated device will then need to be undertaken by Key Opinion Leaders ("KOLs") and possibly other potential customers in the initial, low regulatory regime markets, before such sales can commence.

The KOL data collected to date showed that the device was generally performing the function of separating good quality sperm. However, after remediation of the device, the sperm separation process is expected to improve. What is important to note is that this is an engineering issue that has a solution. It is not an issue with the Felix core technology or science.

Based on initial investigations, Memphasys believes the issue can be readily fixed. Memphasys has confirmed the source of the defect with its engineering and design partners, and with these partners, has already determined various possible alternative ways to address the issue. Memphasys will need to work through these alternatives to determine the best way forward in terms of time, cost and risk. Memphasys will require extra time to implement the fix and then perform the revalidation work.

Memphasys has collected useful KOL data so far. Once this technical issue has been rectified, Memphasys will collect additional KOL test data to determine the true performance of the device in its final form.

Memphasys expects that the modifications will further improve separation performance, but further clinical testing will be required to determine performance of the final unit. Memphasys anticipates that it will be able to continue the testing program with many of the existing KOLs while continuing to recruit new KOLs in selected international markets.

Alison Coutts, Executive Chairman stated: "Memphasys is clearly disappointed that this issue has arisen, especially as it came so late in the validation process. However, that we were able to uncover the issue is testament to the robustness of our verification and validation process. We are now working on resolving the issue as expeditiously as possible."

Memphasys will continue to update the market on its progress in the remediation process and subsequently on results from use of these modified devices by its collaboration partners at University of Newcastle, Monash IVF and at the KOL testing sites.

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 first commercial 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