ASX Release
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Felix Product Development and Commercialisation Update

Anticipated Milestones*

Product Development

- Pre-production Felix device expected to be completed by end of March 2019 quarter.
- Testing of pre-production devices and preparation for production in June 2019 quarter.
- Final Felix clinical device completion anticipated by end of September 2019 quarter.

Regulatory**

- Clinical data for CE Mark regulatory approval at Monash IVF (using Felix clinical device) anticipated to be completed by end of September 2019 quarter.
- Submission filed for CE Mark expected by the end of September 2019.
- CE Mark review and approval anticipated June 2020 quarter.

International KOL *in-vitro* Assessment

- KOL protocols agreed & ethics in place ready for clinical studies during June 2019 quarter.
- First Felix devices planned to be distributed by end of September 2019 quarter to recruited global IVF Key Opinion Leaders ("KOLs") to commence clinical studies.
- KOL assessment program expected to be completed in first half of 2020.

Market Launch

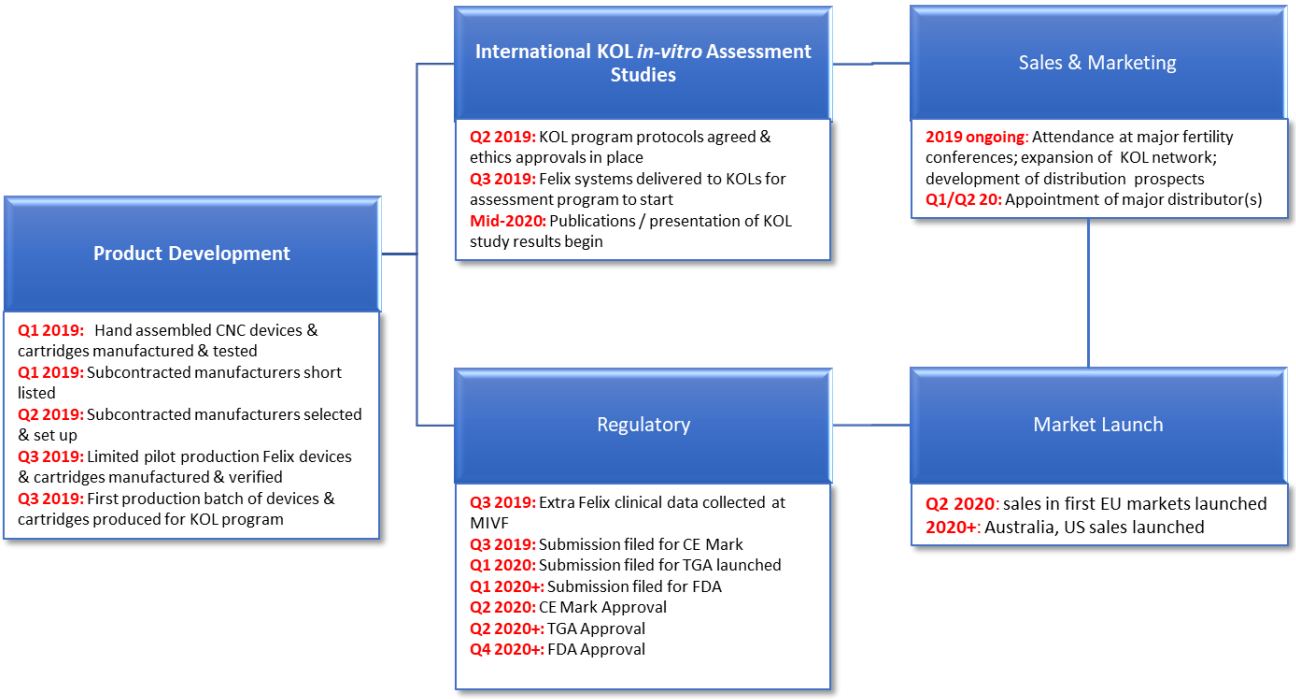
- Commercial sales in selected European Union countries targeted for first half 2020.
- Post EU launch, other territories (Australia, US, other) anticipated in second half of 2020 and beyond.

**The dates outlined in Anticipated Milestones are indicative only and subject to change.*
***Note: Only one KOL (anticipated to be Monash IVF) is required to provide the technical data to allow the technical file to be submitted for CE Mark accreditation.*

Memphasys **(ASX: MEM)** ("Memphasys" or "the Company") remains on track with the product development and commercialisation strategy for its Felix device, a unique device for separating the most viable sperm in a semen sample for use in human IVF.

The technology, developed in conjunction with world renowned fertility expert, Prof John Aitken from the University of Newcastle, provides crucial advantages over current sperm processing methods.

The following table provides an update on the anticipated timing of the Felix product development and commercialisation.



Note: The dates on the table are indicative only, reflecting what Memphasys currently expects will be the most likely commercialisation milestone timeframes.

Product Development:
Key operating parameters optimised/ verified as functionality/ergonomics improved

Hydrix, Memphasys' engineering development partner, is currently finalising the manufacture of three hand-assembled CNC-made, fully functional pre-production devices and 20 cartridges which are anticipated to be manufactured and tested during the March 2019 quarter.

The device will be thoroughly tested with human samples initially at the University of Newcastle and then at Monash IVF Group. When it has passed testing, the final injection-moulded production device will be manufactured at scale, ready for *in-vitro* testing by Monash IVF and by selected KOL IVF clinics globally which is targeted for the September Quarter 2019. Memphasys has been and will continue to work closely with Monash IVF Group to improve the functionality and ergonomics of the Felix device. This has led to a number of improvements to be incorporated into the final commercial device.

Regulatory Plan

Memphasys has appointed the British Standards Institute (BSI) as its notified body for obtaining CE Mark approval and is working towards obtaining ISO13485 accreditation followed by receiving CE Mark approval. The technical file is anticipated to be completed during the September 2019 quarter using initial clinical samples run by Monash IVF.

The Company only requires one KOL (anticipated to be Monash IVF) to provide the technical data to allow the technical file to be submitted for CE Mark accreditation.

Other international KOL studies will be ongoing and will not hold up the regulatory process for Felix to obtain CE Mark approval.

According to the latest in-depth review of all activities required to complete the commercial development of Felix, Memphasys expects to receive first regulatory approval, CE Mark in Europe to sell the device in European markets, in the June 2020 quarter.

Memphasys will then seek regulatory approval in other territories including Australia and the United States.

Key Opinion Leaders (KOLs) using the Felix Device

A number of IVF KOLs in the United States, Europe and the Middle East have formally signed MoUs to undertake *in-vitro* clinical assessments using the Felix device and to assess its ability to select the most viable sperm for human IVF treatments.

Finalisation of the protocol assessments and ethics approvals for the KOL international assessment program are planned by the end of the June 2019 quarter, after which the assessment program is anticipated to be conducted from the September 2019 quarter through to the March 2020 quarter, with KOL publications and presentations on study results anticipated from mid-2020.

The first protocol will allow the KOLs to assess the device against the current sperm preparation techniques, notably "Density Gradient Centrifuge" ("DGC") and "Swim-Up". Additional protocols for further testing will be devised and agreed between each KOL centre and Prof John Aitken, depending on the interest of the particular KOL centre. Memphasys expects some KOLs to test Felix's ability to retrieve the best sperm from frozen semen samples, from testicular biopsies and from a plethora of specific male infertility issues.

The outcomes of these studies will provide further evidence as to the technical capabilities and clinical benefits of the Felix device, provide significant user examples of range of use and further define the commercialisation strategy of the Company.

An i*n vitro* study is to be conducted, most likely by Monash IVF Group, to complete the technical file for seeking CE Mark regulatory approval of the device, which is required for marketing the device in the European Union.

Sales & Marketing

As KOL technical findings on the Felix device are published, Memphasys will accelerate the development of marketing materials and sales booth attendance at major international fertility conferences. Post CE Mark approval and commercial market launch, targeted for the June 2020 quarter, the Company plans to distribute the device directly to the European IVF clinics and andrology centres that wish to use the device in their clinical practices. However, as demand grows, it will also seek to appoint a global distributor, or regional distributors, for distribution of the Felix device.

Equine Application

Progress on the equine technology application is continuing and the Company will update the market on its progress shortly.

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.