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# Memphasys Accelerates Growth with Indian Commercial Supply Agreement Under New Global Go-Direct Strategy

## **Key Points:**

**ASX Code: MEM** 

- First Indian distribution agreement executed under Memphasys' go-direct commercial strategy, with Andrology Center group company Andro Diagnostics, Coimbatore establishing a dedicated Felix™ team to drive product adoption across its network of more than 200 partner IVF clinics.
- Minimum Year 1 commitment post approvals: 1,800 Felix<sup>™</sup> cartridges (A\$98,820 at ~A\$55 per cartridge).
  - o Delivery cadence: 450 cartridges per quarter,
  - o Year 2 committed sales to be a minimum of 2,700(≥ 50 %)
- Builds on multi-year collaboration between Memphasys and Andrology Center, including the first commercial Felix™ sale (2021), follow-up orders (2022), and eleven recorded live births achieved using Felix™ (2023)
- Re-establishes the Felix<sup>™</sup> footprint in India following regulatory reclassification in 2022, which temporarily paused sales.
- Agreement activated upon CE Mark and CDSCO approvals, with CE Mark submission progressing well and outcome expected early 2026.
- Andrology Center Coimbatore will work directly with Memphasys to accelerate Felix™
  distribution and clinical adoption across India under the go-direct model, supporting rapid
  market entry.
- Further expands Memphasys' global commercial footprint, with India joining a growing number of international jurisdictions where binding agreements are already in place or progressing toward completion.

Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to announce it has signed a non-exclusive supply agreement with the Andrology Center Coimbatore (ACC), expanding the Company's Felix™ commercial footprint into the Indian market.

The agreement represents the latest example of how Memphasys' Go-Direct strategy, distinct from previous distributor-led approaches, has provided clients with confidence and catalysed the conversion of long-standing clinical relationships into a structured commercial partnership that deliver near-term revenue and sustainable growth.

Importantly, the Andrology Center group company Andro Diagnostics, Coimbatore (ACC) has committed to establishing a dedicated Felix<sup>TM</sup> team to work directly with Memphasys under this Go-Direct model, ensuring active promotion, adoption, and utilisation of Felix<sup>TM</sup> across the 200 IVF clinics within ACC's network.

The Andrology Center Coimbatore has been a Felix advocate and trusted collaborator for several years, leading key clinical validation milestones for Felix<sup>™</sup>, including the world's first live births using

sperm separated by the device<sup>1</sup>. The Centre services a network of more than 200 fertility clinics across 57 locations, providing direct access to a substantial portion of India's rapidly expanding assisted-reproduction market.

MEM suspended sales of Felix<sup>™</sup> System in India following changes introduced on 9 August 2022 by the Indian regulator, the Central Drugs Standard Control Organisation (CDSCO)<sup>2</sup>, which saw the Felix<sup>™</sup> System reclassified as a *medical device* rather than laboratory equipment. The new supply agreement will commence once CE Mark and Indian CDSCO approvals are secured.

Under advice from regulatory consultants the regulatory approval for Felix<sup>™</sup> System in India, and the trigger for the commencement of this agreement, is estimated approximately three (3) months post-CE Mark approval, now expected in early 2026.

# **Key Commercial Terms**

Item	Details
Agreement Type	Non-exclusive supply agreement (five-year term, annual review)
Activation	Upon CE Mark and CDSCO approvals
Minimum Year 1 Commitmen	t 1,800 Felix™ cartridges (~A\$98,820)
Delivery Schedule	450 cartridges per quarter
Year 2 Commitment	≥ 2,700 cartridges (≥ 50 % increase)
Felix® Consoles	Supplied free of charge to accelerate adoption across network clinics

## Market Opportunity - India's IVF Sector Expanding Rapidly

The Indian IVF market was valued at USD 1.06 billion in 2023 and is forecast to grow to USD 1.82 billion by 2030(CAGR  $\approx 7.8 \%$ )<sup>3</sup>. Approximately 300,000 IVF cycles are performed annually, with forecasts suggesting growth to 500,000–600,000 cycles in coming years.

With male-factor infertility contributing to ~50 % of cases and an increasing shift toward ICSI-based cycles (> 70–80 %), Felix<sup>™</sup> is ideally positioned to meet demand for faster, high-integrity sperm selection. Its six-minute processing time allows clinics to increase throughput and reduce cost per cycle - a key advantage for emerging Tier II/III clinics.

#### **Regulatory Progress**

Memphasys' CE Mark application, lodged in June 2025, is progressing well, with an outcome anticipated by early 2026.

Achieving CE Mark certification will unlock access to the European Economic Area and streamline regulatory approvals in India, Australia, the Middle East and other CE-recognised territories, supporting accelerated commercial rollout of the Felix™ System.

## **Growing Contracted-Sales Pipeline**

Further work is under way in India to expand Memphasys' contracted-sales commitment pipeline, building on this agreement and targeting additional volume-based arrangements with leading fertility

<sup>&</sup>lt;sup>1</sup> Refer ASX announcement dated 15 September 2023

<sup>&</sup>lt;sup>2</sup> Refer ASX announcement dated 9 August 2022

<sup>&</sup>lt;sup>3</sup> https://www.grandviewresearch.com/industry-analysis/india-in-vitro-fertilization-market-report

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networks. These initiatives add to the binding sales pipelines already in place or expected to be finalised soon in other jurisdictions including Japan, New Zealand and the Middle East, positioning the Company for a step-change in revenue generation during FY 2026.

On the signing of this agreement, Memphasys CEO, Dr David Ali, said:

"This agreement marks another tangible step in converting clinical validation into revenue. The Andrology Center Coimbatore has been one of Felix's earliest advocates, having demonstrated its clinical impact through successful live births and repeat orders. Formalising this partnership under our new commercial framework transforms years of collaboration into a defined supply relationship that delivers near-term growth potential.

Importantly, we are now broadening our commercial pipeline in India and other markets to secure further binding contracts and expand the recurring cartridge base that underpins our long-term revenue model."

Dr Tara Mahendran, Scientific Director of Andrology Center Coimbatore and Managing Partner of Andro Diagnostics, said:

"We are delighted to see Felix returning to the Indian market under this new commercial model. Our clinicians have experienced first-hand the system's ability to improve outcomes in challenging male-factor cases. Partnering with Memphasys to expand access across our network aligns perfectly with India's growing fertility sector and our commitment to providing world-class technology to our patients."

### **Strategic Alignment**

The supply agreement builds on the Company's CE Mark progress and complements its binding contracts and advanced negotiations in Japan, New Zealand and the Middle East<sup>4</sup>.

It demonstrates disciplined execution of Memphasys' commercialisation roadmap - securing recurring cartridge demand while scaling manufacturing to achieve gross margins below A\$40 per cartridge.

Further updates will be provided as additional commercial agreements are finalised.

Authorised by the Board of Memphasys Limited.

#### **ENDS**

For further information, please contact:

Dr David Ali 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

<sup>&</sup>lt;sup>4</sup> Refer ASX announcements dated 24 October 2025 & 18 September 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<sup>™</sup> 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 $^{\text{\tiny M}}$  as a new global standard in sperm preparation for IVF.

Website: www.memphasys.com

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