



ASX Release

Felix Device Development On-Track

Sydney, 3 May 2018

Memphasys (**ASX: MEM**) reports that development of Felix, the device that MEM is commercialising, is proceeding according to plan. Felix separates the most viable sperm in a semen sample for use in IVF and provides unique and critical advantages over current sperm processing methods.

An updated presentation on development of the Felix device is attached.

Over the past few months, MEM and the University of Newcastle researchers have been conducting optimisation studies (slide 10) in preparation for final design and build of the Felix clinical system which MEM plans to take to market.

With its product development partner, Hydrix, MEM has also completed a regulatory plan for achieving TGA, CE Mark and FDA registration.

Key milestones to first revenues are provided in slide 11.

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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.

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ASX: *MEM*

Felix Device development update: A unique device to treat male infertility

May 2018

Alison Coutts

Executive Chairman, *Memphasys Limited*



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Pressing need for improvements in IVF

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

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 decades¹
 - 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



Sperm quality,
rather than quantity,
is the issue

Human ART¹ 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)

MEM's accessible Market:

- MEM's initial market(IVF, ICSI²): > \$600 million
- Plus IUI³ market: ~ \$1.2 billion

¹Assisted Reproductive Technology (i.e. all assisted reproductive technologies)

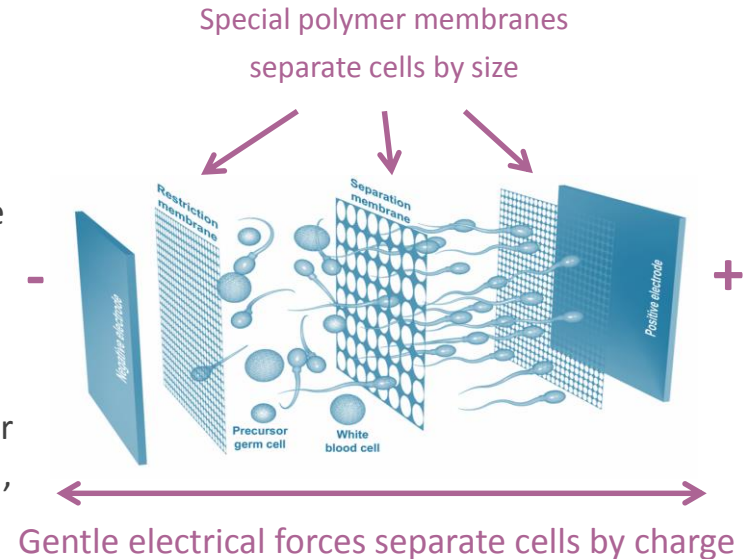
²Intra-Cytoplasmic Injection

³Intra-Uterine Insemination

MEM's technology provides better chance of success

Memphasys

- 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 methods¹



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

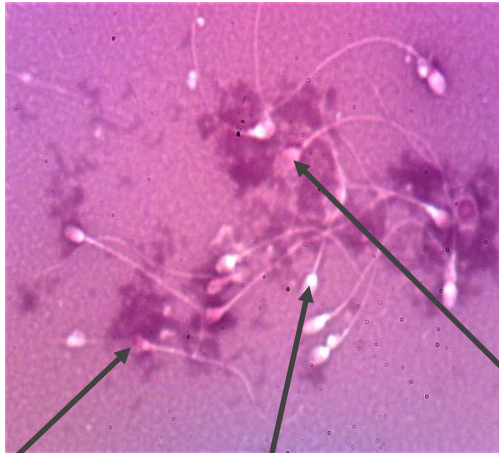
- In 2008 in a small independent study at Westmead IVF, higher success rates (human births) were achieved for IVF couples using MEM's lab-based prototype device, the CS10
- In 2017, in preparation for developing a commercial device for use by IVF clinics, MEM built a prototype device with reusable cartridges 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

Sample before treatment



After treatment – 6 minutes



Dead
sperm

Viable
sperm

Macrocephalic sperm
(large head)

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

Recent Felix optimisation studies by MEM and Uni Newcastle in preparation for final design & build

Evaluation conditions	Testing regimen
Electrical conditions	Voltage, current, run time
Membranes	Pore size, pore density, thickness, hydration time
Electrode material	Cheaper alternatives to the present platinised titanium
Buffers	Selection of optimum commercial IVF buffers
Sample loading	Optimisation to improve present sample handling method
Work flow integration	Replacement of current multiple-step, labour intensive lab practices
Cartridge packaging	Wet vs dry /sterilisation/ shelf life

Key activities to Felix clinical product launch

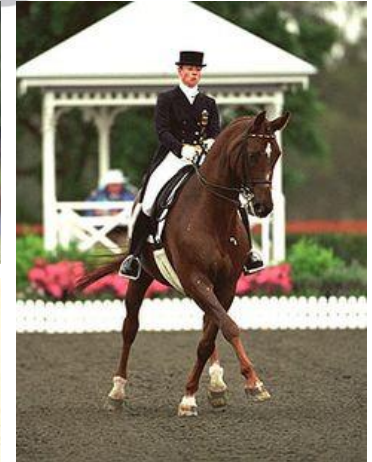
Memphasys Felix Commercialisation Milestones		2018			2019			
		Jun Qtr	Sep Qtr	Dec Qtr	Mar Qtr	Jun Qtr	Sep Qtr	Dec Qtr
1 Felix Product Development								
Key operating parameters for Felix system ^(*) optimised by testing at MEM/ Uni of Newcastle/ leading IVF clinic								
Pre-production Felix system completed, tested, & approved								
Production Felix systems delivered for approval testing by MEM/ Uni of Newcastle/ leading IVF clinic								
Production batch of 20 Felix systems delivered for KOL sites								
2 Regulatory								
Regulatory plan for CE/TGA/FDA completed								
Meetings EU and FDA regulatory authorities								
CE/TGA regulatory filing; then approval					FILE		APPROVE	
FDA regulatory filing; then approval						FILE		APPROVE
3 International KOL(**) IVF Clinic Assessment (10-15 centres)								
Initial MOUs with international KOL IVF clinics completed								
Agreements for international Felix system assessments completed								
Initial Felix systems delivered to KOL IVF assessment sites								
International KOL study initial results available								
4 Sales								
Initial sales of Felix systems in Aust and EU								
(*) "Felix system" comprises a bench top device plus single-use disposable cartridges as required for market launch								
(**) KOL'- Key Opinion Leader								

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 <i>B.E (Chem), MBA, Grad Dip Biotech</i>	International project management, strategy consulting, capital markets, technology commercialisation, board & senior mgt experience
Ross Harricks Bus. Development <i>BE, MBA INSEAD</i>	30 yrs medical device commercialisation in UK, USA and UK
Dr Jack Zhao Senior Scientist <i>MD, B. Sc Biochem</i>	Medical devices, biological research, bioprocessing
Dr Hani Nur Senior Scientist <i>PhD, B.Sc (Chem)</i>	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 <i>B.Juris LLB</i>	Funds management, banking, law, corporate advisory and capital raising for small/mid cap clients.

Technology Partners

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

Corporate Statistics

Memphasys

Corporate Statistics

Shares on issue

4.45 billion

Market capitalisation

\$8.9 million @ \$0.02c

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	<u>1.3</u>
		71.5

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

Investment highlights

Memphasys

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

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 granted 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 <i>in-vivo</i> 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 <i>In-vitro</i> 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

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 equipment 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