

Memphasys Submits CE Mark Application for Felix™: Commercialisation Strategy Momentum Builds

Highlights:

- CE Mark application submitted, delivering on H2 FY25 target,
- CE Mark regulatory clearance possible within 6-12 months, however MEM, together with its regulatory advisors, are proactively evaluating opportunities to reduce this timeline,
- CE Mark regulatory approval will unlock EU commercial access and accelerate approvals in the Middle East, India, and Australia,
- Europe conducts over 500,000 IVF cycles annually; ~US\$4–5 billion - the world's largest IVF market¹,
- Builds on Felix™ commercial activities in low regulatory markets - Japan, Canada and New Zealand, and
- Direct commercialisation approach adopted to accelerate Felix™ market entry and build early momentum; distributor engagement remains a longer-term focus.

Memphasys Limited (ASX: MEM) a biotechnology company focused on developing and commercialising innovative products for assisted reproduction and disease diagnosis/prevention is pleased to announce the on-schedule submission of its CE Mark regulatory dossier for the Felix™ sperm separation device - the latest milestone in the Company's intensified focus on global commercialisation.

Following the timely and successful completion of the Felix™ phase III clinical trial in 2024², this regulatory milestone reinforces the Company's operational momentum under current leadership and its determination to convert clinical innovation into **commercial outcomes**.

The European market sees over **500,000 IVF cycles** annually, representing the largest IVF market globally. With an average cost per cycle of **US\$8,000–10,000**, the total market value is estimated at **US\$4–5 billion** and growing at a compound annual **growth rate of 5–6%**.

Streamlining workflows and improving sample turnaround times remain key operational objectives for fertility clinics globally, as clinics seek to maximise throughput and improve clinical processes in the high-cost IVF infrastructure. The Felix™ system directly addresses this need by significantly reducing sperm preparation time to just **6 minutes** with Felix™ as compared to approximately **30 minutes with conventional centrifuge-based methods**. This fivefold reduction

¹ <https://www.rechargecapital.com/news/europe-rising-infertility-in-a-fragmented-market>

² Refer ASX announcement dated 24 March 2025

enables faster processing, improved scheduling efficiency, and better resource utilisation - all highly desirable outcomes for IVF clinics operating in capacity-constrained environments.

Memphasys CEO & Managing Director Dr David Ali said:

“Submitting the CE Mark application on schedule is a clear indicator we are delivering on the commercialisation commitments made to investors. Our focus is to convert scientific innovation into near-term revenue and scaling into meaningful markets”.

*“While Europe represents a significant future commercial opportunity for Felix™, we are not waiting to commercialise in other regulatory markets. Felix™ can be sold in **Japan, Canada, and New Zealand**, and we are now gearing up to actively execute structured direct go-to-market plans in these markets.”*

Why CE Mark Matters

The CE Mark is a globally recognised certification that confirms a medical device complies with stringent European Union standards for safety, health, and environmental protection. Achieving CE Mark certification allows Memphasys to commercialise Felix™ across the European Economic Area (EEA) and additional key international markets that recognise CE regulatory equivalency.

Europe’s IVF sector, with over **500,000 cycles annually**, offers significant opportunity for Felix™. The CE Mark also streamlines regulatory processes in India, Australia, Middle East and multiple APAC territories — enabling faster commercial rollout. Memphasys remains committed to achieving milestones with discipline and urgency, bolstered by strong interest from international clinics and Key Opinion Leaders (KOLs). Further updates will be provided as the CE review progresses.

Further, Memphasys continues to execute its commercialisation strategy in regions where Felix™ can be sold and used, with an initial focus on advancing its direct sales approach in those targeted markets with lower regulatory requirements.

Direct Sales Approach Advancing

The Company remains committed to fostering strategic distribution partnerships and continues to explore a range of opportunities in this space. However, given the unique positioning and first-in-class nature of the Felix™ device, the timing and capabilities of potential partners to date have not fully aligned with the specific requirements of early-stage commercialisation.

Following a careful review, the Board has determined that a more direct approach in the initial phases of market entry will provide the best opportunity to build awareness and demonstrate the value of Felix™. This approach allows MEM to guide and shape market development activities, ensuring they are tailored to the distinctive attributes of the technology. Importantly, it also lays a strong foundation for engaging with distributors in both our current markets and future regions, including the EU, once CE Mark approval is secured.

While partnerships remain an important component of MEM’s long-term strategy, MEM recognise that distributors are typically not positioned to create new markets from the ground up. By leading early business development efforts, MEM believes it can generate stronger

traction, establish meaningful customer relationships, and more effectively support future distribution arrangements.

In Japan, New Zealand and Canada MEM is actively engaged in commercial discussions with several leading IVF clinics. The Company look forward to keeping shareholders informed as it progresses and refine its immediate direct go-to-market strategy.

Authorised by the Board of Memphasys Limited.

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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