ASX Release
6 November 2019

UPDATE ON COMMERCIALISATION OF FELIX DEVICE

Felix Production System – comprising the console and disposable cartridge

Single-use disposable cartridges for distribution to KOL sites

HIGHLIGHTS

- Initial Felix system cartridges and consoles for the KOL assessment program produced, with first devices distributed to KOL Monash IVF and University of Newcastle who had both previously tested the pilot production devices and cartridges.
- Both are now thoroughly testing the new production devices, including packaging, labelling and operating instructions, prior to the wider KOL rollout which will commence in the coming weeks and be staggered over the coming months.
- Monash IVF also undertaking formal KOL protocol assessments using clinical samples covering a wide array of male fertility issues likely to be experienced by commercial IVF centres.
- Outcomes of protocol assessments undertaken to provide further evidence of the technical capabilities and commercial opportunities of the Felix device in commercial IVF centres, with KOL sites expected to be some of the first to purchase the Felix system cartridges and consoles.
- Commercial pathway being finalised, prioritising major and/or strategic markets with regulatory environments aligned to the Company's commercialisation objectives and early commercial sales timeframes.
- Initial commercial sales are expected to occur in mid to late 2020, subject to meeting any requisite legal and regulatory certifications and gaining market support by KOLs in specific targeted jurisdictions for the use of the Felix device in their clinics/ andrology centres.
- ASRM Scientific Congress & Expo in USA attended and meetings held with six of the current KOL groups and three potential strategically important additional KOLs, with India-based Nova Pulse IVF Group since signing an MoU to participate in the KOL study at their Ahmadabad clinic (one of 19 they have across India).
- Positive early stage discussions about potential distribution also held with three major global market leaders in the IVF business.

Memphasys Limited **(ASX: MEM)** ("Memphasys" or "the Company") continues to advance the 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, with key milestones continuing to be met and the Company on track for commercial sales from mid CY2020[1].

Commenting on the production and distribution of the KOL devices and the commencement of the protocol assessments, Memphasys Executive Chairman Ms Alison Coutts said:

"It is exciting to finally see the consoles and cartridges produced and that the KOL evaluation program is underway.

"With respect to market strategy, the company, together with our regulatory advisors, has been proactive in analysing a range of sizable early strategic test markets with lower lead times than CE Mark in Europe and the US FDA and we have come up with a number of new, highly attractive markets which we are verifying."

MEM's manufacturer of the Felix cartridge, W&S Plastics ("W&S"), has produced 300 cartridges, with a further 200 to be delivered by mid-November and 2,000 in early December. Three consoles have also been produced, with a further 15 to be supplied in early December and in early 2020.

The consoles and cartridges are to be used for the Key Opinion Leader ("KOL") assessment program, engineering verification and clinical validation.

Commencement of Felix device roll out to Key Opinion Leader (KOL) sites

The first consoles and cartridges have been distributed as part of the KOL assessment program, with Professor Michelle Lane at Monash IVF and Professor John Aitken's research facility at the University of Newcastle now testing the devices. Monash IVF is using clinical samples, covering a wide array of fertility issues, whilst the Aitken lab is using university donor samples.

Monash IVF and the University of Newcastle had previously tested the pilot production devices and cartridges and are now undertaking rigorous assessment of the current Felix devices which will be used in the global KOL assessment program. In addition to evaluating the device's performance, they are also assessing the packaging, labelling and instructions for use, to ensure the wider KOL roll-out occurs successfully and that the KOL sites will be able to follow the study protocol with the instructions and processes provided.

A Clinical Applications executive with a PhD and clinical expertise in reproductive medicine has been recruited to oversee the KOL program and provide support to the KOLs.

Further initial KOL sites are on track to receive their Felix devices and to commence protocol assessments within weeks, with the wider rollout to occur in a staggered manner over the coming months.

Attendance at American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo – key meetings held/ strategic KOL MOU agreement signed

[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

In October, Memphasys representatives attended the 75th American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo in Philadelphia where world renowned fertility expert and co-inventor of the Felix technology Professor John Aitken was a keynote presenter.

The ASRM Congress was a significant success for the Company. Together with Professor Aitken, Company executives held meetings with six of the current thirteen KOLs and with three potential and strategically important additional KOLs.

The Company signed a Memorandum of Understanding (MoU) with India-based Nova Pulse IVF Group, who the executives met at the event, to take part as a KOL in the assessment of the Felix device at their Ahmadabad clinic.

With 19 IVF clinics in 15 cities across India, Nova IVF is a leading IVF clinic research group which aims to bring advanced Assisted Reproductive Technology (ART) to India.

The Company believes India represents a sizable early market for Memphasys, providing a regulatory environment aligned to the commercialisation objectives and timeframes of the Company.

Commenting on the signing of the key KOL MoU with Nova Pulse IVF, Ms Coutts added:

"The signing of Nova IVF to take part in the KOL assessment program represents a major achievement in this regard since our regulatory advisors believe India has a regulatory pathway which may result in a quicker path to commercialisation and sales of the Felix device being achieved much sooner than in many other markets.

In addition to signing Nova IVF, we are close to signing two additional KOLs, one of which is based in a country also with a relatively quick path to commercial sales. We look forward to providing an update once these MoUs are finalised."

Regulatory Update

MEM is prioritising major and/or strategic markets with regulatory environments aligned to the Company's commercialisation objectives and early commercial sales timeframes, whilst pursuing regulatory certifications in higher regulatory hurdle markets such as Australia, Europe and the USA.

The Company's preparation is on track to file a request for a pre-submission meeting with the TGA in Q4 CY2019 which should clarify regulatory requirements and potential timeframe for Australian regulatory certification.

To be deemed a commercial device, the current devices being manufactured (and provided to KOLs) must also pass the verification and validation ("V&V") process. Verification is commencing now and is expected to be complete by year end. Validation, which follows, is expected to be completed by mid-2020. The two long lead time items are manufacturing clean room set up and validation at W&S and biocompatibility studies on cartridge materials sampled from the final validated process.

The Company proposes to initially use regulatory-certified media in the Felix device rather than its own proprietary media to enable faster regulatory certifications in high regulatory hurdle markets. However, these commercial media will require the necessary regulatory approvals for

expanded indications for use with the Felix device in certain markets. MEM is assessing how to best expedite approval for this expanded use.

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