



ASX Release

MEMPHASYS' INVESTOR PRESENTATION

Sydney, Thursday 24 November 2016

Memphasys Limited (ASX: MEM) is providing an investor presentation entitled 'New Horizons in Artificial Reproduction'. The presentation focusses on the Company's SpermSep business and provides investors with an overview of Memphasys' current and proposed activities in this business area.

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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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New horizons in artificial reproduction

Alison Coutts | Executive Chairman

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An Australian bio-separations company

*Separating high value components (e.g. sperm) from biological fluids
for global markets
using proprietary membranes (size) and electrophoresis (charge).*



Original SpermSep prototype device

Corporate and investment summary



KEY ASSET "SpermSep"

A unique device for

- selecting the best, most viable sperm for artificial reproduction in humans (IVF) and animals
- improving outcomes for male factor infertility, thus increasing the probability of pregnancy and birth of healthy offspring

LEAD PROGRAM

Next generation clinical grade device for human IVF

- earlier lab grade device proven to work
- next gen device under development
- to be supplied to global IVF Key Opinion Leaders ("KOLs") shortly for their adoption/ endorsement
- *in-vitro* clinical data from KOLs to be used for regulatory approvals ahead of global sales, expected in around 2 years.

CORPORATE SNAPSHOT

ASX Code: MEM

Shares on issue: 569m

Sector: Biotech & Life Science

TOP SHARE HOLDERS %

Andrew Goodall 39.2

Mark Gell 3.9

Alison Coutts 3.6

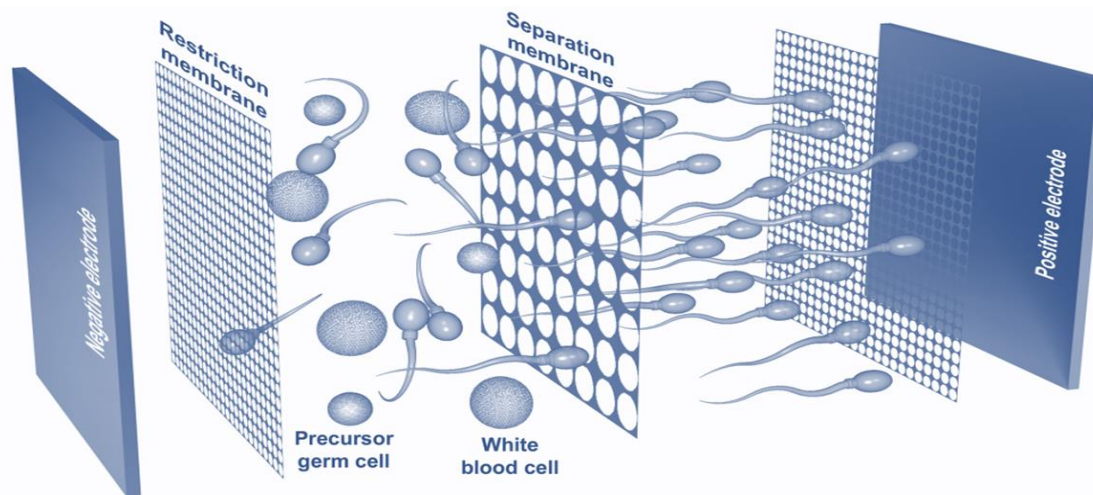
B Arthur Pty Ltd 2.9

CGAM Pty Ltd 2.6

Premium Investment Holdings 1.9

Key asset: SpermSep technology

- SpermSep can accurately separate the best sperm for fertility treatments such as IVF
- It uses a bench-top instrument with disposable, single-use cartridges to separate sperm from semen samples
- Sample is loaded into the cartridge and the sperm removed after quick processing
- Prototype extensively trialed; separates best quality sperm without DNA damage
- In 2016 Monash IVF tested 68 *in-vitro* patient samples and concluded the device “beneficial”

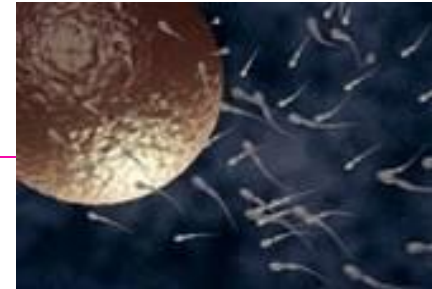


Key asset: SpermSep technology

- To perform IVF the most viable sperm must be separated from the semen sample
- Current sperm separation techniques (“DGC” & “Swim Up”) have limitations:
 - DGC increases physical and DNA damage from oxidative stress to the extracted sperm
 - Swim Up requires high motility sperm and has low volume yield
 - both methods require lab tech time in multiple processes

SpermSep advantages:

- Quick push-button process
- Cleanly extracts the most viable, genetically undamaged sperm gently without added damaging physical force (e.g. centrifuging)
- Lack of sperm DNA damage is more likely to lead to fertilisation, pregnancy to term, successful birth and healthy progeny
- Applicable for both traditional IVF and ICSI (single sperm injected into egg)



SpermSep's Inventor: Prof John Aitken

Professor Aitken is a world renowned expert in reproductive biology and the inventor the SpermSep technology.

As he explains: “SpermSep selects the best sperm from ejaculate, which makes the process of sperm separation for *in vitro* fertilisation faster and more accurate. In assisted conception, the best sperm needs to be selected because it will impact the development potential of the embryo.”



About Professor John Aitken and his research team:

Professor Aitken, a male reproduction specialist, is Chair of Memphasys' Scientific Advisory Committee.

He is Director of the University of Newcastle's Priority Research Centre for Reproductive Science, leading a 50-strong research team studying fertility and contraception which has attracted over \$50 million in funding and generated more than \$37 million in research income. He has published over 480 research articles, given more than 350 invited lectures and filed 12 patents. His work has been cited >16,000 times and has the highest citation index in his field.

New South Wales Scientist of the Year in 2012, Professor Aitken has been elected a Fellow of both the Royal Society of Edinburgh and the Australian Academy of Science and is currently President of the International Society of Andrology.

The global market for IVF treatments



Couples with fertility issues		~50 million	Australian couples seeking IVF: 1 in 6
Global IVF clinic business	Cycles/year	~15 million	570,000 in Australia
	IVF babies/year	~350,000	10,500 in Australia
	Numbers of IVF clinics	~3,000	EU is largest market, Asia is fastest growing
IVF market size	2012	USD 9.3 billion	Australia: AUD 470 million
	Forecast 2020	USD 21.6 billion	
Human IVF consumables market		USD 450 million	~USD 300/IVF cycle
Cost to patient per cycle		~USD 1.5	India
		~USD 30,000	USA
Growth rate	~ 5-10% p.a. Higher growth in Asia & E. Europe than W. Europe & N. America		

Source: Vitrolife 2013 and 2015 Annual Report, Cooper/Origio Investor Report, June 2012

SpermSep: Addressing male infertility – an unmet medical need

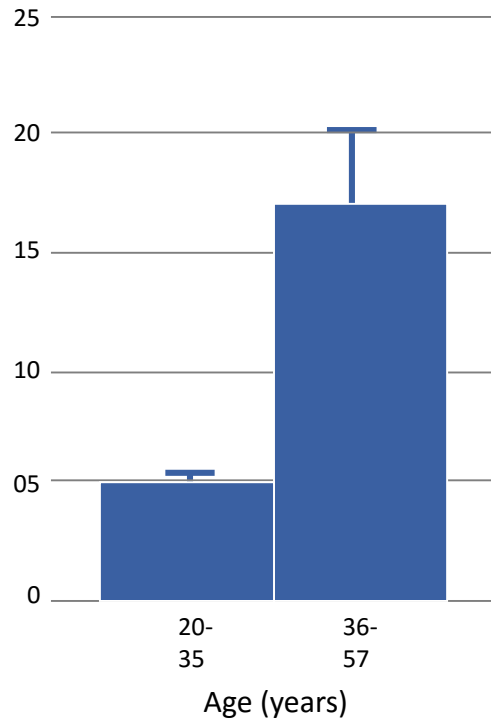
Male infertility:

- a major issue for over 40% of infertile couples
- increasing globally in developed and developing world
- highly correlated with age and affects fertility in a third of men over 40
- adversely affected by chronic disease and poor lifestyle
- correlated with DNA damaged sperm

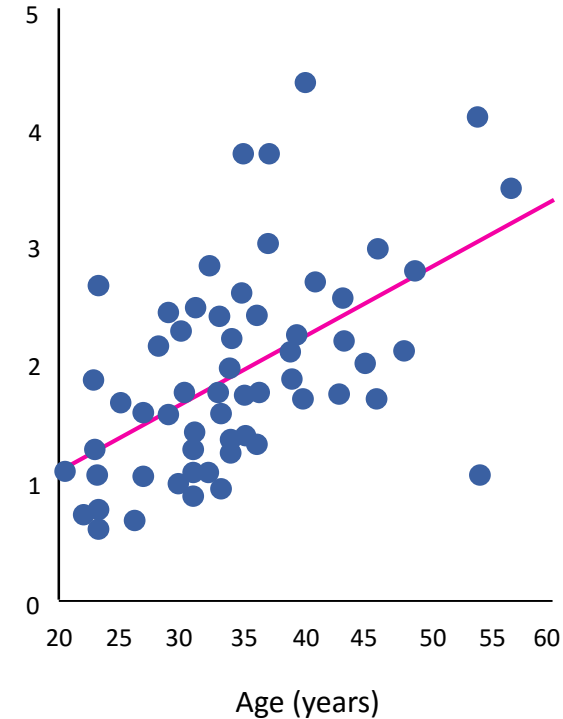


Age and DNA damage play a major role

Sperm with highly damaged DNA
(%)



Log percent highly damaged DNA
(%; $P < 0.0001$)

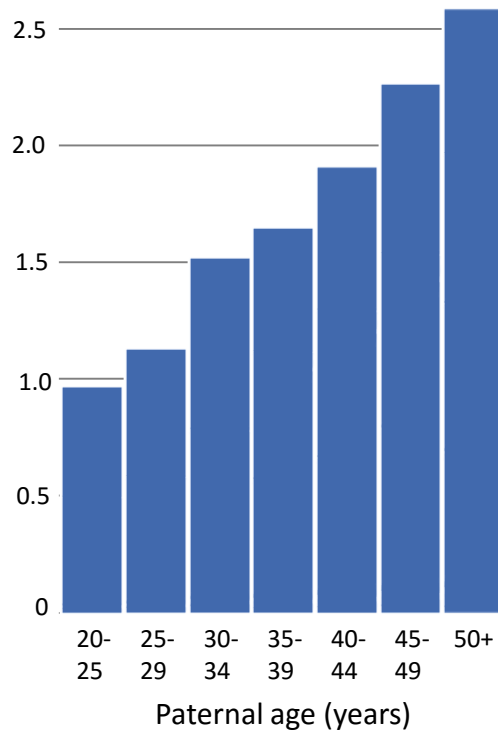


Source: Reproduced with permission from The University of Newcastle Australia; Singh, Muller and Berger, 2003

Effects of age and DNA damage

Bipolar disease

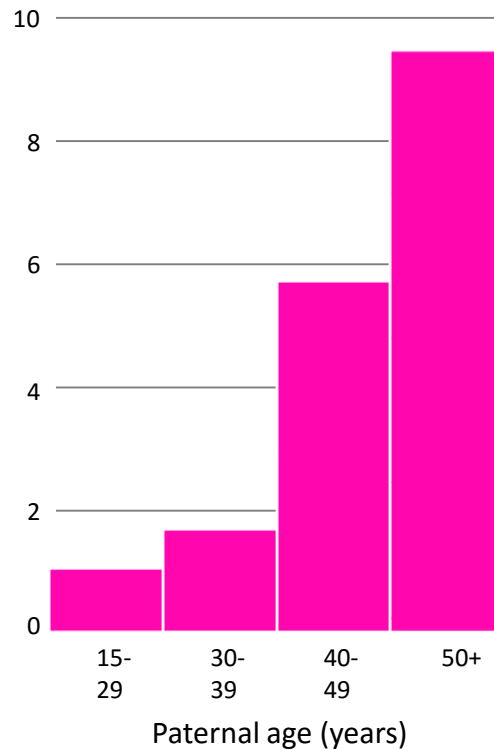
Odds ration



Frans et al. Arch Gen Psychiatry (2008) 65 1034-1040

Autism

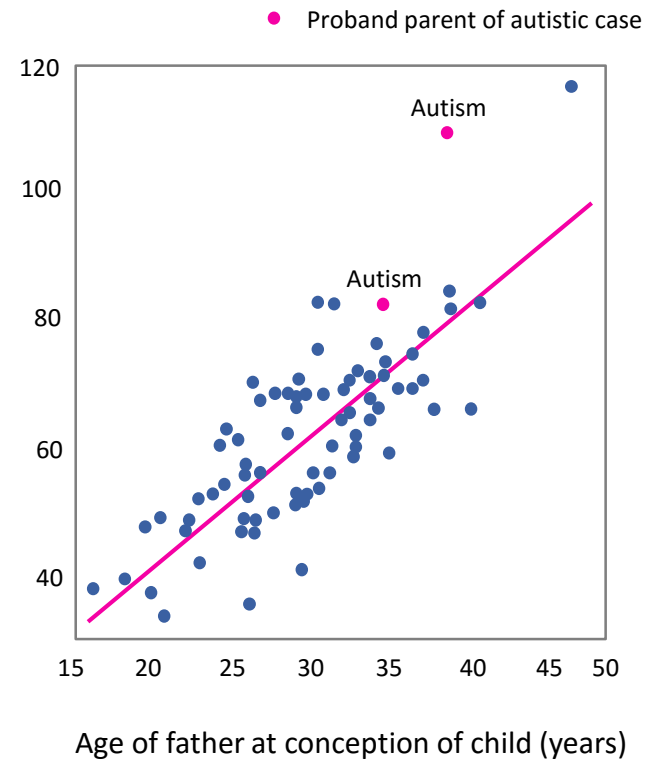
Odds ratio



Reichenberg et al. Arch Gen Psychiatry (2006) 63 1026-1032

Mutation rate

Number of de novo mutations called

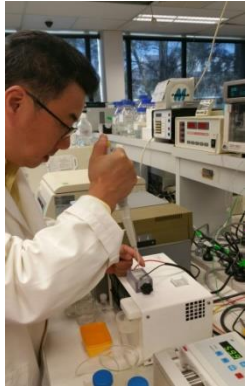


Kong et al., Nature 470; 156 (2012)

Source: Reproduced with permission from The University of Newcastle Australia

Business model – Strategy to create value

- We are developing a second-generation clinical SpermSep device



← optimising operating parameters of a low-cost, single-use sterile cartridge

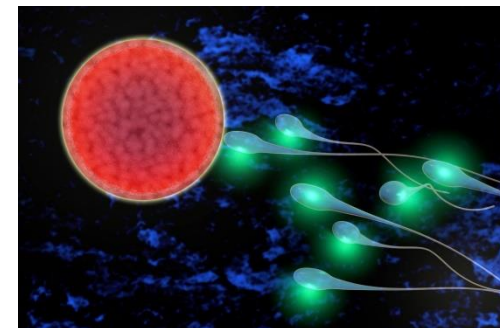
new biocompatible hydrogel polymer membrane established



- Now ready to finalise design and build of the next generation clinical SpermSep device
 - ★ completed initial design and performance specifications
 - ★ determined approximate development cost and schedule and have engaged a specialty engineering contracting firm to build the prototypes and final product
- Global market launch of next generation device with regulatory approval planned in approx. 2 years
- Global distribution partner to be engaged
- Major and recurrent revenue derived from the device's single-use disposable cartridges

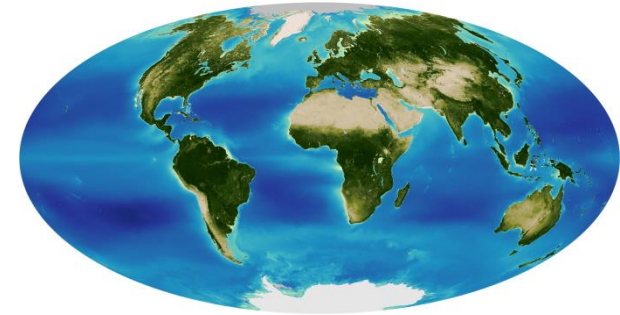
Comparison with current treatments

- Swim Up and DGC are the current techniques to process sperm for human IVF
- Both are lab separation processes using multiple washing and centrifuging steps
- These processes are not only time consuming and laborious but also impart DNA damage to the sperm through
 - shear forces in centrifuging;
 - oxidative stress to the DNA from the the density gradient medium used in DGC
- SpermSep will be the first automated non DNA - damaging lab instrument for preparing sperm samples for IVF
- Our focus is to establish SpermSep as the standard method for sperm preparation in human IVF clinics.



SpermSep: Path to market

- Develop up to 30 fast prototype next gen SperSep devices for KOL clinical assessment/ adoption/ endorsement
- Conduct *in-vitro* clinical trials of these devices in leading global IVF centres under leadership Prof John Aitken (Uni. of Newcastle)
 - We expect clinical results will lead to endorsement by IVF Key Opinion Leaders
 - KOL endorsement and publishing trial data will help establish global market adoption
- Develop commercial “SpermSep2” clinical device while trial in operation
- Majority of revenue will come from the single-use disposable cartridges
 - pricing will be established based on clinical trial results and feedback
- Establish a networked, cloud-based data collection system to provide important information and value added services for IVF clinicians, industry and end users.



- In-depth regulatory plan is in development
- Advice received is that *in-vivo* trials (embryo fertilisation and tracking to birth) will not be required for regulatory approval
- Regulatory approval to be based on:
 - demonstration of device's electrical and biological safety
 - surrogate end point data on sperm quality obtained from the *in-vitro* study data
 - *Surrogate sperm quality assessment measures are well established and accepted*
- Pregnancy and birth outcome data will be collected after the device is approved for human use
 - Anticipate that data will show multiple, unequivocal benefits of SpermSep over current sperm preparation methods
- Aim is to position SpermSep as the global standard for sperm preparation in IVF clinics.

Key milestones and indicative funding required



	Milestone	Months	Cumulative \$m
1	First 3 prototypes for performance validation study	6	1.5
2	Recruitment of approx. 20 international KOLs* to participate in Clinical Assessment project	9	2.1
3	Production Prototypes built for Clinical Assessment project	12	2.9
4	CE Mark regulatory approval sought**; first clinical devices built	18	4.7
5	Publication of first results by KOLs from Clinical Assessment project; Market launch & first revenues	24	6.8

* KOL: Key opinion leader in clinical IVF

** Based on historical data

Patents

- Memphasys has the following patents:
 - its electrophoresis membrane separation process
 - Its SpermSep cartridge design for sperm separation
 - the newly-developed polymer membranes for various biological separations
- It has an exclusive license from University of Newcastle for their patents on the application of this SpermSep process in sperm separation

University collaborations

- Memphasys has the following research partnerships:
 - With University of Newcastle (Prof John Aitken) and for fertility research; and
 - With University of Melbourne Chemical and Biomolecular Engineering (Prof Sandra Kentish) for membrane and bioseparations research

- Powerful, well protected Australian technology already proven to work
- Global market potential in fast growing healthcare sector
- Targeting use in both mature and developing country markets
- Initial focus is human IVF: very high unmet clinical need for male fertility treatments
- Near term commercialisation opportunity
- Experienced management and board to drive development and secure distribution, licensing and sales.

Contact details



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Equine market – the next application

- Thoroughbred racehorse breeders not allowed to use artificial reproduction
- Initial focus will be standard bred horse market*
- Australia is third largest global market
- Investigating improvements to equine reproduction with commercialisation program part funded by ARC Linkage Grant via University of Newcastle
- Working with global market leader in animal reproduction, Minitube GmbH
- Work to date has demonstrated research device works on fresh equine sperm
 - Next step is develop new device and undertake *in-vitro* and mare *in-vivo* tests to confirm performance.



* Artificial reproduction is allowed in all horses apart from thoroughbreds.

- In 2014 Memphasys spun out PrIME Biologics (“PrIME”) in Singapore and agreed to take principal responsibility for payment of a debt to a third party as part of the agreement to receive B class non-voting shares in PrIME.
 - The debt has now been repaid by PrIME, who were guarantors of the loan repayment
 - Memphasys is in litigation against PrIME and its major investor, Manukan
 - We remain hopeful a negotiated settlement will be reached
- Litigation involves two separate actions in the Singapore High court
 - The means of payment by Memphasys against the third party debt payout made by PrIME
 - The ownership of a machine, the “GF100”, a key part of PrIME’s cGMP plasma processing facility and for which PrIME had paid rent to Memphasys
- Memphasys remains confident the value of its B class shares in PrIME exceeds the debt payout. Negotiations between the parties are focused on the description and use of the GF100 machine and the quantum net payment to be received by Memphasys from the sale of its B class shares and transfer of the GF100 machine to PrIME