

Memphasys Secures TGA Approval for Felix™ System, Unlocking Commercial Sales in Australia

Highlights

- **Felix™ System approved by the Therapeutic Goods Administration (TGA) and included on the Australian Register of Therapeutic Goods (ARTG)**
- **Approval granted approximately two months ahead of previously guided timeframe**
- **TGA resubmission enables immediate commercial sale and clinical deployment of Felix™ across Australia**
- **Following CE Mark approval in Europe and existing compliance in selected international markets, TGA approval establishes Australia as a major high-regulatory commercial market for Felix™**
- **Early approval accelerates activation of advanced commercial discussions and revenue generation**

Memphasys Limited (ASX: MEM) (“Memphasys” or “the Company”) is pleased to announce that the Felix™ System has received approval from the Australian Therapeutic Goods Administration (TGA) and has been successfully included on the Australian Register of Therapeutic Goods (ARTG).

Importantly, TGA approval has been granted approximately two months ahead of the Company’s previously guided timeframe, representing a material acceleration of Memphasys’ Australian commercial rollout.

Ahead-of-Schedule Approval Reflects Execution Momentum

The Company had previously guided the market to expect Australian regulatory clearance by April 2026. Receipt of approval in February 2026 materially de-risks the near-term commercial pathway, compresses time to market and brings forward revenue-generating activity.

Early approval reflects the strength of the Company’s regulatory, manufacturing and quality systems, and underscores Memphasys’ ability to execute to plan - and ahead of schedule.

Following CE Mark approval in Europe and existing compliance in selected international markets, TGA approval establishes Australia as a significant high-regulatory commercial market for Felix™.

Lindley Edwards, Chair of Memphasys, commented:

“Securing TGA approval for Felix™ approximately two months ahead of our stated timeline is a strong validation of the quality of the technology, the robustness of our regulatory strategy and the discipline of our execution.

Just as importantly, this approval allows us to accelerate commercial activity in Australia, bringing forward engagement with IVF clinics and converting advanced discussions into revenue-generating outcomes sooner than anticipated.”

What Early TGA Approval Means for Commercialisation

With ARTG inclusion now secured, Memphasys is immediately authorised to:

- market and sell the Felix™ System in Australia,
- deploy Felix™ consoles into IVF laboratories,
- supply Felix™ cartridges on a recurring per-procedure basis, and
- transition from pre-commercial readiness into active market deployment.

Australia represents a strategically important initial market, with more than 60,000 fresh IVF cycles performed annually where Felix™ has a direct clinical application. Early regulatory clearance positions Memphasys to capitalise on these opportunities earlier than expected.

Acceleration of Advanced Commercial Discussions

Memphasys has been engaged in advanced commercial discussions with Australian stakeholders, including IVF clinics and potential distribution partners, in parallel with the regulatory process. The earlier-than-expected approval enables these discussions to move immediately into execution and deployment phases.

The Company’s Australian commercial strategy is focused on building an installed base of Felix™ systems and establishing scalable, recurring cartridge revenue streams linked to IVF procedure volumes.

Global Commercial Momentum Continues

The Australian approval follows the Company’s CE Mark certification¹ and complements ongoing regulatory and commercial progress across multiple jurisdictions, including markets where Felix™ has already been compliant and in use.

Outlook

With Australian regulatory approval now secured earlier than anticipated, Memphasys is entering a phase of accelerated commercial execution. The Company will continue to update shareholders as Australian commercial agreements are finalised and as further regulatory and commercial milestones are achieved internationally.

Authorised by the Board of Memphasys Limited.

Ends

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¹ Refer ASX announcement dated 29 December 2025

About Memphasys

Memphasys Limited (ASX: MEM) is an Australian-based reproductive biotechnology company commercialising the Felix™ System, a patented bio separation technology that isolates the most viable sperm cells for human assisted reproduction.

By combining electrophoresis and size-exclusion membranes, Felix™ delivers a fast, gentle and standardised sperm selection process that enhances sperm quality and reduces laboratory time. The system replaces traditional centrifugation, which can cause cellular stress and DNA damage, offering clinicians a superior, repeatable alternative.

Memphasys' commercial strategy focuses on building contracted sales through direct and distribution-led channels, scaling production to improve margins, and establishing Felix™ as a new global standard in sperm preparation for ART procedures.

Website: www.memphasys.com

The Felix™ System is a registered trademark of Memphasys Limited. All rights reserved.

Forward Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on Memphasys's current expectations, estimates and projections about the industry in which Memphasys operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the control of Memphasys, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. Memphasys cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Memphasys only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. Memphasys will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.