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Memphasys Identifies Potential Expedited FDA Pathway to US IVF Market

Board reassessment identifies potentially faster pathway into US$5.9 billion USA IVF market while maintaining focus on near-term global commercialisation

Highlights

- **Board reassessment of the US regulatory strategy has identified a potential expedited pathway for Felix™ to seek FDA clearance, replacing the more complex De Novo pathway previously contemplated.**
- **The Company has identified a medical device it believes may provide an appropriate predicate, potentially enabling Felix™ to pursue the FDA's more established 510(k) clearance pathway.**
- **Memphasys will now undertake a Pre-Submission (Q-Submission) engagement with the FDA to seek feedback on the proposed pathway, predicate and supporting evidence before proceeding to a formal submission.**
- **The US represents a significant long-term commercial opportunity, with approximately 500 clinics providing assisted reproductive technology (ART) services and more than 435,000 ART cycles reported annually.**
- **The US IVF market was estimated at approximately US$5.9 billion in 2025, representing approximately 20% of the global IVF market by revenue.**
- **The US regulatory program will be strategically ringfenced and progressed in parallel, with the Company's immediate commercial focus remaining firmly on accelerating Felix™ adoption and revenue generation across Europe, Australia and New Zealand, Asia and MENA.**

Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to advise that a reassessment by the Board of the Company's US regulatory strategy for the Felix™ Sperm Separation System has identified a potentially faster, cost effective and more direct pathway towards FDA clearance.
Memphasys had previously anticipated that Felix™ would need to progress through the FDA's De Novo classification pathway because a suitable predicate device had not been identified.

Given the strategic importance and size of the US fertility market, the Board determined that the previous regulatory approach warranted further assessment.

Following this reassessment, and working with specialist regulatory advisers, the Company has identified a legally marketed device it believes may provide an appropriate predicate for Felix™. This creates the potential for Felix™ to pursue the FDA's established **510(k) pathway**, based on demonstrating substantial equivalence, rather than the De Novo pathway previously contemplated.

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The Board believes this represents an important development in the Company's US strategy and provides a potentially more efficient pathway towards accessing one of the world's largest and most valuable fertility markets.

Significant US Market Opportunity

The United States represents an important long-term commercial opportunity for Felix™.

Approximately **500 US clinics provide ART services**, with the latest comprehensive CDC national data reporting **435,426 ART cycles across 457 reporting clinics in 2022**.

The US IVF market was estimated at approximately **US$5.9 billion in 2025**, representing approximately **20% of the global IVF market by revenue**.

The scale and value of the US market reinforce the strategic importance of establishing a credible and capital-efficient pathway to US market entry for Felix™.

Next Step – Engagement with the FDA

The Company's next step will be a **Pre-Submission (Q-Submission) engagement with the FDA**.

This process will enable Memphasys to seek FDA feedback on the proposed predicate, regulatory strategy, testing requirements and supporting evidence before committing to a formal regulatory submission which the Company is targeting to undertake in Q1 CY2027 .

Subject to the outcome of this engagement and completion of any additional work required, Memphasys intends to progress towards a formal 510(k) submission.

US Strategy Ringfenced – Commercial Execution Remains the Priority

Importantly, the US regulatory program will be strategically ringfenced and progressed in parallel with the Company's existing commercialisation activities.

Memphasys' immediate priority remains unchanged: accelerating Felix™ adoption, cartridge sales and recurring revenue generation in markets where regulatory approvals and commercial infrastructure are already in place or advancing.

The Company continues to focus heavily on its growing commercial footprint across Europe, Australia and New Zealand, Asia and MENA, where Memphasys has established and continues to expand its network of distributors, IVF clinics and commercial partners.

The US strategy therefore represents an additional long-term growth opportunity, rather than a change in the Company's immediate commercial priorities or management focus.

The Board believes this disciplined approach will allow Memphasys to continue executing on the commercial opportunities immediately in front of the Company while establishing a pathway into a major future market for Felix™ in a cost-effective manner that is not expected to significantly impact cashflow in the short-term.

Memphasys Executive Chairman David Tasker said:

"The Board's reassessment of our US regulatory strategy has identified a potentially faster and more direct pathway for Felix™ into a US$5.9 billion IVF market representing around 20% of the global market.

We will pursue this opportunity in a disciplined and ringfenced manner, while maintaining our immediate focus on driving Felix™ adoption and revenue across Europe, ANZ, Asia and MENA."

Commercial Momentum Continues

Felix™ commercialisation continues to build across global markets, with additional repeat orders now received from existing partners and clinics in Italy, the UK and MENA. These repeat orders provide further validation of Felix™ in clinical practice and demonstrate growing customer adoption. The Company's immediate priority remains clear: convert its expanding global footprint into increasing Felix™ cartridge sales, repeat orders and recurring revenue.

Authorised by the Board of Memphasys Limited.

Ends

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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

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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. Such statements are subject to certain risks and uncertainties and are not guarantees of future performance. Memphasys cautions 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.