ASX Release

Market Update on Commercialisation Progress of Felix Device

Sydney, Thursday 22 February 2018

Memphasys announces that its re-usable cartridge prototype device has successfully completed optimisation studies. Memphasys has now engaged its engineering development partner, Hydrix, to commence development of the Felix clinical device, which will use sterile, disposable cartridges. These consumable cartridges are positioned to build a strong recurring revenue business model for MEM.

When completed, the device will be placed into selected leading key opinion leading IVF clinics globally and through *in-vitro* studies to be conducted in these clinics its performance in preparing sperm for IVF will be assessed and compared with the current lab-based methods which are labor intensive, costly and contribute to sperm DNA damage.

The attached presentation provides an update on the development of the Felix clinical device.

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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.

Memphasys

ASX: ***MEM***

Developing a unique device to treat male infertility

Alison Coutts

Executive Chairman, *Memphasys Limited*

Feb 2018

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Pressing need for improvements in IVF

Memphasys

IVF:

- **Is expensive**
  - up to $10,000 per try, average of 2.2 tries before successful pregnancy, success not always possible
- **Is physically and emotionally draining**
- **Increases risk of miscarriage and chance of having genetically impaired offspring**

What if there were a technology that:

- **Increased the likelihood of pregnancy, and**
- **Enabled the birth of a genetically healthy baby?**

What would that be worth?

Need to improve male fertility

Memphasys

Male infertility

- **Is a factor in nearly 50% of infertile couples**
- **Affects ~1/3rd of men over 40**
- **Has been rapidly increasing for the past few decades**[1]
  - environmental and lifestyle factors are likely causes
- **Is strongly linked with lifestyle factors** e.g. obesity, smoking; **and with chronic disease** e.g. cardiovascular disease and diabetes
- **No meaningful advances in male infertility treatments since the advent of IVF**

[1] *eg Chinese male sperm counts have halved over the past 20 years; developed countries also have rapidly increasing infertility rates*

Human ART[1] market is large and rapidly growing; the accessible market for MEM is also large

Human ART market statistics	
Couples with fertility issues	>50 million
Australian couples seeking IVF treatments; Children born by IVF	1 in 6 1 in 25 in Australia 1 in 15 in Denmark
IVF treatments market size 2012/2020	US$9.3bn / US$21.6bn (F)
Estimated no. cycles per year, worldwide	~6 million
IVF consumables market	US$450m
Approx. consumables cost per IVF cycle	$400
Av. cost to patient per cycle: developing/developed countries	~$1,500 / ~$10,000 *(india) / (Aust/USA)*

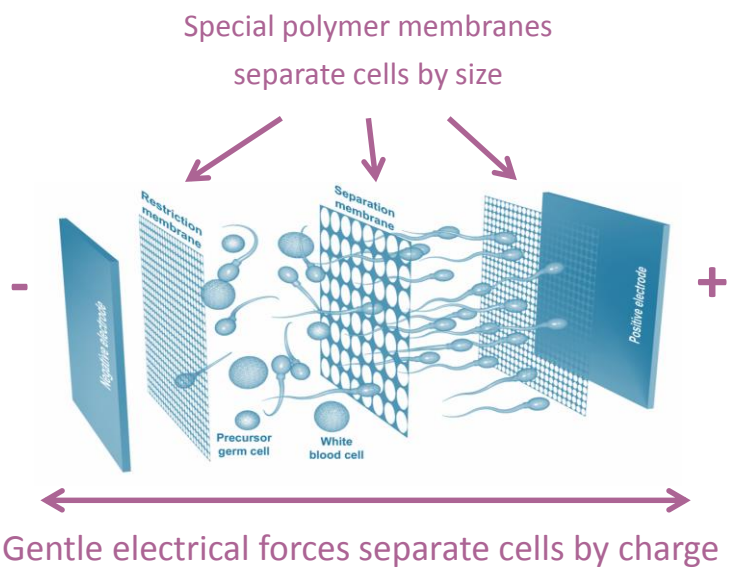
[1]*Assisted Reproductive Technology (ie all assisted reproductive technologies)*
[2] *Intra-Cytoplasmic Injection*
[3] *Intra-Uterine Insemination*

MEM's accessible Market:

- MEM's initial market(IVF, **ICSI[2]): > $600 million**
- Plus **IUI[3] market: ~ $1.2 billion**

MEM's technology provides better chance of success

- Memphasys has unique, patented IP for separating the 'best' quality sperm from IVF semen samples
  - The technology was developed in conjunction with world renowned fertility expert, Prof John Aitken
- The best quality sperm have the most negative cell surface charge – a sign they have been properly developed and have minimum DNA damage
- Sperm DNA damage
  - greatly increases with paternal age
  - is a major factor in the inability to conceive, to miscarry or to give birth to a child with genetic damage e.g. dwarfism, bipolar disease, epilepsy, autism etc
- .



Memphasys' 'Felix' device has major advantages over current IVF sperm processing methods[1]

Current IVF sperm processing methods[1]	MEM's 'Felix' device
30-40 minutes of slow multi-stage manual processes	5 minute automated process
Involve washing and centrifuging which damage DNA	Gentle, no centrifuging, no cell damage
Do not remove DNA-damaging semen constituents (mostly white blood cells and dying or dead sperm cells)	Removes the DNA-damaged sperm, and unwanted semen constituents
Both techniques cannot treat some poor sperm samples; 'Swim up' has very limited use.	Can be used on nearly all poor sperm types, and with the different IVF techniques
DNA-damaged sperm can unknowingly be selected **DNA damage decreases pregnancies; increases probability of genetically damaged progeny**	**Selects best quality, least DNA-damaged sperm** **Likely to increase probability of pregnancy and birth of healthy baby**

[1]. *Differential Gradient Centrifugation ('DGC') /'Swim Up'*

‘Felix’ device key development progress to date

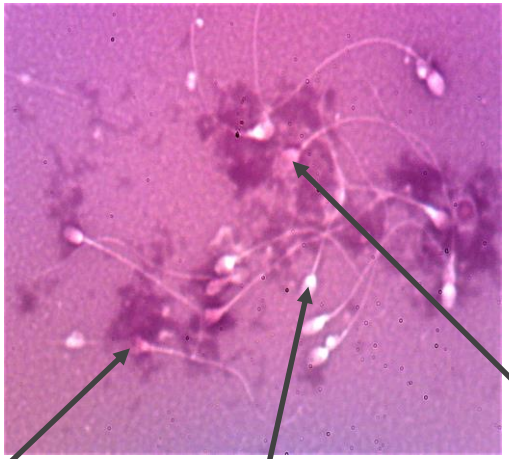
- **In 2008 in a small independent study at Westmead IVF, higher success rates (human births) were achieved for IVF couples using MEM’s lab-based prototype device, the CS10**
- **In 2017, in preparation for developing a commercial device for use by IVF clinics, MEM built a prototype device with reusable cartridges and optimised its cartridge design and operating parameters with input from Prof. John Aitken’s research team at University of Newcastle**
- **MEM has commenced development of the clinical Felix system with Hydrix, MEM’s engineering partner**
- **Felix will have a sterile single-use cartridges with high margins, building a recurring revenue business model for MEM**

**in-vitro testing of this device by ~15 leading global IVF key opinion leaders is anticipated to start in Q1 ‘19*

Reusable prototype cartridge test results on healthy male semen sample

Memphasys

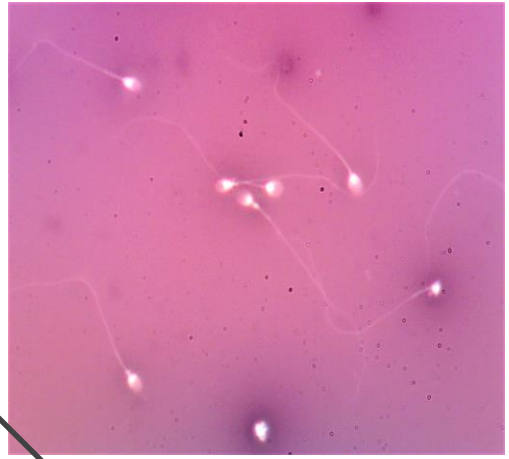
Sample before treatment



Dead sperm

Viable sperm

After treatment – 6 minutes



Macrocephalic sperm (large head)

- **Separation of viable sperm; with no semen debris**
- **Intact membranes & acrosomes**
- **Higher average motility & morphology**
- **Reduced DNA damage**

Key activities to clinical product launch

Memphasys

Design/build Felix 'fast prototypes' for international KOL assessment

Conduct International KOL IVF clinics assessment with fast prototype (15 sites)

Develop/manufacture Felix clinical system

Regulatory filings & approvals (CE, FDA)

EU/Aust market launch …then USA

Feb 18

4Q 19

The next application for MEM's technology: Equine Artificial Insemination ('AI')

- **Memphasys and the University of Newcastle (with a National ARC Grant) are applying our sperm selection technology to equine AI**
- **Horses have large pregnancy failure with both natural and artificial insemination; stallions are bred for traits other than fertilising potential and sperm quality is an issue.**

Semen state	Equine pregnancy rate, per cycle, with AI, (%)
Fresh	62
Chilled	45
Frozen	<30

- **Lack of fertilising success leads to large economic losses for the industry and provides a commercial opportunity for MEM**

NOTE: No assisted reproduction technologies, including AI, are allowed to be used with thoroughbreds for the racing industry. Despite this limitation there is a large demand for equine AI in many other breeds.

MEM's equine AI progress and strategy

- The current Felix prototype has demonstrated that it efficiently selects the most viable sperm from fresh equine semen
- MEM plans to design and build a new, purpose-built device with substantially larger cartridge volume and the high sperm yield required for equine AI.
- The equine AI industry primarily uses fresh and chilled semen; freezing is predominantly for international markets.
- MEM's technology works well with fresh semen but not so well with frozen; the freezing process not only damages the sperm but also disrupts cell surface charge.
- MEM could also process semen prior to the chilling or freezing process to ensure only the "best" quality sperm is harvested and the DNA-damaging dead cells and white blood cells are removed.

Experienced Management, Board and Partners

Management Team	
Alison Coutts Exec Chairman *B.E (Chem), MBA, Grad Dip Biotech*	International project management, strategy consulting, capital markets, technology commercialisation, board & senior mgt experience
Ross Harricks Bus. Development *BE, MBA INSEAD)*	30 yrs medical device commercialisation in UK, USA and UK
Dr Jack Zhao Senior Scientist *MD, B. Sc Biochem*	Medical devices, biological research, bioprocessing
Dr Hani Nur Senior Scientist *PhD, B.Sc (Chem)*	Specialist polymer membranes development
Pablo Neyertz CFO	

Board	
Alison Coutts, Chair	
Andrew Goodall Non-Exec director	International commercial property investment and management. HNW investor
John Pereira Non-Exec director *B.Juris LLB*	Funds management, banking, law, corporate advisory and capital raising for small/mid cap clients.

Technology Partners	
Fertility Research	**Prof John Aitken** *Research Centre for Reproductive Science, Uni Newcastle*
Membrane & Bio Devt	**Prof Sandra Kentish** *Dept of Chem and Biomolecular Eng, Melb. Uni*
Design & Product Devt	**Hydrix** *Melbourne*
Bioprocessing Strategy	**Dr Tim Oldham** *Tijan Ventures, Melbourne*

Corporate Statistics

Corporate Statistics	
Shares on issue	4.45 billion
Market capitalisation	$9.9 million @ 0.2c

	Top 10 Shareholders	%
1	Andrew Goodall	29.7
2	Alison Coutts	19.9
3	Red Edge Enterprises Pty Ltd	3.9
4	Rodney Wellstead	3.9
5	J & Tw Dekker Pty Ltd	3.0
6	Nutsville Pty Ltd	2.8
7	John Aitken	2.5
8	Hawera Pty Ltd	2.2
9	Mr Adam Davey	2.0
10	Mrs Leanne Vidovich	1.3
		71.5

The top 20 shareholders hold 80% of the stock on issue

Investment highlights

Unique, patented sperm separation technology

- Developed with world-renowned reproduction specialist - Professor John Aitken

Felix Human IVF Application

- Proven to work; low technology risk
- Development of the next generation Felix device on track
- Need for better sperm processing for IVF
- Large, fast-growing global IVF market
- Close to having a commercial device with disposable cartridges for sale to IVF clinics globally
- Relatively small funding and time frame required

Next Application: Equine AI

- Passed proof of concept
- Substantial commercial opportunity

Thank you

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Appendices

Key activities to clinical product launch

Cartridges & devices
- Finalise cartridge design
- Complete functional prototypes for testing
- Produce devices & cartridges for *in-vitro* trial
- Design and implement trial incl. data collection system

KOL IVF clinics recruitment & training
- Design proposed clinical programs
- Obtain MOUs for KOL clinic participation
- Recruit internal KOL support personnel
- Deliver Felix systems to KOLs & train KOLs on use

Clinical device manufacturing
- Finalise engineering development of device & cartridges
- Complete audit of potential mfrs
- Negotiate and award mfg contract
    - Manage manufacturing contract

Regulatory
- Complete reg roadmap
- Attend meetings with regulators eg FDA
- Draft technical file for reg. filings
    - Collect extra clinical data for CE, TGA, FDA
        - Set up cFDA clinical data collection in China
            - File CE, TGA
                - File FDA

KOL clinical study
- Roll out study with KOL centres & collect data
- Service KOL, troubleshoot issues, collect & analyse data
    - Prepare abstracts, presentations & publications

EU/Aust market launch
…then USA

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Patents

	Jurisdiction	Expiry /Prov. patent application date	Held by
Cell separation	US	Oct'24	MEM
Sperm cell separation by electrophoresis*	US, Au, UK	Oct '24	Uni Newcastle
Polymeric membranes & uses thereof	US	Feb'22	MEM
Biocompatible polymeric membranes		Provisional application Apr'16	MEM
Sperm separation by electrophoresis		Provisional application Oct'16	MEM
Electrophoresis device		Provisional application Oct'16	MEM

**Uni Newcastle has grated MEM an exclusive worldwide license to apply MEM's platform separation technology to sperm separation. However, this Uni Newcastle sperm separation patent can only be used with MEM's cell separation patent and in conjunction with MEM's device for sperm separation.*

Felix development milestones achieved

2007	2008 - 2014	2014	2015 - 2016	2017	2018
MEM's former lab-based machine used for successful human births in small independent *in-vivo* trial at Sydney IVF and Westmead IVF	Development hiatus	Development re-initiated under new MEM management.	New bio-compatible membrane & small prototype developed with improved fluid dynamics	Engineering development partner, Hydrix, engaged. New re-usable cartridge developed for optimisation studies	New Hydrix contract for developing disposable cartridges signed
Prof John Aitken published numerous papers in leading reproduction journals on benefits of selecting sperm based on MEM's separation method.		Key partnerships with Minitube, Prof John Aitken (Uni Newcastle) and Prof Sandra Kentish (Uni Melb) initiated.	New patenting	Successful internal and Uni Newcastle *In-vitro* optimisation studies using fresh semen	Development commenced
		New research started using bovine semen.	Successful testing and feedback on prior lab-based machine by Monash IVF Group	Performance specification for disposable cartridge prototype developed	
				$400K NSW Medical Device Fund Grant won	

MEM's Technology Development and Animal ART Marketing Partners

- **University of Newcastle** – Prof John Aitken and his team assisting in process optimisation and testing prototype Felix cartridges, managing KOL assessment trials
- **Hydrix** – Melbourne-based specialist medical device development partner developing the next generation Felix clinical devices
- **University of Melbourne Chemical and Biomolecular Engineering Department** – development of a new biocompatible and readily manufactured hydrogel membrane for Felix; and 'smart' membranes for future commercial applications
- **Minitube GmbH** – largest global distributor of animal ART products; assisting in development of core bio-separation technology for applications with animal reproduction
- **University of NSW School of Women's & Children's Health** – will undertake further in-vitro testing and validation of Felix cartridges with types of poor male semen
- **Monash IVF Group and Westmead Fertility Centre** - small in vivo trials have demonstrated successful human births ; Felix beta test sites for clinical products

Equine AI market size statistics

Memphasys

Australia		
	Estimated number of registered, breeding non-thoroughbred horses in Australia	**76,548**
	Standard bred breeding horses*registered in Australia	**22,755**
	Standard bred breeding horses in Australia as % of total non-thoroughbred breeding horses registered	**29.7%**
	No. standard bred foals born pa in Australia (the major breed, after thoroughbreds)	**6,927**
	No. standard bred horses bred by AI (98.5%) in Australia	**6,823**
	Australia's share of equine global market	**15%**
Global		
	Estimated no. standard bred foals bred by AI	**45,487**
	Estimated total non-thoroughbred foals bred by AI (extra 50%)	**68,231**
AI costs		
	Approx capital cost of equiment for AI per establishment	**$4,000 - $6000**
	Approx consumables cost per AI cycle	**$300 - $400**

- Other breeds include Arabian, stock horse, quarter horse, warmblood, paint horse, appaloosa, pony
- Source: The Horse Industry, June 2001, Industry Interviews, www.horsefund.org