

ASX Release ASX Code: MEM 10 July 2020

First milestone achieved for vesting of performance options

Highlights

- MEM board has approved the vesting of performance options following achievement of its initial milestone, being that the company satisfies all legal and regulatory requirements (as applicable) to distribute its Felix device in its first market jurisdiction (Canada) by 30 June 2020.
- Achievement of the milestone provides a pathway for first commercial sales of the Felix device for Q4 CY2020 once requisite verification and validation (V&V) activities are successfully completed.
- Canada represents a key early market for MEM with 16,852 IVF treatment cycles initiated and 16,939 cycles of frozen embryo transfers, producing 9,324 clinical pregnancies in 2018.¹
- MEM is in the process of finalising legal and regulatory requirements in other early markets (Japan, India and New Zealand).

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to announce the Company has satisfied all legal and regulatory requirements to distribute its Felix device — a unique device for quickly separating high quality sperm from a semen sample for use in human IVF procedures — in the market jurisdiction of Canada, a significant market for IVF treatments.

Commercial sales are expected to occur upon the Company completing verification and validation (V&V) tests on the final manufactured product. Commercial sales continue to be expected to occur in Q4 CY 2020.

Health Canada, the regulatory authority for medical devices, has declared the Felix device will not be classified as a medical device on the basis that medical devices must directly interface with the patient – for example, a device involved in the administration of a fertilised egg to the patient. As the Felix device is used to provide sperm for fertilisation (an upstream process) with no direct patient interface, it is therefore not classified as a medical device.

With Felix not being classified as a medical device, it will not be subjected to the regulatory rigours that are required for medical devices.

The Felix device has also passed testing as per the Electromagnetic Compatibility Requirements (IEC 61326) and Safety Requirements for Electrical Equipment (IEC 61010) under Canada Standards Association (CSA) standards – the safety standards setting body in Canada for electrical appliances, medical devices, machinery and equipment.

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¹ Canadian Fertility & Andrology Society (CFAS), 2019

Importing & Marketing of Felix in Canada

Following due diligence of the Canadian market, Memphasys is initially planning to undertake direct sales of the Felix device to private clinics.

Canadian IVF market

The Canadian IVF market represents a key early market for Memphasys and the Felix device for the following reasons:

- In 2018 (latest available data), there were 16,852 IVF treatment cycles initiated and 16,939 cycles of frozen embryo transfers, producing 9,324 clinical pregnancies.²
- The presence of private funding (such as private and provincial health insurance funding) for IVF treatments in Canada boosts the adoption of IVF treatment in infertile couples.³
- The average cost of IVF ranges between \$7,750 to \$12,250 CAD. The cost of IVF with ICSI treatments in Canada costs around \$11,860.⁴
- At the end 2018, there were 37 IVF centres in Canada.⁵

Vesting of Performance Options

With satisfaction of all legal and regulatory requirements in its first market jurisdiction completed by 30 June 2020, the Memphasys board has agreed the first milestone has been met in the vesting of an initial set of 11,200,000 performance options to staff and consultants. 8,000,000 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

 $^{^{\}rm 2}$ Canadian Fertility & Andrology Society (CFAS), 2019

³ Allied Market Research Report, 2019

⁴ Allied Market Research Report, 2019

⁵ Canadian Fertility & Andrology Society (CFAS), 2019

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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 first commercial 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