ASX: MEM

24 July 2024

# Sales, Product Development and Clinical Trial Update

**Key points:**

- **Felix™ System:**
  - **achieved repeat commercial sales in Japan and multiple live births in Japan and India**
  - **exclusive distribution agreements for Japan, Canada and New Zealand secured with subsidiaries of Vitrolife Group, a world-leading global provider of medical devices, consumables and genetic testing services dedicated to human IVF and reproductive health market**
  - **Japan is one of largest markets in early access category and represents ~14.5% of global IVF market**
  - **addressable market in Japan is 20% of total market, as currently no Japanese insurance reimbursement category for Felix™ System**
  - **Vitrolife Japan KK and Memphasys working to access remaining addressable market once current clinical trial is completed by end of current calendar year**
- **Clinical Trial and TGA Submission:**
  - **Clinical trial of Felix™ System steadily gained further momentum during the June quarter**
  - **"Swim-up" aspect of trial completed Density Gradient Centrifugation (DGC) trial arm 50% completed**
  - **New sites continue to be added, with trial completion expected to be end of current calendar year, with results analysis and regulatory submission filed with TGA as soon as possible post that date**
  - **MEM continues to evaluate a range of initiatives to increase speed of trial**
- **Oxidative Stress Measurement System**
  - **Priority product given its innovative nature and its ability to offer true product differentiation.**
  - **Study to establish baseline and thresholds for oxidative stress likely to be associated with meaningful events in reproductive performance being finalised, details to be announced shortly**

Australian reproductive biotechnology company Memphasys Limited (ASX: MEM) (the Company) is pleased to provide an update on the sales progress of its Felix ™ System, timing of its clinical trial and the development of its extended portfolio of products providing assisted reproductive technology (ART) in humans and animals.

Memphasys's most advanced product, the Felix™ System, which has achieved repeat commercial sales in Japan and achieved multiple live births across couples in Japan and India, is an automated device with single-use cartridges for preparing sperm for human IVF procedures. The device gently separates sperm from a semen sample in six to seven minutes using electrophoresis and size exclusion membranes without causing damage to sperm DNA.

In addition, Memphasys is advancing several other projects to extend its commercial product pipeline, most notably its Oxidative Stress measurement system, which is being developed by MEM in conjunction with the University of Newcastle (UoN) under the direct guidance of Memphasys's Scientific Director and global Andrology expert, Laurette Professor John Aitken, and Klean Gene Pty Ltd, a company established by experienced animal sector executives Michael Cameron and Rod Wellstead.

## FELIX™ SYSTEM COMMERCIAL ROLL-OUT

To expedite and support the commercial rollout of the Felix™ System, MEM has chosen to secure distribution partners who have the clinical reach and sales/ marketing capacity to support Memphasys's goals in one (or more) key markets.

In Japan, Canada and New Zealand, Memphasys has entered into exclusive distribution agreements with local subsidiaries of The Vitrolife Group (Vitrolife AB), a publicly listed company on the NASDAQ Stockholm Exchange with

a market capitalisation of approximately A$3.06 billion. Vitrolife AB is a world-leading global provider of medical devices, consumables and genetic testing services dedicated to the human IVF and reproductive health market.

Founded in 1994, it employs 1,100 people across 33 countries and its products and services are available in more than 125 countries. Vitrolife AB has manufacturing sites in Sweden, Denmark and the USA and a direct presence in 25 countries, including Japan, with the balance serviced by distributors. Known within the human IVF market for innovation and technology leadership and premium quality product bands, Vitrolife AB predominantly markets its own products and very selectively markets others.

**JAPAN**

The Japanese market is among one of the largest markets in the early access category and represents approximately 14.5% of the global IVF market, with fresh IVF Cycles increasing from 269,111 in 2018 to 699,111 by 2026 (160%).[1]

In August 2023, Memphasys entered into an exclusive distribution agreement with Vitrolife AB subsidiary Vitrolife Japan KK[2], giving immediate access to the unreimbursed IVF market in Japan which is approximately 20% of the total IVF market.

An initial sales order from Vitrolife KK of 30 sterile single-use Felix™ cartridges and console to the prestigious Kobe ART clinic occurred in April 2023. Vitrolife Japan KK is progressively incorporating the Felix™ System into nine of its clinics in the private health sector via a total of 500 Felix™ cartridges and nine Felix™ consoles. These figures exclude sales Memphasys undertook prior to the Vitrolife distribution agreement.

In May 2024, Memphasys published positive findings from a Japanese clinical trial conducted in Q4-FY2024 in which the Felix™ System outperformed a sperm preparation method comprising two widely used alternative processes, a combination of Density Gradient Centrifugation followed by SwimUp (DGC+SU). [3]

The clinical trial conducted by the Reproduction Clinic Osaka, Japan, a Key Opinion Leader, and an early adopter of the Felix™ technology, reported clear benefits from using the Felix™ System across most clinical measures over the alternative sperm preparation methods (See Figure 1).

The key findings from the Japanese clinical trial include the following material results:

- **Processing Time**: The Felix™ System significantly reduces the sperm processing time from approximately 1 hour (using existing methods) to about seven minutes, enhancing laboratory efficiency and patient convenience.
- **Blastocyst Development Rate**: The Felix™ System showed a blastocyst development rate of 58.4%, higher than the 52.9% achieved by DGC+SU. This suggests that the Felix™ System may enhance embryo development stages critical for successful implantation and pregnancy.
- **Good-Quality Blastocyst Development Rate**: The rate was 35.7% with the Felix™ System compared to 26.1% with DGC+SU, indicating a higher proportion of viable embryos for transfer, which can improve IVF success rates.
- **Embryo Utilisation Rate**: The Felix™ System demonstrated an embryo utilisation rate of 58.0%, better than the 54.3% with DGC+SU, implying a more efficient use of embryos generated during the IVF process.

Memphasys is now undertaking a larger clinical trial to conclusively demonstrate absolute benefits of the Felix™ System, with this trial expected to be completed by the end of the current calendar year.

A paper on the results of the Japanese clinical trial at the Reproduction Clinic Osaka was presented at the European Society of Human Reproduction and Embryology (ESHRE) conference held in June 2024.[4]

Vitrolife and Memphasys continue to advance sales activities, however it should be noted this activity will not be significantly expanded until the wider clinical trial is completed in the current calendar year and results published shortly thereafter.

[1] Global IVF services Market 2019 - 2026 by Allied Market Research, 2018
[2] Refer to ASX announcement dated 7th August 2024.
[3] Refer to ASX announcement dated 20th May 2024.
[4] "A novel electrophoretic sperm isolation system achieves equivalent ICSI outcomes to the combined density gradient centrifugation and swim-up method in a shorter processing time" S Sayaka Kitahara, Shimpei Mizuta, Yuka Iwamoto, Kazutaka Doi, Yasuhiro Ohara, Hidehiko Matsubayashi, Tomomoto Ishikawa / Reproduction clinic Osaka; Hassan W. Bakos, R. John Aitken / University of Newcastle and Memphasys

Memphasys and Vitrolife Japan KK believe that currently the addressable market for the Felix™ System in Japan is 20% of the total market, as there is currently no Japanese insurance reimbursement category for the Felix™ System. Vitrolife Japan KK and Memphasys will be working to access the remaining addressable market once the current clinical trial is completed by the end of the current calendar year.

**CANADA AND NEW ZEALAND**

In January 2024, Memphasys announced exclusive five-year distribution agreements with Vitrolife subsidiaries in the Canadian and New Zealand markets on similar terms to the Company's agreement with Vitrolife KK.[5] These markets present a strong opportunity for early commercial access to build the Felix™ brand and access key opinion leaders to legitimise the product in their landscape.

Following these agreements, training for application of the Felix™ System have commenced in both markets, representing the initial steps of the sales onboarding process. In addition, Vitrolife has visited the major clinics in New Zealand and at least one major clinic is undertaking a preliminary assessment of the Felix™ device.

Vitrolife and Memphasys continue to advance an expansion of sales activities, however it should be noted this activity will not be significantly expanded until the wider clinical trial is completed by the end of the current calendar year.

**OTHER EARLY ACCESS JURISDICTIONS**

Memphasys has identified and is continuing to seek distribution agreements in other early access jurisdictions with various potential distributors, including Vitrolife AB.

**CLINICAL TRIAL AND TGA SUBMISSION UPDATE**

Memphasys's clinical trial of the Felix™ System, being managed by clinical research organisation Mobius Medical Pty Ltd (Mobius), steadily gained further momentum during the June quarter.

It is largely being conducted in collaboration with leading Australian reproductive and fertility services company, Monash IVF Group Ltd (MVF) and seeks to assess the safety and performance of the Felix™ System versus the traditional sperm preparation techniques: Swim-up and Density Gradient Centrifugation (DGC).

The Company has completed the "swim-up" aspect of the trial and continued to take proactive steps to increase the participation rate for the Density Gradient Centrifugation (DGC) trial arm and to reduce the overall study timeline. To date 50% of the DGC rate has been completed.

The Monash IVF clinic (Fertility North) was recently added to the trial to accelerate patient recruitment[6], with MEM now ready to commence final training for recruitment at the new site.

Based on opening of the new clinic, and if recruitment as indicated by modeling proceeds as expected, the trial is expected to be completed by the end of the current calendar year, with results analysis and regulatory submission to be filed with the TGA as soon as practical post that date. MEM continues to evaluate a range of initiatives to increase the speed of this trial.

In Japan, the Kiba Park Clinic will be joining the clinical trial and is currently submitting the study documents for ethics approval. This is expected to assist in both the overall clinical trial and the proactive activities of Memphasys and Vitrolife Japan KK in seeking a new insurance reimbursement category for the Felix™ System.

**OXIDATIVE STRESS MEASUREMENT SYSTEM ADVANCING**

As detailed in ASX announcement dated 19 July 2024, Memphasys' Oxidative Stress measurement system for use in the animal portfolio has been elevated as a priority given its innovative nature and its ability to offer true product differentiation.

[5] Refer to ASX announcement dated 2nd January 2024
[6] Refer to ASX announcement dated 20th May 2024.

Memphasys considers its Oxidative Stress measurement system will have important applications in the reproductive animal industry, as well as potentially in other industries. Oxidative stress results from low levels of antioxidant protection, which are linked to infertility in animals (and in humans) and to levels of DNA damage in both sperm and eggs.

The Oxidative Stress measurement system offers several advantages:

- **Rapid Point-of-Care Assessment:** Oxidative Stress measurement system provides an extremely rapid assessment of antioxidant activity, with the potential of enabling immediate identification of animals requiring antioxidant supplementation and monitoring the consequences of such supplementation.

- **Wide Range of Applications:** Oxidative Stress measurement system can be used in various situations within the cattle industry, including monitoring oxidative stress in dairy and beef cattle, guiding nutritional supplementation, and optimising reproductive performance.

- **Commercial Potential:** Oxidative Stress measurement system holds substantial commercial merit due to its ability to differentiate itself in the market with unique features and applications that address significant needs in the industry.

In consultation with industry, Memphasys and Klean Gene have identified the need to conduct a study to establish a baseline and thresholds for oxidative stress likely to be associated with meaningful events in reproductive performance. Determination of these events when correlated with reproductive performance could provide significant value to the animal industry.

Memphasys has developed a prototype methodology for oxidative stress measurement which will be applied to such a study. Applying its early-stage oxidative stress measurement prototype, the study design is intended to include both longitudinal and retrospective analyses to identify oxidative stress thresholds in bovines and potential correlations with productive performance.

Memphasys is currently exploring industry partnerships and defining appropriate clinical on-farm partners for data and blood collection. Once this process is complete, Memphasys will provide a detailed update on study progress, including partners, commencement date, and completion date.

**ENDS**

Approved for release by the Board of Memphasys Limited.

**For further information, please contact:**

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## Appendix

**Figure 1: Results of the Japanese trial comparing DGC+SU vs. the Felix™ System**

| | DGC+SU | Felix™ System |
|---|---|---|
| **Processing time** | ~1 hour | ~7 minutes |
| **Fertilisation rate** | 81.0% | 80.6% |
| **Blastocyst development rate** | 52.9% | 58.4% |
| **Good-quality blastocyst development rate** | 26.1% | 35.7% |
| **Embryo utilisation rate** | 54.3% | 58.0% |

**Definition of key terms**

**Blastocyst Development Rate**, measures the percentage of embryos that reach the blastocyst stage, a critical phase in embryo development occurring around five to six days after fertilisation.

Reaching the blastocyst stage is significant because embryos at this stage have a higher chance of successful implantation into the uterus, leading to pregnancy and a live birth.

- **Good-Quality Blastocyst Development Rate**, indicates the percentage of embryos that not only reach the blastocyst stage but also meet specific quality criteria, suggesting they are more viable and likely to result in successful pregnancies.

  High-quality blastocysts are crucial for improving the success rates of assisted reproductive technologies (ART) like IVF. They potentially increase the likelihood of implantation and reduce the need for multiple embryo transfers.

- **Embryo Utilisation Rate**, is the percentage of embryos that are deemed suitable for transfer or freezing after the fertilisation and development process.

  A higher embryo utilization rate implies a more efficient ART process, as it indicates that a greater proportion of embryos are viable for use in treatments, potentially leading to more successful pregnancies per cycle of IVF.