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FELIX COMMERCIALISATION UPDATE

Highlights

- **Verification & Validation (V&V) enters final stages**
- **Positive Felix Key Opinion Leader (KOL) data continues to be received from initial sites in line with expectations**
- **W&S Plastics overseeing cleanroom validation to ISO7/ISO8 standards with cartridge manufacturing underway**
- **On track for potential first sales of Felix device in Q4 CY2020 in less regulated markets**
- **The Board approves ESOP options following satisfaction of all legal & regulatory requirements in 2nd and 3rd market jurisdictions – Japan & NZ**

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to confirm it remains on track for first commercial sales of its Felix device in Q4 CY2020 for early markets, with Verification and Validation (V&V) testing entering final stages, which is required before commercial sales can commence.

The Felix device is a novel automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures.

The Felix device consists of a console as well as single-use cartridges which contain the cell separation technology and are used for each IVF cycle. The cartridges combine an electrophoresis technology with size exclusion-based membranes, patented hydrogels, and other polymer membranes to separate sperm cells from semen samples.

Following biocompatibility characterisation of the Felix disposable cartridge, better medical grade materials have been adopted for two components. This has made the compliance with biocompatibility regulations more robust.

Final V&V activities are now underway, and the tests required for early market sales are expected to be completed by late November. This initial subset of the full V&V testing requirements allows Felix to be sold in less regulated markets including Japan, Canada, NZ and India.

Cleanroom Update

Although COVID-19 has caused inevitable delays to supply chains with changes to some component suppliers and delayed material, the Company is still on track for potential initial sales in less regulated markets before the end of December 2020.

Validation of the cleanroom to ISO7 and ISO8 standards is being completed by the cartridge manufacturer, W&S Plastics. Final production cartridges will be produced in the cleanroom and are scheduled to be sterilized by mid-November, followed by completion of V&V for early markets. Shipments to customers in early markets may then commence by end-December.

Felix International KOL Assessment Program Update

The Company continues to make good progress with its KOL assessment program, despite many of the 13 KOL IVF clinics in 8 countries being shut down for 4-5 months due to COVID-19. The comparative data received so far for Felix versus their current sperm separation methods is demonstrating how Felix use can be optimized in a clinical IVF setting.

Early KOL Felix comparison study data has been received from sites in Shanghai, Tokyo, Toronto, Gothenburg, Ahmadabad (India), Melbourne and Isfahan (Iran). KOL centres in Auckland, Muenster (Germany), Clermont (France), New York, and Boston were seriously delayed by COVID-19, but all have now commenced the '50 patient samples' protocol. Data from most sites should be completed and supplied to the study's Principal Investigator, Prof John Aitken (University of Newcastle) by end-December for analysis and reporting in 1st Quarter 2021.

Early Market Update

Memphasys has now satisfied all legal and regulatory requirements to distribute its Felix device in the market jurisdictions of Japan and New Zealand. This is in addition to Canadian market, where Memphasys has already conformed it has met the legal and regulatory requirements to sell the Felix Device in that market (refer ASX announcement dated 10 July 2020). Commercial sales in one (or more of these) jurisdictions are expected to begin upon the Company completing V&V tests on the final manufactured product, and the Tokyo and Auckland Felix KOL assessment studies have been completed.

Japan

Felix has been assessed by a Japanese regulatory laboratory, AoLight Regulatory Laboratories, which declared that Felix is a non-medical device, and can therefore be imported and sold in Japan as laboratory equipment rather than as a medical device, significantly reducing the regulatory requirements for the product.

The Felix device has been certified for Electrical Safety (IEC 606010-1:2010 (Ed3.0) and Electromagnetic Compatibility to EN 61326-1: 2013 (IEC 61326-1: 2012 ED 2.0) by EMC Technologies, who have Accreditation for Conformity Testing by Japan's VCCI authority (Company Number: 785).

In the Japanese market, Memphasys is planning to initially undertake direct sales of Felix to a selection of leading IVF clinics, before appointing a distributor.

The Japanese IVF market represents a key early market for the Felix device for the following reasons:

- Japan has the highest rate of IVF treatment in the world, and the lowest [pregnancy] success rate of about 20%. One reason for this is the increasingly advanced age of recipients. [1]
- In 2020, 689,000 IVF cycles are forecast to be performed in the Japan market, and this is expected to reach 1,107,000 by 2025, growing at a CAGR of 12.0% from 2019 to 2026. [2]
- There are roughly 600 IVF clinics in Japan that help infertile couples. [3]

[1] Akiko Matsumoto, president of the NPO Fertility Information Network (Fine)
[2] Allied Market Research Report, 2019
[3] Klaus Jacobsen, President of Origio Japan, EuroBiz Japan Aug 2020

- Fresh IVF cycles were forecast to make up 52% of all IVF cycles in Japan in 2020 [4]

New Zealand

In New Zealand (NZ), Felix is also classified as a laboratory instrument rather than as a medical device. Memphasys' Felix KOL study site in NZ (Fertility Plus, Auckland) is about to begin the study protocol, and sales in NZ can commence once this protocol and Felix early market V&V are completed.

Felix has been registered on NZ's Web Assisted Notification of Devices (WAND) database. In the NZ market, Memphasys is planning to sell directly into the NZ market from its Sydney HQ.

The NZ IVF market is as follows:

- In 2017, 6,990 IVF cycles were performed in the New Zealand, and is expected to reach 12,830 by 2025, growing at a CAGR of 7.8% from 2019 to 2026.[5]
- Fresh IVF cycles was the largest segment in the market, with 5,300 IVF cycles completed in 2018 and is expected to reach 11,190 cycles by 2026.[6]

ESOP Options Approved

With satisfaction of all legal and regulatory requirements in its second and third market jurisdictions completed by 30 September 2020, the Memphasys Board has agreed that the Company has met the second milestone in the vesting of a set of 5,600,000 performance options to staff and consultants. 4,000,000 of these performance options were granted to the Executive Chairman, Alison Coutts, after shareholder approval was received for their issue on 21 October 2019. The options expire on 21 October 2021 and are exercisable at a price of $0.1142.

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 artificial reproduction, most particularly for human IVF.
Website: www.memphasys.com

[4] Allied Market Research Report, 2019
[5] Allied Market Research Report, 2019
[6] Allied Market Research Report, 2019