ASX Release
16 June 2020

ASX Code: MEM

Felix Device commercialisation on track, despite Covid19

Felix Assessment Program with International Key Opinion Leaders (KOLs)

- **Positive Felix KOL data received from initial sites, with additional data expected in coming weeks as additional sites recommence accepting patients and continuing Felix assessments.**
- **Strategic partner and KOL site, Monash IVF, has re-started IVF services and the Felix assessment program following the Australian Government's recent decision for recommencement of elective surgery.**
- **Completion of Felix KOL assessment trial is independent of Felix Verification and Validation, which is a parallel process.**

Felix Verification & Validation (V&V)

- **Felix cartridge production cleanroom has been completed after a delay due to Covid19, with all equipment scheduled to be installed and cleanroom certification to ISO7 and ISO8 planned for completion by end July 2020.**
- **Felix V&V validation test using final production devices on clinical samples planned to be undertaken at Monash IVF in Q3 2020.**

Felix Product Development

- **Despite some delays to Product development process due to Covid19, first Felix commercial sales still expected in Q4 2020.**

MEM Sufficiently Funded

- **MEM is fully funded for all planned KOL, V&V and commercialisation activities through to Q1 2021, with ~$2.3 million in cash reserves as at 1 June 2020.**

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") remains on track for first commercial sales of the Felix device to be in Q4 2020, despite delays caused by Covid19. Felix is a unique, automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures.

As at 1 June 2020 the Company has ~$2.3m in cash reserves, sufficient to fund the planned KOL assessments, V&V activities, product development and key commercialisation activities.

Felix International KOL Assessment Program Update

The Company has made important progress as part of the KOL assessment program with positive early data received from initial KOL sites and additional data is expected in coming weeks.

The Australian Government's recent decision to allow elective surgeries to recommence, including IVF services, has enabled Felix testing at Monash IVF to resume. With IVF services now permitted, Monash IVF is continuing its collaboration with Memphasys, which is considered a high strategic priority for both companies.

The testing initially involves Monash's participation in the Felix KOL program but also extends to other services to be provided by Monash IVF including validation studies on the final device with clinical samples and assessment of alternative commercial media that could be used with the Felix device.

With Covid19 restriction measures in place, KOL clinics in USA, Canada, Europe, India and Iran have been temporarily shut. While positive initial data has been received from a number of these sites, the final Felix KOL trial outcomes from these sites will be delayed.

Clinics in China and Japan are beginning to accept patients again with IVF demand ramping up and their involvement in Felix KOL assessment program resuming. It is expected more of the KOL Felix assessment data will be received from these sites in the following months. The New Zealand clinic, which had been temporarily shut due to Covid19, is also gradually re-opening.

The Felix KOL assessment program is independent of Verification and Validation, which is a parallel process. Some early feedback from the KOL trials has been used to monitor the usability and performance of the Felix device and also ensures appropriate validation of the device.

Felix V&V Update

Memphasys has made significant progress in the Felix verification and validation (V&V) process, with key milestones achieved. V&V is an internal testing process and it, together with clinical data using the final manufactured device (i.e. post V&V), is required to be completed before sales in highly regulated markets can occur. Sales in less regulated markets (i.e. Japan, New Zealand and Canada) may commence following completion of a subset of the full V&V testing requirements The cleanroom at W&S Plastics, the cartridge manufacturer, has now been completed. Installation and successful completion of test runs of the full suite of equipment for final cartridge manufacturing and cleanroom certification to ISO7 and ISO8 are expected by end July 2020.

W&S is in the final stages of preparing to manufacture Memphasys' proprietary hydrogel membranes (previously made at Memphasys), with technology transfer having been completed. For this purpose, Memphasys has transferred some specialised equipment to W&S. Whilst Memphasys has made sufficient membranes for the initial Felix KOL assessments, the final quality build cartridges require the membranes to be made and assembled at W&S in a cleanroom environment.

After validation of the cleanroom to ISO7 and ISO8 standards, final quality build cartridges will be produced and sterilised, ready for use in Validation tests. After passing requisite Verification and Validation activities, the cartridges will be ready for commercial use in early markets.

One validation test requires the use of clinical semen samples, which are planned to be provided by Monash IVF's Adelaide-based andrology centre. Whilst that centre has remained open it experienced smaller than usual volumes due to Covid19, but volumes are now increasing. It is now able to test the performance of the device in its intended environment of an IVF clinic or andrology centre. This Felix testing is part of the Validation process and is separate from the Felix KOL assessment program currently underway.

Formal clinical trials for highly regulated markets including Australia, USA and Europe will subsequently be required before regulatory approvals and sales can occur in these markets, however no such trials are required for the targeted early markets such as NZ, Canada, Japan and India.

Product Development Update

The Company is successfully progressing Felix product development, with development partner Hydrix continuing to work with Memphasys, ensuring Verification is on track.

W&S Plastics, a major supplier of respirators, had been asked to significantly increase production of respirators to cater for Covid19. Despite this, W&S have kept resources available for Memphasys and are continuing their work on the commissioning of Felix cartridge production. Both W&S (Felix cartridge manufacturer) and SRX Global (Felix console manufacturer) have 'critical supplier' status and will remain open during Covid19 constraints.

Whilst Memphasys anticipates the overall product development program will be delayed by approximately three months due to the impact of Covid19 on some suppliers, the delays are not likely to impact expected first sales of the Felix Device, which remains on track for Q4 2020.

Chairman Line of Credit Cancelled

As a result of the strong financial position of the Company and strong support shown to Memphasys by its substantial and other investors, the line of credit facilities the Company had in place with Chairman Alison Coutts (refer ASX announcements dated 23 February 2017 and 3 July 2017) have been terminated by mutual consent.

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 assisted reproduction, most particularly for human IVF procedures.

Website: www.memphasys.com