ASX Release
12th September 2019

Operational Update

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to provide an operational update regarding product development and commercialisation of the Felix device, a unique device for separating high quality sperm from a semen sample for use in human IVF procedures.

During the current quarter a range of key product development, research and regulatory activities have advanced.

Limited production of Felix devices & cartridges to be manufactured by end of quarter

A significant milestone will be accomplished during the remainder of this quarter – a limited pilot production of Felix devices, which will comprise consoles and fully disposable cartridges.

MEM's cartridge manufacturer W&S Plastics ("W&S") and console manufacturer, SRX Global, are now planning for production of the first batch of 500 cartridges and 25 consoles respectively. Further batches will then follow.

The devices will be used in an additional verification and validation process during the following months and will also be used as the initial supply of devices for the Key Opinion Leader ("KOL") assessment program.

During the quarter, researchers under the guidance of Professor Michelle Lane at Monash IVF used the benchtop re-usable prototype device in a range of testing with clinical samples, including samples of low sperm count. The prototype device emulates the operations of the final, disposable cartridges. During this testing, Professor Lane's group has successfully evaluated the use of various commercial media (the liquid in the cartridges that conducts current and is also conducive to sperm) in comparison with Memphasys' in-house proprietary media and has determined that certain commercial media can be substituted for the previous in-house media used in the device.

The commercial media works in a similar manner to the Company's own media (which the Company may submit for regulatory approval at a later date), however the use of commercial media has the potential to provide an easier regulatory pathway.

KOL Assessment program

In parallel with the verification and validation process, the first production batch of devices will be rolled out for first testing by KOLs under the KOL assessment program, starting at end of September 2019.

Memphasys plans to commence the KOL program via a staggered release of devices, which will optimise the effectiveness of the program and allow the Company to target certain key jurisdictions as an immediate priority.

A Clinical Applications Executive with specialist expertise in reproductive medicine, as well as experience in the IVF industry and sales and marketing, has been recruited to oversee the KOL program and provide local support as necessary. The Clinical Applications Executive will also assist in assembling the technical file for regulatory submissions.

Verification and Validation ("V&V") process

The V&V process will require that the full design and manufacturing process of the device has been satisfactorily completed, including (but not limited to) the following key activities:

- The setting up of a biologically controlled manufacturing environment at W&S
- Cartridge gamma sterilisation, post manufacturing at W&S
- Traceability demonstration of all key components used in the manufacturing process and demonstration of final product packaging and labelling
- Full electrical safety testing, and Mouse Embryo Assay testing ("MEAs") at Monash IVF, as verification that the cartridge manufacturing process is biologically safe to use
- Requisite shelf life testing of cartridges and consoles
- Clinical testing, independently performed by Monash IVF, to show the device meets its intended use.

This activity will occur during Q4 2019 and is a key step in the roll out of the commercial grade Felix device. It will run in parallel to the KOL assessment program.

Regulatory Update

The need to complete validation work, together with the changing regulatory framework in Europe, will have an impact on the completion of the technical files required for regulatory submissions, most notably the CE Mark application which was expected to be lodged in the current quarter and the FDA application, which was planned to be lodged in Q1 2020.

Despite expected delays to submitting applications to these two jurisdictions, Memphasys, together with its regulatory advisors, has been actively evaluating a range of sizable and/ or useful early test markets (outside of the above-mentioned markets) with lower regulatory hurdles, which provides a greater chance of seeing commercial sales of the Felix device in mid to late 2020.[1]

[1] Subject to meeting any requisite legal and regulatory approvals and gaining market support by KOLs in the specific targeted jurisdictions for the use of the Felix device in their clinics/ andrology centres.

CE Mark application (Europe)

Following increasing uncertainty with regard to European regulations, in particular the revised Medical Devices Regulation (MDR) which will take full effect in May 2020, together with the need to include validation data from Monash IVF using the final cartridges and commercial media, the Company will not complete CE Mark regulatory submission during Q3 2019.

The arrival of the Medical Device Regulation (MDR) brings a substantially increased workload for Notified Bodies which oversee the certification process – with substantially increased and more stringent requirements for the Notified Bodies and manufacturers to address. A number of Notified Bodies have left the industry and the majority of Notified Bodies have not qualified to assess manufacturers according to the MDR. This has placed further strain on the regulatory resources available to assess CE Mark applications.

Given the uncertainty in timing for the availability of Notified Bodies to asses new manufacturers under the MDR, Memphasys is uncertain of the submission and approval timeline for CE Mark approval at this time. Memphasys affirms its intention to continue with a CE Mark submission, regardless of the changing regulatory landscape, and will provide updates to shareholders as further information comes to hand.

Australian Therapeutic Goods Administration (TGA)

Memphasys is currently planning for a pre-submission meeting with the TGA in Q4 during which the full submission process will be discussed. During Q4 2019, Monash IVF will be gathering data on Felix device performance as part of the validation process. This and other data will be used in the formal submission to the TGA, which is planned for Q1 2020, but timing will largely depend on the amount of Felix data and other V&V data to be submitted.

US FDA

On the advice of its regulatory consultant, Memphasys intends to seek a pre-submission meeting with the FDA to confirm the Felix device can be assessed under the *de novo* regulatory process and also to confirm the specific technical and clinical data requirements for its application.

It takes approximately three months to complete the pre-submission process, for which a comprehensive data file must also be included.

Memphasys is currently compiling a substantial quantity of technical information and data from clinical IVF samples for its pre-submission data file, however as a large volume of this information will only be gathered in Q4 CY2019, it does not anticipate being in a position to request the pre-submission meeting with the FDA until late Q1 2020/ early Q2 2020.

Other markets with potential faster path to commercial sales to be targeted

Given the expected delays to submitting CE Mark and FDA regulatory applications, the Company, together with its regulatory advisors, has been actively evaluating a range of sizable and/ or useful early strategic test markets (outside of the above-mentioned markets) with lower regulatory hurdles.

Memphasys is already working with KOLs in a number of these markets. Memphasys believes that targeting these other markets first (but while still pursuing the other above-mentioned markets) would provide early and valuable clinical KOL user feedback to enable well-considered pricing to be set and it would also enable a quicker path to commercialisation and early sales.

Subject to meeting any requisite legal and regulatory approvals and gaining market support by KOLs in the targeted early jurisdictions for the use of the Felix device in their clinics/ andrology centres, Memphasys believes it will commence commercial sales of the Felix device in mid to late 2020.

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.