

Initial feedback positive from first Key Opinion Leaders

HIGHLIGHTS

- Initial Key Opinion Leader sites in Japan, India, Canada, USA and Iran took delivery of the Felix device (consoles and cartridges) in late December 2019/early January 2020, received in-person instructional presentations from Memphasys executives and ran initial tests of the device using clinical samples;
- Early feedback from all of the five Key Opinion Leader sites was positive, with devices working as planned (i.e. quick and easy to use, separating sperm with improved average progressive motility than in the semen samples);
- With initial device testing now complete these Key Opinion Leader sites are planning to commence Protocol A assessments in the coming weeks;
- A Key Opinion Leader Agreement has been signed with a prominent New Zealand IVF clinic;

Australian-based bio-separations company Memphasys Limited (ASX: MEM) (“Memphasys” or “the Company”) is pleased to advise that further to the announcement dated 19 December 2019 the initial shipments of the Felix device – a unique device for quickly separating high quality sperm from a semen sample for use in human IVF procedures – have been shipped to the first Key Opinion Leader (“KOL) sites, with initial positive feedback received.



Completion of initial Felix device testing at Japanese KOL: 2nd from left Vikram Chaudhari (Memphasys Project Engineer & QA Manager), 3rd from Left Alison Coutts (Memphasys Executive Chairman) and 6th from Left Dr Tomomoto Ishikawa, CEO of Reproduction Clinic (KOL in Osaka and Tokyo, Japan).

Commenting on the initial feedback from this prominent KOL sites Memphasys Executive Chairman Ms Alison Coutts said:

“To be on hand when these prominent IVF clinics received and tested the Felix device was such an important and exciting time for everyone involved with the development of the Felix device.

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We were confident on how the Felix device would perform, but to see how easily and quickly it was able to be used and that it performed exactly as expected in various commercial IVF settings was extremely satisfying.

Based on this positive initial feedback from the sites, we are now eagerly anticipating their commencement of the Protocol A assessments, which they have indicated will commence within weeks.”

In addition to the Felix device at Monash IVF, a total 6 consoles and 320 cartridges were dispatched by end of December 2019. As previously advised, the majority of IVF centres to receive these first Felix devices for the KOL assessment program are in countries believed to have a regulatory framework that aligns to the Company’s commercialisation objectives of seeking early commercial sales timeframes. These include sites in Japan, India, Canada and Iran.

These markets, plus New Zealand where Memphasys has now secured a KOL partner, are highly attractive for Memphasys, with a recently released independent research report¹ concluding these counties will continue to support both a sizable and rising number of IVF procedures each year.

Country	IVF cycles in 2018	Expected fresh IVF cycles by 2026	% growth rate	KOL in market (Y/N))
Japan	269,110	699,110	160%	Y
India	169,800	489,840	188%	Y
Canada	6,360	21,140	232%	Y
Iran ²	N/A	N/A	N/A	Y
New Zealand	5,300	11,190	111%	Y

A US site also received and tested the Felix device as part of this first batch. Another device was provided and demonstrated in China. The USA, China and Europe represent large target markets for the Company. Memphasys expects to deliver further Felix devices to the remaining KOL sites (including in the US and EU) during Q1 2020, noting that the US, EU and China are markets with longer regulatory lead times than the markets Memphasys are targeting for early commercial sales.

Memphasys has commenced the Felix device verification and validation (“V&V”) process, required to be completed before regulatory registration (if required) and commercial sales in these early target markets can commence, and expects V&V to be completed by mid-CY2020.

New Zealand KOL secured

Memphasys is pleased to advise it has signed a KOL Memorandum of Understanding (“MoU”) with Fertility Plus, a leading established fertility clinic based at the National Women’s Hospital in Auckland, New Zealand.

Fertility Plus provides a comprehensive range of fertility investigations and treatments which are both publicly and privately funded. It has been a leading IVF treatment provider in New Zealand, advancing research and evidence-based care for more than 35 years.

¹ Kunsel & Joshi 2019, ‘Global IVF Services Market: Opportunity Analysis and Industry Forecast, 2019-2026’, *Allied Market Research*, pp. 1-744.

² While no country-specific data was available for Iran, the Middle Eastern region is deemed to be a growth market for IVF services, with the region as a whole completing 81,350 fresh IVF cycles in 2018. The region is expected to complete 128,340 fresh IVF cycles by 2026.

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With Fertility Plus being part of Auckland District Health Board (“DHB”) which has three major facilities: Auckland City Hospital, Starship Children's Hospital and Greenlane Clinical Centre, it has access to the best specialists and expertise available. Its services are integrated with the general gynaecology, maternity and medical services at Auckland DHB, ensuring support for all aspects of a patient’s fertility treatment and ongoing care. Fertility Plus also has close links to the Auckland University Medical School.

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

ENDS

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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

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