



ASX Release  
9 April 2019

## **MEMPHASYS CONTINUE TO MEET FELIX PRODUCT DEVELOPMENT MILESTONES, APPOINTS FIVE ADDITIONAL KEY OPINION LEADERS**

### **Highlights**

#### **Felix Product Development**

- Successfully completed the manufacture of hand-assembled CNC-made pre-production devices and cartridges.
- Conducting ongoing testing of device and cartridges ahead of large-scale manufacturing.

#### **Appointment of sub-contracted manufacturer**

- Sub-contract manufacturers have now been shortlisted.
- In process of identifying and finalising contract with chosen subcontractor(s).

#### **Appointment of KOLs**

- A further five Key Opinion Leaders (“KOLs”) appointed to undertake *in-vitro* assessments of Felix device.
- Two more KOLs are currently being finalised.
- A total of 12 KOLs now appointed across Europe, Nth. America, the Middle East and Australia.

#### **KOL Program Protocols**

- Protocol “A” for all KOLs to follow has been developed and distributed to the KOLs.
- Finalisation of protocol assessments and ethics approvals remain on target for end of June 2019 quarter.

---

Australian-based bio-separations company Memphasys Limited (**ASX: MEM**) (“Memphasys” or “the Company”) is pleased to provide an update regarding the appointment of Key Opinion Leaders (KOLs) and the product development strategy for its Felix device, a unique device for separating the most viable sperm in a semen sample for use in human IVF.

Pleasingly, all milestones detailed in the “Felix Product Development and Commercialisation Update” (ASX announcement dated 29<sup>th</sup> January 2019) remain on track or have been achieved.

The Felix product development and commercialisation timeline can be found in the Appendix to this announcement.

### **KOL Update**

A number of IVF KOLs in North America, Europe and the Middle East have formally signed Memoranda of Understandings (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 versus current methods.

Memphasys has now signed a further five (5) MoUs with globally significant research and IVF clinic groups to take part in assessments of the Felix device.

This now brings the total number of centres who have so far agreed to participate in the assessments to twelve (12). The five new centres include:

CrEATe Fertility (Toronto, Canada)

Cornell Weill Medical Centre (NY, USA)

Hospital No. 9 Fertility Clinic (Shanghai, China)

Livio AB (Stockholm, Sweden)

Monash IVF Group<sup>1</sup> (Melbourne, Australia)

Memphasys is in the process of finalising the remaining two KOLs, located in Japan and the United Kingdom. This will bring the total number of KOLs to 14 with no further recruitment of KOLs required.

As previously outlined, the KOL clinical assessment studies will assess Felix's performance for IVF clinics in preparing sperm from diverse semen types when compared with the current lab-based methods.

The outcomes of the Felix clinical assessments will provide further evidence as to the technical capabilities and broaden the clinical validation of the Felix device, providing significant clinical data support for the Felix market launch.

### **KOL Protocol Update**

Memphasys, with input from world renowned fertility expert Prof John Aitken from the University of Newcastle and Monash IVF Director of Science and Innovation, Prof. Michelle Lane, has now developed the first protocol (Protocol A) which has been distributed to all KOLs, including the five recently signed organisations.

Protocol A allows KOLs to assess the Felix device against their 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 Aitken, depending on the interest of the particular KOL centre.

Finalisation of Protocol A for the KOL international Felix Assessment program remains on track, to be completed by the end of the June 2019 quarter.

### **Product Development Update**

Hydrix, Memphasys' engineering development partner, has now completed the manufacture of hand-assembled CNC-made, fully functional pre-production devices and 20 cartridges.

Testing of the Felix devices by Memphasys and Prof Aitken's laboratory have now been completed with each device performing in line with expectations.

---

<sup>1</sup> KOL MoU is in addition to Collaborative Agreement between the parties (see ASX Announcement 18 September 2018)

Testing of both the pre-production device and cartridges will continue with the objective of making improvements and improving efficiency for large-scale manufacturing which will require significant capital expenditure.

### **Subcontracted Manufacturers Update**

Memphasys has now shortlisted subcontract manufacturers and is working through a process to identify and finalise a contract with the chosen subcontractor(s).

The Company will update the market once the manufacturer has been appointed.

**Commenting on the significant progress made, Memphasys Executive Chairman, Alison Coutts, said:**

*“I am pleased with what our company has recently achieved in the product development and commercialisation of the Felix device with the assistance of Prof John Aitken.*

*We are meeting our key milestones within the timeframe that we have set out and remain on target to deliver Felix devices to KOLs for assessment program to commence in September Quarter 2019. I look forward to updating shareholders again in the near future as we move closer to commercialisation.”*

ENDS

**For further information please contact:**

Alison Coutts  
Executive Chairman  
Memphasys Limited  
T: +61 2 8415 7300  
E: [alison.coutts@memphasys.com](mailto:alison.coutts@memphasys.com)

David Tasker  
Managing Director  
Chapter One Advisors  
T: +0433 112 936  
E: [dtasker@chapteroneadvisors.com.au](mailto:dtasker@chapteroneadvisors.com.au)

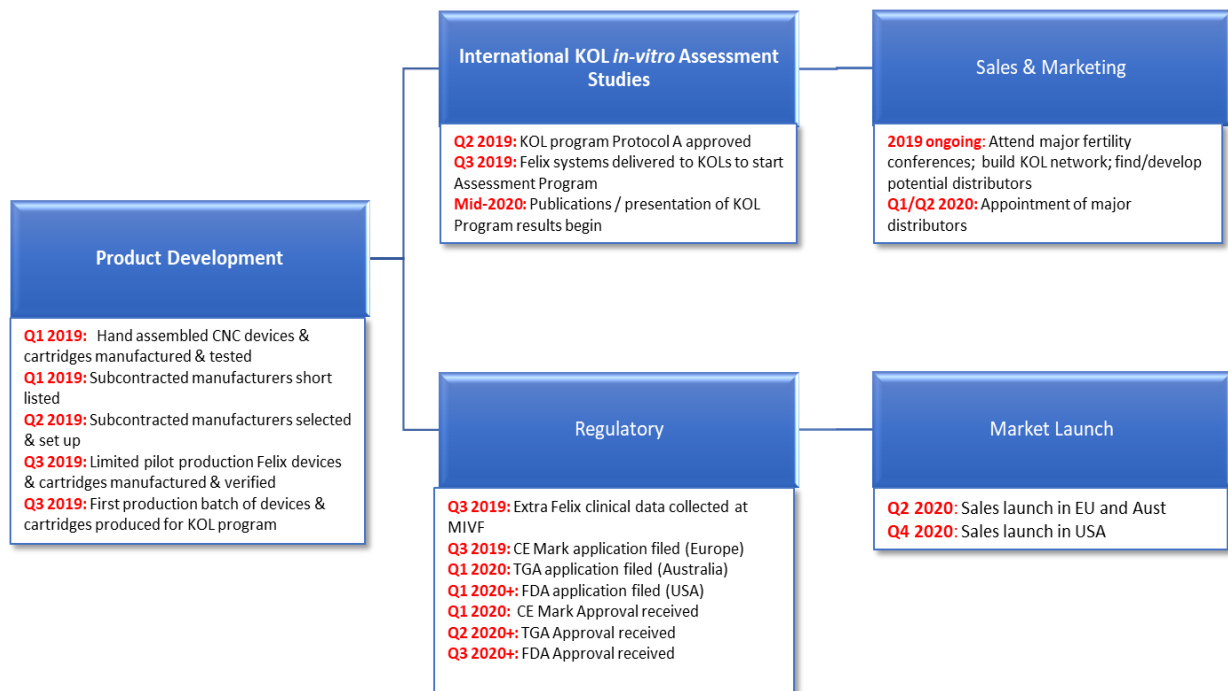
### **About Memphasys:**

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.

## Appendix

### Felix product development and commercialisation timeline



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