



# Creating high value product portfolio targeting the growing fertility industry

Alison Coutts CEO & Managing Director, Memphasys Limited. May 2022



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# Memphasys (ASX: MEM) Investment Proposition

- A MedTech company focused on **reproductive biotechnology**
- Developing **world class product portfolio** (devices, diagnostics and media products) addressing major human and animal reproduction issues
- Research & Development led by **international fertility expert** and MEM's Scientific Director, Distinguished Laureate Professor John Aitken, and his research team based at University of Newcastle ("UoN")
- MEM board and management has **significant experience** in **developing** and **selling medical products**
- First commercial product - The **Felix™ Device** – has **achieved pathfinder sales milestones**, with increased marketing / sales activities underway
- Additional development programs advancing the product portfolio



Distinguished Laureate Professor John Aitken, global leader in reproductive biology:

- Published over 650 research articles
- Work cited ~55,000 times (h-index of 120, highest citation index in his field and in the top 5% for all of Biology and Biochemistry).
- Ranked #1 in the world in the cell biology of spermatozoa and germ cells (Source: Expertscape.com).
- Life work is source of MEM's new product ideas

# Board & management with strong commercialisation experience



**Robert Cooke**  
Non - Executive  
Chairman

- A highly strategic and results focused private health care leader with 40+ year career in the health industry.
- Experience spans executive leadership of publicly listed and privately owned healthcare companies, overseeing numerous M&A transactions and management of private and public hospitals in Australia, Asia and the UK.
- Non-Executive Chairman of OptiScan Imaging (ASX: OIL), a global leader in the development of microscopic imaging and related technologies for surgery and medical research.
- Former Managing Director & CEO of Healthscope, one of Australia's leading private hospital, medical centre and pathology operators, and led the \$1.73 billion buyout of Healthscope with two of the world's largest private equity companies, TPG and The Carlyle Group.



**Alison Coutts**  
Managing  
Director & CEO

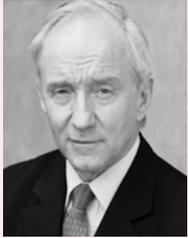
- Strong entrepreneurial background having worked in a number of diverse industries
- International engineering experience as a project manager with Bechtel Corporation
- Management consulting experience, serving as a strategist with Boston Consulting Group
- Formerly an executive search consultant with Egon Zehnder
- Co-founded life-sciences focussed investment bank eG Capital
- Co-founded ASX-listed Micro-X Ltd
- Former Chair of CSIRO's Health Sector Advisory Council



**Paul Wright**  
Non-Executive  
Director

- More than 30 years' experience in the development and sales of innovative medical devices and diagnostic tools
- Former CEO of international medtech companies Invetech, Vision BioSystems & Universal Biosensors
- Strategic management consulting experience with 8 years at Bain and Company
- Currently a non-executive director of design, engineering and technology commercialisation company Hydrix and an advisory board member for unlisted digital wastewater services company, Waterwerx Pty Ltd.

# Board & management with strong commercialisation experience



**Ross Harricks**  
Business  
Development  
Manager

- Long established track-record in the medical technology industry
- Specialised in assisting companies through the commercialisation process, having worked with and been on boards of ResMed, Cardiex, VentraCor and PainChek, among others
- Former General Manager of EMI Electronics Group in Australia, which originally invented and commercialised the CT Scanner.
- Formerly Group Marketing Executive of the Nucleus Group which founded Telectronics, Cochlear and Ausonics



**Dr. Tony Poulton**  
Manager –  
Special Projects

- Employed by major US multinationals including Syntex, Merck Sharp & Dohme, Johnson & Johnson Medial, Tyco, Covidien, Medtronic and Cardinal Health 1988 – 2019
- Hands on “go to market” experience with over 60 medical device product groups across surgical, medical, respiratory, patient monitoring, critical care, interventional, retail pharmacy and extended care patient categories
- IVOMEC Pour On for Cattle launched mid 90’s - still the largest revenue single animal health product ever launched in Australia.



**Kea Dent**  
Regulatory  
Advisor /  
Consultant

- Successfully built up and sold medical device manufacturing business (Dentsleeve) to Canadian competitor
- Specialist Advisor to the Therapeutic Goods Administration (TGA): Contributes to the TGA’s key regulatory functions for medical devices.
- Consultancy specialises in providing an extensive range of business and regulatory services to manufacturers and sellers of medical devices and IVD’s

# Highly Prospective Core Product Development Pipeline

Product Development Program	Proof of Concept	Prototyping			Development of Go-to-Market Product	Clinical Trials & Regulatory Filings	Market Launch
		Prototype Development	UoN lab Validation	Field trial			
1. <b>Felix™ Device</b> (Sperm separation device for human IVF)	●	●	●	●	● Regulated markets	● Regulated markets	● Regulated markets
2. <b>ROSA</b> (Rapid oxidative stress assay)	●	●	●	●	●	●	●
3. <b>Samson™ Device</b> (Rapid equine pregnancy prediction assay)	●	●	●	● In progress	●	●	●
4. <b>SemPort</b> (Central lab human semen analysis from distantly located donors)	●	● In progress	● In progress	●	●	●	●
5. <b>AI-Port</b> (Ambient temperature semen transport device for animal Artificial Insemination)	●	● In progress	●	●	●	●	●

**Other products in development include:**

- a long-term ambient temperature storage medium for human sperm (already defined)
- improved media for sperm isolation, fertilisation and cryopreservation.
- a new concept for isolation of a small number of extremely high-quality sperm for ICSI

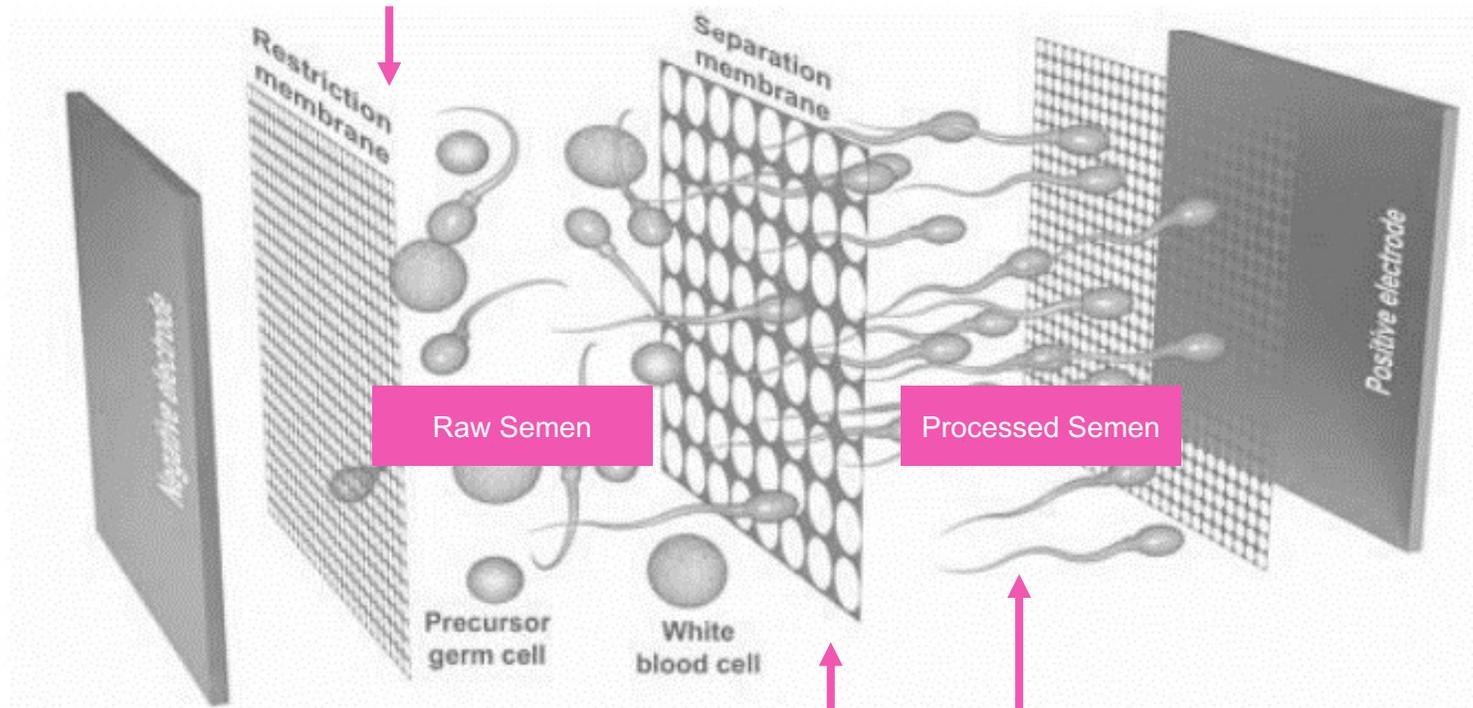
# MEM's First Commercial Product: Felix™ Device

- A patented, rapid, automated device used in human IVF procedures
- Selects quality sperm based on negative charge and size
- Less DNA damage than processes using centrifugation (e.g. DGC, most prevalent method)
- Uses gentle electric forces to safely and efficiently “pull” charged sperm through a membrane
- Much faster and easier to use than traditional sperm separation methods

The logo for the Felix™ device, featuring the word "Felix" in a large, white, sans-serif font with a trademark symbol (TM) to its upper right, set against a dark teal background.

# Felix™ Device - How it works

Allows ion transfer but blocks sperm passage



Separates sperm from other cell types

Mature, negatively charged sperm harvested after 6 minutes

# Felix™ Device - Advantages over current processes

## Current sperm separation processes used for IVF

- DGC (density gradient centrifugation) and Swim up\*
- Cost at least ~A\$80 (for each technique) per cycle
- DGC is more frequently used

Felix™ Device	Current processes
One step, automated process in one vessel	Each involves multi-step laboratory processes
Takes 6 minutes	Each takes at least 30 minutes
Gentle; does not cause DNA damage	Cause DNA damage with centrifuging
Processes a wide variety of semen samples including poor ones	Are limited in their ability to process poor samples



Felix™ Device, with disposable, single use cartridge (the recurrent revenue source)

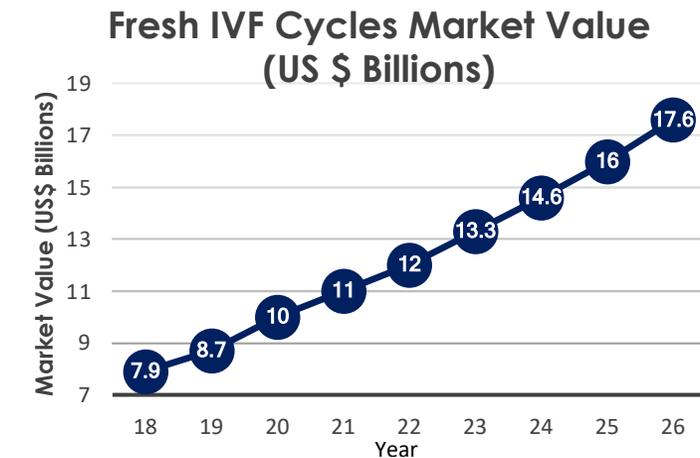
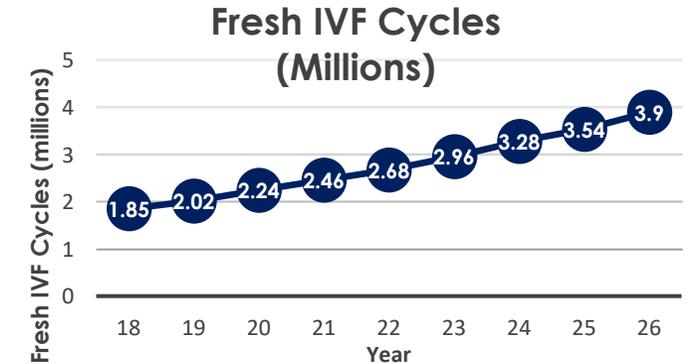
\* A semi-automated swim up process, Zymot, is also commercially available but it still takes the same time as Swim up

# Felix™ Device - Potential Market Size

- IVF global use is accelerating, but IVF's success rate remains stubbornly low
- Aust. and NZ pregnancy rate per cycle is only 16.5% with fresh embryos implanted (58% of cycles) but 28% when the embryo was frozen/thawed<sup>2</sup>
- Average of 2.2 IVF cycles before success, averaged for all women <40yo
- IVF costs US\$8,000-US\$15,000 per cycle in developed countries
- IVF slightly increases risk of miscarriage *and genetic impairment of offspring*
- Male sperm count has halved in the last 30 years
- In ~50% of infertility cases a male factor contributes
- Sperm separation for IVF is currently based on multi step laboratory techniques, DGC or Swim up
  - No meaningful advances in sperm preparation & selection for IVF since the advent of IVF ~40 years ago

Source:

1. Global IVF services Market 2019 - 2026 by Allied Market Research, 2018
2. UNSW report on Assisted Reproductive Technology in Australia and New Zealand, 2019



# Felix™ Device - Pathway to Market

- Key Opinion Leaders (KOLs) are the esteemed practitioners the wider IVF sector looks to for innovation & leadership
- KOLs in 13 IVF clinics in 8 countries are *completing in vitro* assessments of Felix™ Device with results due in 2Q 2022
- KOL clinics are the likely first buyers of new products
- Focus is on building early sales in four selected countries with low regulatory barriers for the Felix™ Device – India, Japan, Canada and New Zealand – initially targeting KOLs who have assessed the system, using both *in vitro* data and *in vivo* embryo data
- Australia, China and USA are priorities for next regulatory approvals



# Felix™ Device - Commercialisation path

## Early Markets

- KOLs in place in all 4 early markets
- Pathfinder repeat sales achieved in India; more expected
- **Embryo quality assessments** of the Felix™ Device Vs. incumbent method are the usual process before a sales order is received
- Sales Manager being recruited.

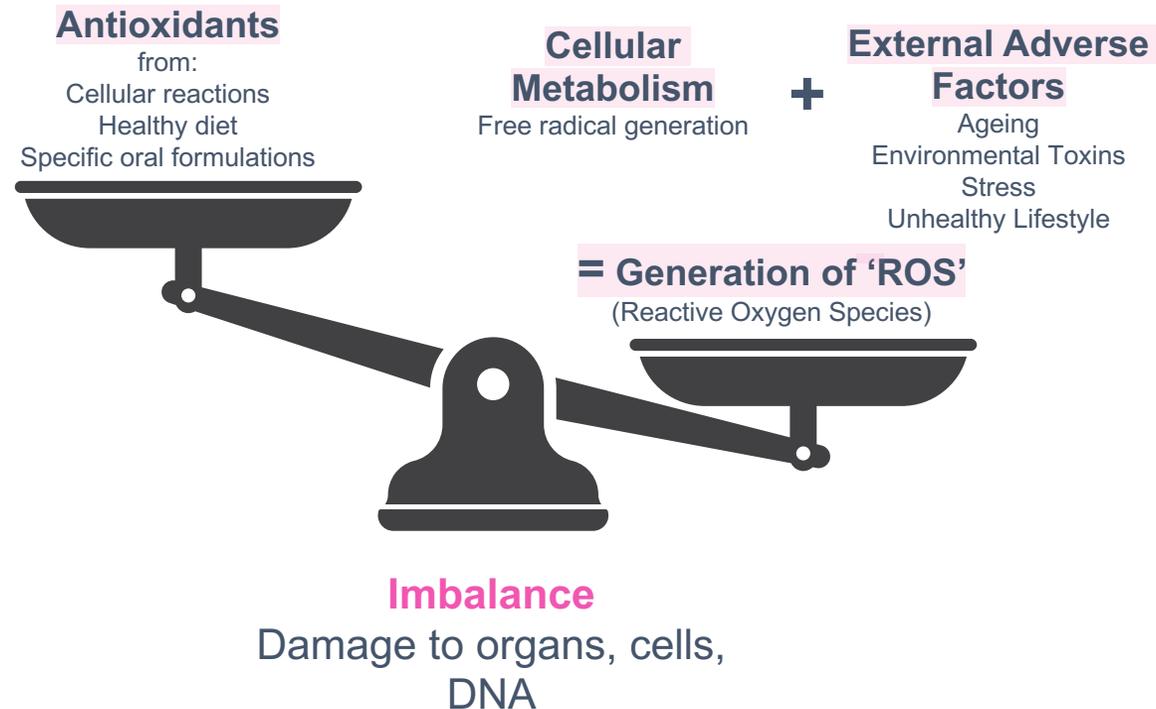
Country	Fresh IVF Cycles in 2018	Expected fresh IVF cycles by 2026	% growth rate	KOL engaged in market	% of global market <sup>3</sup>
Japan	269,110	699,110	+160%	✓	14.5%
India	169,800	489,840	+188%	✓	9.2%
Canada	6,360	21,140	+232%	✓	0.3%
New Zealand	5,300	11,190	+111%	✓	0.3%

## Regulated Markets

- Commercialisation activities in more regulated markets (Australia, USA, China and EU) require formal clinical trials ahead of regulatory submission
- Clinical trial with Monash IVF<sup>(1)</sup> has started in Australia
  - Ethics approval received; first patient to be recruited & treated ~ May 2022
  - Anticipated to finish within calendar year 2022 with aims to:
    - demonstrate the safety and performance<sup>(2)</sup> of the Felix™ Device
    - generate clinical data for future TGA regulatory submissions and for other regulatory bodies
- Clinical trials in USA planned for FY23 after pre submission meeting with FDA
- Plans underway with Chinese partner, Diagens, for Chinese clinical trials aimed at NMPA approval

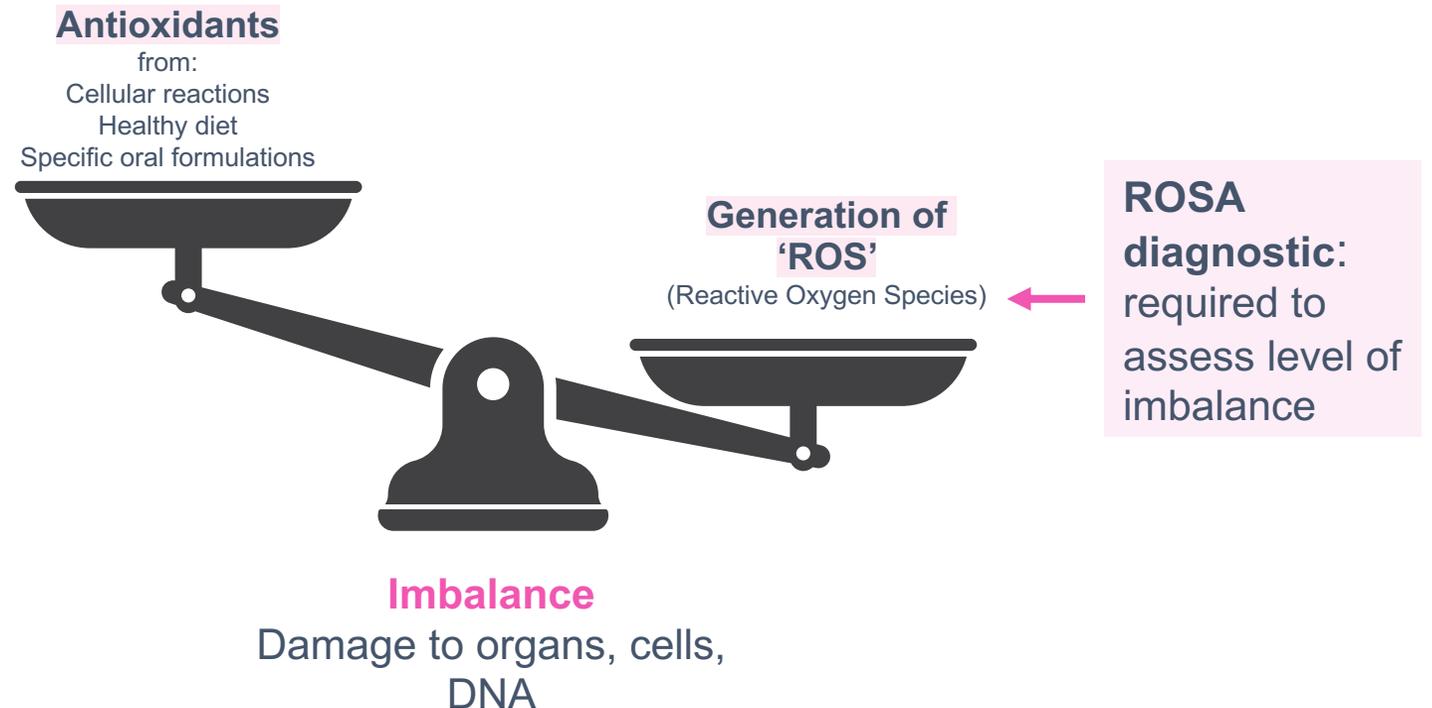
## 2. ROSA (Rapid Oxidative Stress Assay)

- Oxidative stress is an imbalance between reactive oxygen species and antioxidant protection within the body
- This imbalance increases with age and can lead to serious diseases
- It also severely affects **fertility** in both humans and animals.
  - Adversely affects sperm, eggs, embryos, the developing foetus and its placenta
  - Is a major contributor to lack of conception, still births/ recurrent pregnancy loss, pre-term labour and sudden newborn death



# ROSA - Clear need for a diagnostic device

- For males, oxidative stress in the sperm is a major contributor to infertility
- There is no simple oxidative stress clinical assessment; complex lab tests are required and therefore not often used
- Oxidative stress is important to treat correctly
  - Providing powerful antioxidant therapy when no or little oxidative stress is present can lead to other dangerous conditions
- Clear need for a rapid, accurate **point-of-care diagnostic**
- Diagnostic could be used for:
  - Bodily fluids (semen, blood, follicular fluid, etc) at IVF clinic / doctor's office (& even for some tests at home)
  - ROSA technology could also be used for assessing the semen of valuable horses and for other high value livestock



# ROSA - Major market opportunity



Source:

1. [www.cdc.gov/reproductivehealth](http://www.cdc.gov/reproductivehealth)
2. Pro-rata factor: size of US to other IVF markets, in major markets, using data from Global IVF services Market 2019 – 2026 report by Allied Market Research, 2018
3. Antioxidants Market Size, Share & Growth | Industry Report 2021, <https://www.alliedmarketresearch.co>

# ROSA - Development pathway

- The diagnostic will utilise a novel biochemistry-based assay
- Biochemistry optimisation and validation process underway
  - Early proof of concept achieved
  - Conceptual device design process commenced
  - Ability to develop a technically and commercially robust biochemical assay likely to be known in ~6 months
- Subject to successful optimisation and validation, ROSA prototype to be field tested with chosen international KOLs, to demonstrate its efficacy and determine market opportunity
- International distribution potentially through regional or national partners



# 3. Samson™ Device

**A device used in the breeding shed to provide a pregnancy prediction within an hour after a stallion-mare mating, for both thoroughbreds and horses bred by artificial insemination (AI)**

- Early pregnancy within the breeding season is a major financial advantage to breeders
  - Racing horses all have the same registered birth date of 1 September, regardless of actual birth date
  - Extra growth from early pregnancy in the breeding season is highly valuable<sup>1, 2</sup>
- Samson™ Device has potential to improve efficiency and success of breeding practices
- Currently, pregnancy outcome is not known until 14 days, by which time mare may have missed her oestrus cycle
- Semen quality varies significantly even with the same stallion from each service and day to day
- A quick reliable pregnancy prediction would allow a timely additional service of the mare if necessary and could also enable underperforming stallions to be replaced
- Potentially transformative for industry participants (mare and stallion owners and stud masters) who are financially dependent on successful pregnancy within the breeding season

1. Each additional foal “day of age” demonstrated to be worth an additional >US163 to the owner: difference in foal sale price of US \$23,000 between the oldest (“early season” conception) and youngest (“late season” conception) Hansen CR, Stowe CJ. Journal of Applied Economics 2018; 50: 48-63
2. Over a 1600-meter race, a 2-month age difference = a 1.7 second difference in finishing timeTakahashi TJ. Equine Science 2015; 26: 43 – 48



# Samson™ Device - Value proposition

	Thoroughbreds (Bred naturally)		Horses bred by AI	
Horse type	Thoroughbreds for racing (Not allowed to be bred by AI)		All other horses eg standardbreds (trotters), quarter horses, Australian stock horses, Arabians, polo ponies, warm bloods etc	
~No. of breeding mares	<b>Australia</b> 50,000	<b>USA</b> >1 million	<b>Australia</b> 80,000 (standardbred ~20,000)	<b>USA</b> >7 million
Sample collection method	From dismount ejaculate		From total ejaculate	
Fertilisation efficiency	Average 2 services/ fertilisation attempts per pregnancy (with fresh or chilled semen)			
Samson™ Device anticipated use frequency	At least once per mare in the breeding season. Note Northern hemisphere season for racers is 6 months' apart from Aust./NZ season			
Anticipated pricing model	Baseline: likely to be per use (per insemination)			
	Premium customised fee, per stallion, for extremely valuable matings			

Source: Report on AI in Production Livestock by AgKnowledge, April 2020 commissioned by Memphasys;  
Study by Barents Group commissioned by American Horse Council, 2016; Industry interviews

# Samson™ Device - Progress & Next Steps

- Proof of concept field trial completed in 2021 breeding season for thoroughbreds and standardbreds
- The Samson™ Device initial prediction algorithm ~90% accurate in standardbreds
- If thoroughbred algorithm optimised for individual stallions, pregnancy prediction >85%
- Improved thoroughbred outcome likely requires a customised and optimised algorithm service for each stallion
- Plan to use market-ready Samson™ Device with integrated hardware/software, currently in development, for next Australian breeding season (Sep-Nov)
- The next gen Samson™ Device is to be validated with new matings early next breeding season (Sep-Nov) with initial sales anticipated to follow to participating stud farms if successful field validation is achieved
- Further sales would be then be targeted by appointment of distributors for overseas markets (USA, Japan and Europe) in 2023 and by seeking more direct sales in Aust./NZ



# 4. SemPort

**A human semen transport system to prevent degradation of the sperm for ~3 days to enable a full, accurate semen analysis to be remotely provided on intact semen held at ambient temperature.**

## **The Problem:**

- Sperm do not freeze well and keeping in seminal plasma compounds the problem
  - the majority of sperm are destroyed or damaged in the process
  - Seminal plasma is toxic if stored and causes further loss of viability
  - Sperm motility, a key metric reported in a semen analysis, deteriorates especially quickly with time
- Most IVF clinics do not provide full semen analysis and are increasingly outsourcing this service to specialist diagnostic labs
- Patients wanting semen analysis often not located near specialist diagnostic labs

## **The Solution:**

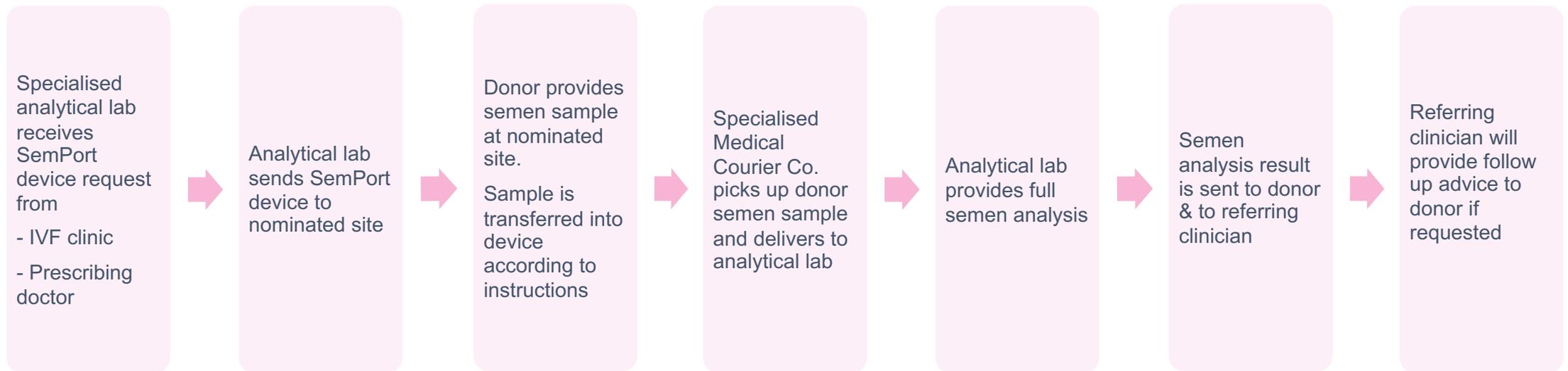
- Customer will be able to provide sample from a nominated collection site. SemPort device is used to send to diagnostic lab for full semen analysis

## **Advantages:**

- Enables donor to provide semen samples in convenient place
- High quality analysis maintained by keeping semen sample at ambient temperature, as if freshly provided

# SemPort: How it will be used

~3 days to keep sample viable for accurate analysis.  
Currently sperm survive <24 hours and many die in that time frame.



Later possibility: Donor could provide the semen sample from home;  
Further subsequent possibility: Sample could be used for IVF (but this involves high regulatory hurdles).

# SemPort - Product development

## Development path:

- Early proof of concept achieved for proprietary long-life semen medium and transport device. Optimisation work proceeding
- Prototype system (medium and device) to be made, ready for clinical testing
- Clinical testing: a range of semen samples at ambient temperatures will be tested to establish how long they will remain viable for accurate semen assessments to be made. Minimum time required is 2 days.
- Subject to successful clinical assessments, a “go to market” product will be made
- Distribution likely to be via regional distributors and/or by JVs with chosen major clinics

## Potential accessible market size:

**~1 million men pa**

## Assumptions\*

- Target market: men seeking IVF treatment
- 2 million estimated couples seeking IVF pa
- 85% of the couples are in accessible geographies (EU, Japan, China, India, US, Asia Pacific) and
- An estimated 50- 60% of the target male population would use such a service if the test was accurate

\*Source: Allied Market Research, Global IVF Services Market, 2018, market interviews

# 5. AI-Port

## Device to store and transport semen for Artificial Insemination (AI) without freezing

- The global AI market is large and extensively used in cattle, pigs, sheep and horses
- Semen for AI is usually frozen so that it can be kept indefinitely, and so it can be transported long distances for remote insemination

### Issue:

- Freezing is very destructive to sperm
- It is particularly damaging to horse sperm. Pig sperm cannot be frozen

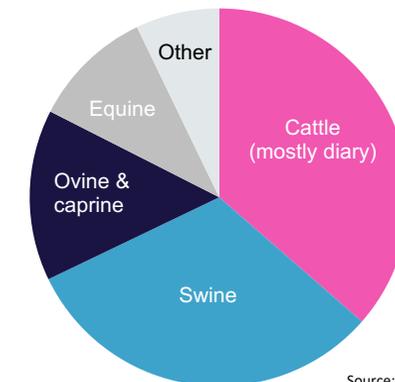
### Potential solution:

A long-life semen storage and transport device would allow fresh semen to be shipped for AI with consequent benefits:

- improving AI success rates
- enabling AI semen straws to be loaded with fewer but more reproductively viable sperm.

## Global Animal AI market, by species.

Total market size: US\$4.2Billion;  
10 year CAGR 6.5%



Source: www.grandviewresearch.com

## Estimated Australian AI use by species

Dairy cattle		85%
Swine		90%
Non-thoroughbred horses		56%

Source: Report commissioned by Memphasys on Artificial Insemination in Production Livestock, April 2020, by AgFutures

# 5. AI-Port use Vs. traditional method

## Traditional Method



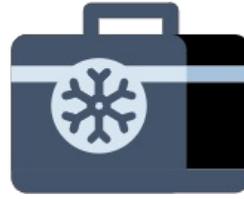
Sample collected



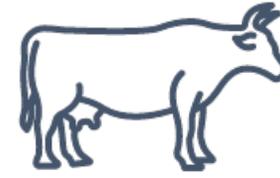
Laboratory assessment for motility, morphology and sperm count



Addition of semen extender, chilling at 4°C overnight



Straws loaded with diluted semen and frozen in liquid nitrogen



AI performed using thawed straws

## AI-Port Method e.g. for bovine AI



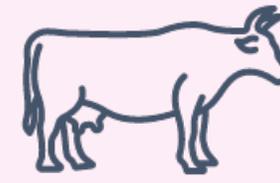
Sample collected



AI-Port used in the field or breeding centre to isolate motile sperm (plus could provide a rapid sperm count)



Motile sperm loaded in straws – could use less per straw than if they were frozen.



AI performed using fresh straws

### AI-Port benefits (from using fresh semen)

- Likely to improve AI success rates
- Would enable semen straws to be loaded with less but more reproductively viable sperm
- Could allow sex-sorted sperm to be transported and inseminated as a fresh sample (few survive sex sorting and double freeze process).
- Alternatively, sample could be frozen after sex sorting if needed to be kept viable for an extended period

# Memphasys Investment Highlights

- Addressing major global human and animal reproductive markets
- First commercial sales of Felix™ Device
- Expanding portfolio of new products to meet unfulfilled reproductive market needs in humans and in high-value animals
- Board & management with strong strategic, medtech commercialisation experience
- Key collaborations with
  - University of Newcastle research team, led by International fertility expert, Distinguished Laureate Professor John Aitken; and
  - Australian human clinical industry partner, Monash IVF



better technology, more life



# Corporate Snapshot

ASX Code	MEM
Share price (as at 14/02/22)	\$0.063
Shares on issue	792.18 million
Market capitalisation	~\$50 million
Cash & Cash Equivalents (as at 31 Dec 21)	~\$1.95 million
Ownership structure – substantial shareholders (as at 1/05/22)	<p>Peters Investments (27.2%)</p> <p>Mr Andrew Goodall (21.6%)</p> <p>Ms Alison Coutts (10.1%)</p>

MEM 12mth Share Price



# Board of Directors



**Robert Cooke**  
Non-Executive  
Chairman

More than 40 years in healthcare, spanning executive leadership of publicly listed and privately owned healthcare companies, overseeing numerous M&A transactions and management of private and public hospitals in Australia, Asia and the UK. MD & CEO of Healthscope (2010-2017), a leading private hospital, medical centre and pathology company. Currently Non-Executive Chair of OptiScan Imaging (ASX: OIL), a global leader in the development of microscopic imaging.



**Alison Coutts**  
Managing  
Director &  
CEO

Extensive experience across a number of industry sectors and disciplines including international engineering project management with Bechtel Corporation in the UK, USA and New Zealand, strategy consulting with Boston Consulting group, executive search with Egon Zehnder International, investment banking at eG Capital, which she co-founded, technology commercialisation over the past 15 years, including co-founding ASX-listed Micro-X, and executive management, currently with Memphasys Ltd. Formerly Chair of CSIRO's Health Sector Advisory Council.



**Mr Paul Wright**  
Non-Executive  
Director

More than 30 years' experience as a highly skilled executive in strategic consulting and the development and sales of innovative medical devices and diagnostic tools. Mr. Wright's background includes developing and implementing commercialisation strategies from early research and development through to developing global product sales channels. Mr. Wright has experience in building distribution partnerships and the direct selling and marketing of highly innovative products internationally. During the past two decades, he has worked as CEO for three leading international Australian technology companies focused on developing, manufacturing and marketing of medical devices and diagnostic instruments.



**Andrew Goodall**  
Non-Executive  
Director

An entrepreneur with a wealth of business and commercial experience who has successfully established a number of businesses throughout his career in Australia and New Zealand. Having had extensive experience in Commercial Property Investment, Mr. Goodall is currently involved in the management of his substantial commercial property interests in New Zealand. Mr. Goodall has been a significant shareholder in Memphasys for many years.

# Appendix 1 : Patents & Trademarks

## Patents Granted For Felix™ Device

Country	Patent Title	Expiry
US	Cell Separation	Jul 26
US	Biocompatible Polymeric Membranes	Aug 37
China	Sperm separation by electrophoresis	Oct 37
US	Sperm separation by electrophoresis	Oct 37
Australia	Sperm cell separation by electrophoresis <sup>1</sup>	Oct 24
UK	Sperm cell separation by electrophoresis <sup>1</sup>	Oct 24
US	Sperm cell separation by electrophoresis <sup>1</sup>	Aug 27

## Trademarks

Felix™ Device trademark registered in Australia, US, UK, EU, India, Japan and Canada

Samson™ Device trademark registered in Australia.

1. Patented under University of Newcastle but Memphasys has sole rights to use under Memphasys' licensing agreement with the University

# Appendix 2: Importance of sperm's negative charge

- During sperm maturation, the sperm head is covered by a glycoprotein and glycolipid coating which has a highly negative electric charge
- Negative charge has been correlated with:
  - Normal morphology (shape)
  - Lower levels of DNA fragmentation
- The Felix™ Device selects only the sperm with a negative charge – with less DNA damage and a more normal shape.

