



ASX Release
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Initial Felix product sales update

Highlights

- Preliminary sales discussions underway with some Key Opinion Leaders (KOLs) in 'early markets' with low regulatory requirements.
- Initial Felix KOL testing results have been positive, with recent testing with Monash IVF and University of Newcastle identifying further technique improvements which KOL partners will now incorporate into Felix assessments.
- Key Opinion Leaders (KOLs) in early markets now wanting to test final Felix production cartridges which are now available, to ensure consistency with earlier results, before resuming sales discussions.
- MEM continues with production of final production cartridges, positioning the Company to fill Felix commercial sales orders in early low regulatory markets from early 2021.
- Initial production capability is 26,000 Felix cartridges per annum, with capacity to increase as required.
- Initial sales of Felix production devices are being negotiated with prestigious Chinese medical research institutions seeking to collaborate with Professor John Aitken and his research group at University of Newcastle to expand Felix clinical utility.

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to provide an update on the commercialisation activities for its Felix device, a novel automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures.

Cleanroom & Verification and Validation

Memphasys has completed its initial run of the production cartridges in its cleanroom facility, located at the Sydney headquarters of manufacturer W&S Plastics. W&S has the capacity to produce approximately 100 cartridges per day (26,000 cartridges annually) within the cleanroom, with the ability to scale up substantially, depending on demand. Validation and verification testing for early markets, with cartridges from the initial production, will be completed in early January (after which time customers from early markets can receive product).

Commercial KOL Sales Update

Memphasys remains in regular contact with its KOL partners and in particular the KOLs in early access markets, which provide an opportunity to accelerate commercialisation of the Felix device.

The Felix device has been operating as expected and initial assessment results from KOL partners has been positive, however, recent testing with Monash IVF and University of Newcastle has identified further

technique improvements. This has led MEM to amend the protocol for using the Felix device, with KOL partners requested to use the amended protocol assessment, and improved technique, moving forward.

Preliminary sales discussions have commenced with some early market KOL partners; however they have requested to conduct further Felix testing with production devices from the initial production run and with the new optimised operating protocols, to ensure consistency with earlier results, before resuming commercial discussions. These devices and cartridges have been sent to these KOL partners, with optimised assessment to occur using these devices in January/ February 2021.

Given the adverse current impact of Covid-19 including shutdown of many of our KOL clinics, and the KOLS in early markets seeking to undertake testing of new optimised protocols for their practices using production devices), the Company now anticipates first KOL commercial sales in 'early markets' to occur in Mar/Apr 2021.

Potential Research Sales and Collaboration with Prestigious Chinese Universities

Following a well-attended Felix 'wet lab' demonstration at the Chinese IVF Congress in November 2020 the Company has been approached and is in advanced negotiations with several leading Chinese medical research institutes which are seeking to use the Felix systems for male infertility research projects in conjunction with Prof John Aitken.

Memphasys is working to get Fast Track regulatory clearance in China, which could potentially enable National Medical Products Administration (NMPA)¹ clearance in 2nd Half 2022. China is the single largest IVF market in the world. It is estimated that in 2012 there were approximately 40 million infertile or sterile individuals in China, with changing lifestyle patterns delaying pregnancies, which has led to declining rates of fertility².

In 2017, the number of IVF cycles performed in China was 302,190 and it is expected to reach 842,890 cycles in 2025. In terms of value, the China IVF services market accounted for \$957.04 million in 2018 and it expected to reach \$2.68 billion by 2026³.

This announcement has been approved for release by the board of Memphasys Limited.

ENDS

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¹ The National Medical Products Administration (NMPA) was formerly the China Food and Drug Administration, CFDA

² Allied Market Research Report, 2019

³ Allied Market Research Report, 2019

About Memphasys:

Memphasys Limited (**ASX: MEM**) specialises in biological separations for high value commercial applications. The Company's patented membrane processes in combination with electrophoresis, the application of an electrical potential difference across a fluid, enable the separation of high value substances or contaminants from the fluid in which they are contained.

The main application of the technology is the separation of the most viable sperm cells for artificial reproduction, most particularly for human IVF.

Website: www.memphasys.com