

ASX Release
ASX Code: MEM

11 February 2025

Memphasys Completes Final Patient Visit in Felix™ Clinical Trial, Data Lock Expected in Two Weeks

Highlights:

- Last Patient Last Visit (LPLV) achieved – all required patient visits, including pregnancy outcomes, are now completed.
- Next milestone: data lock – expected in approximately two weeks.
- Current focus: data clean-up – ensuring accuracy through data management and source data verification.
- Preliminary trial results remain on track for release to the ASX in early March 2025.
- Data will be incorporated into the CE Mark submission, which will enable market entry into Europe, with other jurisdictions, such as Australia and India, to follow shortly after

Memphasys Limited (ASX: MEM) (“Memphasys” or “the Company”) is pleased to announce the completion of the Last Patient Last Visit (LPLV) for its pivotal clinical trial of the Felix™ System, an advanced sperm selection technology for Assisted Reproductive Technology (ART) procedures.

With LPLV achieved, all required patient visits and pregnancy outcomes have now been completed, marking a significant milestone in the clinical study. The next step is the data lock, expected in approximately two weeks, following a final phase of data clean-up, data management, and source data verification to ensure the accuracy and integrity of the trial results.

Final Steps Before Data Lock and Market Release

The current focus is on data verification and quality control, a crucial process that ensures the trial dataset is robust and reliable before moving into statistical analysis. Once the data lock is completed, Memphasys will proceed with final statistical evaluations, keeping the early March 2025 timeline for releasing preliminary trial results.

Regulatory and Commercial Strategy

The trial data will be a key part of Memphasys’ ongoing CE Mark submission, which will allow immediate commercialisation in Europe. Regulatory approvals in Australia and India are expected to follow soon after, with the Therapeutic Goods Administration (TGA) approval process expected to be streamlined given the CE Mark certification.

The Felix™ System trial data will also be shared with current and potential distribution partners, accelerating commercial discussions for licensing, manufacturing, and global market expansion. Importantly, this validation is expected to enhance sales by existing distributors in their respective markets.

Memphasys Managing Director & CEO, Dr David Ali, noted that this marks the home stretch in the company’s rigorous clinical journey:

“With all patient data now collected, our team is focused on ensuring every data point is verified and ready for statistical analysis. It’s a meticulous process, but a necessary one as we prepare for regulatory approvals and commercial discussions. We look forward to sharing the trial results very soon.”

The Company will continue to provide updates as the trial progresses through this final phase.

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

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For further information, please contact:

Dr. David Ali
Managing Director & CEO
Memphasys Limited
Tel: +61 2 8415 7300
E: david.ali@memphasys.com

David Tasker
Managing Director
Chapter One Advisors
Tel: +61 433 112 936
E: dtasker@chapteroneadvisors.com.au

About Memphasys Limited

Memphasys Limited (ASX: MEM) specialises in advanced reproductive biotechnology, developing medical devices, diagnostics, and proprietary media for human and animal applications. With flagship technologies like the Felix™ and RoXsta™ Systems, Memphasys is committed to delivering transformative solutions that enhance fertility outcomes worldwide.

Website: www.memphasys.com