

**MEMPHASYS**  
REPRODUCTIVE BIOTECHNOLOGY

# *Creating novel fertility solutions*

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# Memphasys Investment Proposition


















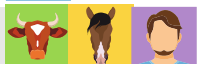
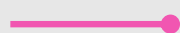
- Memphasys is a medtech company (ASX: MEM) focused on reproductive biotechnology
- Developing high value product portfolio (devices, diagnostics and media products) addressing major global human and animal reproductive markets
- Source of new product pipeline: global Fertility Expert, Laureate Professor John Aitken and his research team at University of Newcastle (“UoN”)
  - MEM employs Professor Aitken part time, supports 7 UoN researchers and has a commercially attractive licensing agreement with UoN for new discoveries
  - MEM team of engineers and scientists “productises” the discoveries
  - Ability to develop the more technically challenging pipeline projects will be established within next six months
- Most advanced product: The Felix™ device, co-developed by Professor John Aitken with MEM for sperm separation in human IVF
  - Important milestone reached with first sales of two Felix™ devices



John Aitken, global leader in reproductive biology:

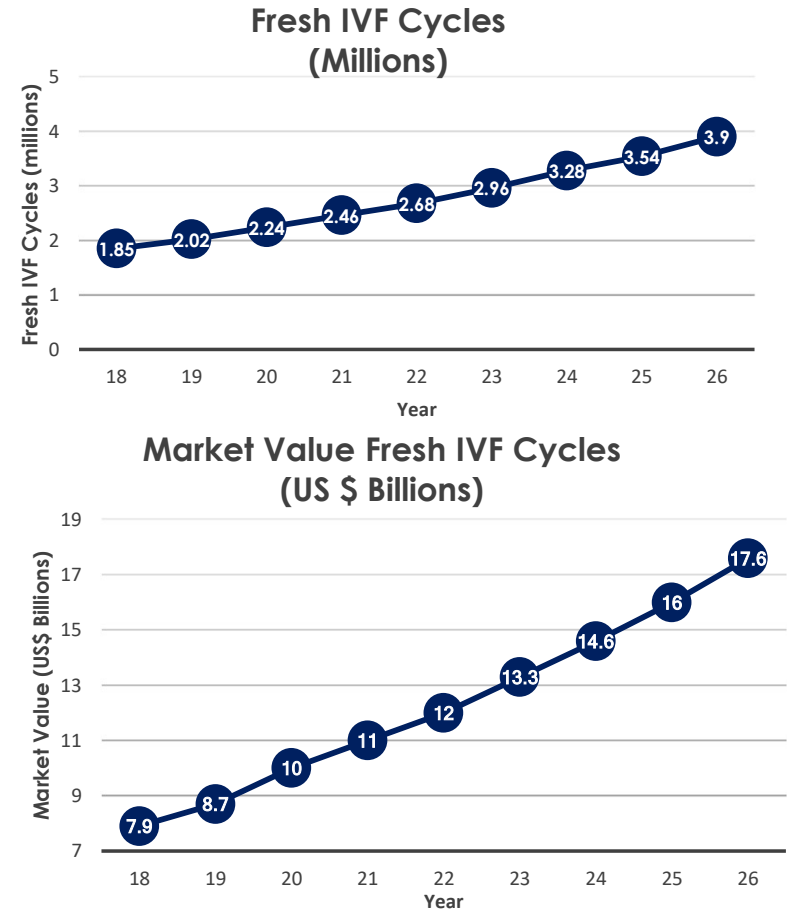
- published over 650 research articles
- work cited ~55,000 times (h-index of 120, highest citation index in his field and in the top 5% for all of Biology and Biochemistry).
- ranked #1 in the world in sperm biology and fertilisation (Source: Expertscape.com).
- Life work is source of MEM’s new product ideas

# Memphasys Core Product Development Pipeline

| Product  | Initial target use   | Technical complexity (High/ Low) | Addressable market  | Development stage (POC = proof of concept) |
|--|--|----------------------------------|---|--|
| 1 <b>Felix device (sperm separator for IVF)</b>                                    |    | High                             | Niche  Large    | Initial sales; Clinical trials             |
| 2 <b>"SODA"</b><br><i>(rapid in situ oxidative stress diagnostic)</i>              |    | High                             | Large  Diverse  | Early; biochemistry evaluations            |
| 3 <b>"SAMSON"</b><br><i>(rapid in situ diagnostic)</i>                             |  |                                  |   |  |
| a) Total motile sperm count indicator  |    | Low                              | Niche  Large    | POC  |
| b) Pregnancy predictor   |    | High                             | Niche    | POC  |
| 4 <b>"SEMPORT"</b><br><i>(For ambient temperature semen storage and transport)</i> |  |                                  |   |  |
| a) Quality analysis for remotely provided semen sample                             |    | Low                              | Niche    | POC  |
| b) For AI <i>(without freezing sperm or prior to "sex sorting" process)</i>        |   | Low                              | Large    | Early; concept developed                   |
| 5 <b>Cryopreservation</b>  |  |                                  |   |  |
| Retrieval of cryopreserved sperm for IVF   |  | Low                              | Niche    | POC  |
| Improved cryopreservation methods  |  | High                             | Large    | Early; Initial concepts developed          |

# Human IVF market

- IVF use is accelerating, but IVF's success rate remains stubbornly low
- Average of 2.2 IVF cycles before success, averaged for all women <40yo
- IVF slightly increases risk of miscarriage *and genetic impairment of offspring*
- Male fertility rates in global decline
- ~50% of infertility cases attributed to the male
- 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



# Animal Reproduction Market

- Two main methods of reproduction in the livestock industry\* :
  - natural cover
  - artificial insemination ("AI")
- World wide AI rates\*\* in farmed animals:

|                         |   |     |
|-------------------------|---|-----|
| Dairy cattle            |  | 85% |
| Pigs                    |  | 95% |
| Non-thoroughbred horses |  | 56% |

- Natural cover is used by many livestock farmers and is also mandated for thoroughbred (racehorse) breeding; other horse breeds\*\*\* are permitted to utilise AI
- Frozen semen is generally utilised for AI due to its longevity and ability to be shipped over long distances, but is detrimental to sperm quality in horses (vastly reduces viable sperm) and cannot be used in pigs (kills the sperm)
- Size of market of breeding horses in Australia \*\*:
  - >140,000 horses bred in Australia;
  - ~45,000 are thoroughbreds bred for racing
  - Australia is the second largest breeder of thoroughbreds globally; the USA is the largest.

\*ICSI (intracellular sperm injection), a type of IVF used predominantly in human IVF, is also sometimes used on very high value animals

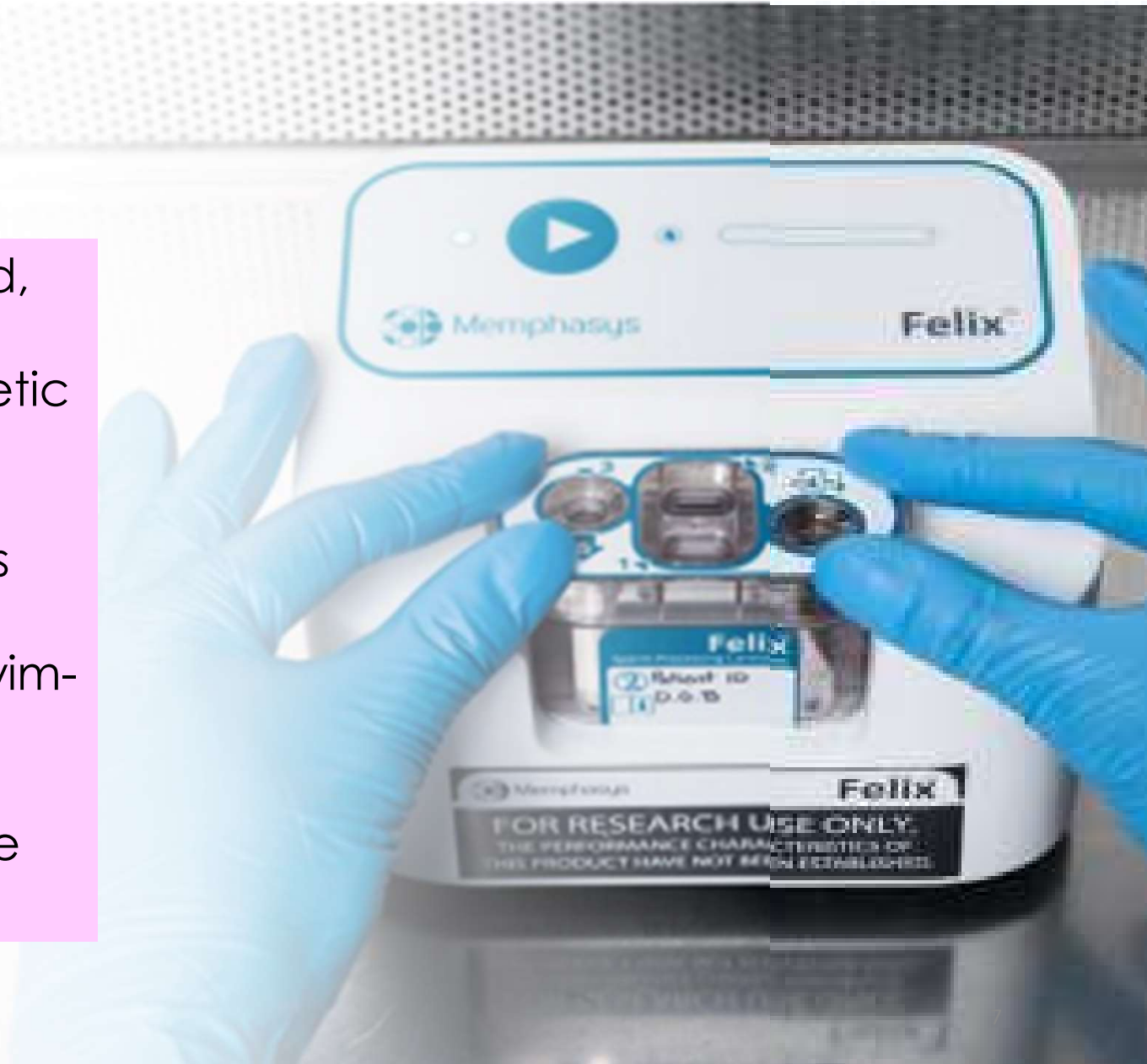
\*\*Report commissioned by Memphasys on Artificial Insemination in Production Livestock, April 2020, by Agknowledge

\*\*\* standardbreds (trotters), quarter horses, arabs, eventers, polo ponies etc

# 1. Felix™ Device – For Human IVF

The Felix™ is a patented, rapid, easy to use and automated membrane-based electrophoretic device.

This separation method offers potential benefits over conventional methods used (Swim-up and Density Gradient Centrifugation (DGC)) by separating sperm by negative charge and size



# Advantages of Felix™ 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™  | 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 |

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

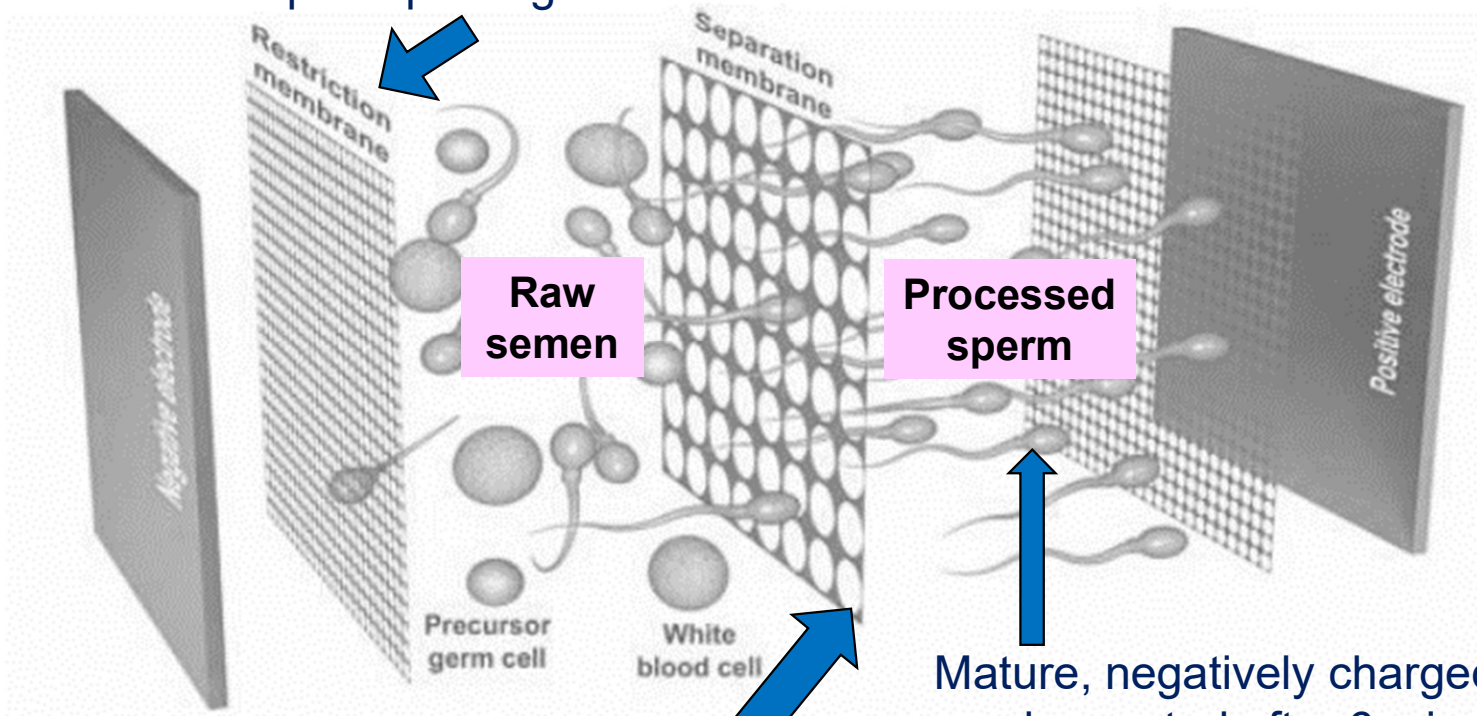


**Felix console and disposable, single use cartridge (the recurrent revenue source)**



# Felix™ Technology

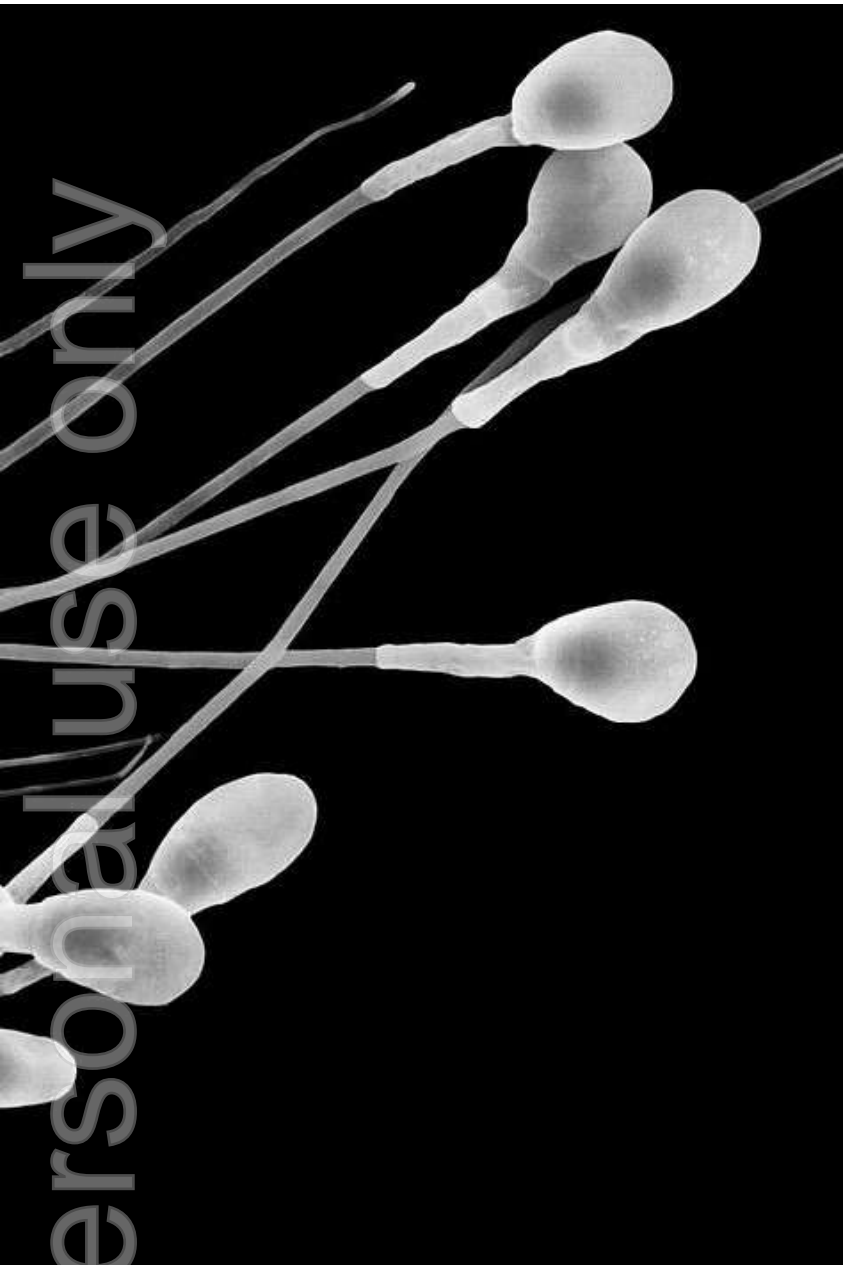
Allow ion transfer but  
block sperm passage



Separates sperm  
from other cell types

Mature, negatively charged sperm  
harvested after 6 minutes

personal use only



## 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

# Felix™ device commercialisation progress

- KOL *in vitro* testing (results to be published)
  - 15 global KOLs testing; completion expected first half 2022;
  - Results showing Felix™ handles the widest range of semen samples and selects sperm with less DNA damage than the DGC process and comparable with swim up
- Clinical trial with Monash IVF, Memphasys' clinical industry partner has started
  - Ethics approval received; first patient to be recruited shortly
  - Anticipated to finish within calendar year 2022
  - Aims:
    - ✓ To demonstrate the safety and performance\*\*\* of the Felix™ System
    - ✓ To generate clinical data for future TGA regulatory submissions and for other regulatory bodies
- Clinical sales process:
  1. *in vitro* testing (parameters such as DNA damage, motility, morphology, vitality), then ...
  2. embryo quality testing/ small clinical trial against current sperm separation processes, plus
  2. publishing of papers and speaking at conferences on *in vitro* test results and clinical trial results
- Clinical sales of Felix™ device are starting in low regulatory markets\*
  - Initially targeting key opinion leader ("KOL") sites that have tested the device
  - First clinical sale in Dec 2021 with KOL in Coimbatore, India; Research-use sale also achieved with a Chinese KOL

\*India, Japan, Canada, NZ

\*\*Trial end point – embryos from Felix are non inferior to DGC and/or Swim up

# Felix™ Device Pathway to Market

- Initial focus is on building sales in four selected countries with low regulatory barriers for Felix:

| 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%                            |

24% of global market



- Now hiring sales development manager for boosting Felix device sales effort

## 2. The “SODA” oxidative stress diagnostic

- Oxidative stress occurs when there is an imbalance of reactive oxygen species production (primarily from metabolism\*) and the body's ability to counter the adverse effects of these products
- Oxidative stress is pervasive in many serious diseases including Alzheimers, cardiovascular disease and diabetes and increases with age
- It also severely damages fertility in both humans and animals.
  - Adversely affects sperm, eggs, embryos, the developing foetus and its placenta, and is a major contributor to lack of conception, still births/ recurrent pregnancy loss, preterm labour and sudden newborn death
  - Thought to increase susceptibility to genetic diseases in the offspring such as Down Syndrome (in aged mothers) and Autism (in aged fathers).
  - Prevalent in common female reproductive pathologies\*\*
  - For males, prevalent in semen samples with poor motile sperm count and high white blood cell count.
- A useful diagnostic is required as no such diagnostic exists

\*Damage arises mostly from mitochondria, a key part of the cell responsible for respiration and energy production

\*\* eg Polycystic ovarian syndrome, endometriosis, pre-eclampsia and intrauterine growth restriction.

# Need for oxidative stress diagnostic

- It is important to determine if, where, and how much, oxidative stress is present
  - Determining whether the oxidative stress is local or systemic will indicate the treatment required
  - Providing powerful antioxidants when no or little oxidative stress is present can lead to reductive stress, a different but also dangerous condition
- Currently oxidative stress is diagnosed with complex laboratory equipment
  - because of the complexity of the process, such tests are not often used
- Memphasys is utilising novel biochemistry and device design to develop a rapid point-of-care diagnostic
  - to be used on bodily fluids (semen, blood, follicular fluid etc)
  - for home use (quick semen analysis) and for clinical use (eg doctor's office, IVF clinic)
  - Technical feasibility to develop such a diagnostic will be known within 6 months

\*Damage arises mostly from mitochondria, a key part of the cell responsible for respiration and energy production

\*\* eg Polycystic ovarian syndrome, endometriosis, pre-eclampsia and intrauterine growth restriction.

### 3. The “SAMSON” device: two potential products

#### Equine pregnancy predictor

- Developing a rapid onsite in-vitro diagnostic test to assess stallion semen for probability of successful mare pregnancy.
- For thoroughbred and non-thoroughbred (eg standardbred) horses
- High variability of semen quality, even within the same stallion from day to day
- Aust Field Trial completed and results due shortly (1 Q 2022)
- Potential application for other species (cattle, pigs and sheep)

#### Simple at-home test for initial diagnosis of sperm quality

- Samson device's principles could be applied to developing a simple rapid, at home diagnostic for determining total motile sperm count
- This would be an initial test to determine if further testing at an IVF clinic is required or not

### 3. The “SEMPORT” semen long life storage & transport device

#### For comprehensive human semen diagnostic from remote donor

- Normally semen is frozen if transported over long distances and this severely affects diagnostic accuracy
- Product maintained at ambient temperature for up to 7 days would enable direct courier shipment of semen from remote donor to the diagnostic laboratory for full semen assessment
- Great demand to avoid the need for semen donor and diagnostic assessment lab to be closely located and for semen sample to be provided from location chosen by donor eg at home
- Product will require a device and use of proprietary media
  - Media developed, now being optimised
  - Prototype device in development

#### For ambient temperature animal AI

- Device likely to also have use for animal AI if scaled up
- Each device would need to be tailored for the species, which is not difficult



# 5. Cryopreservation projects

## Felix™ device use with cryopreserved semen/ sperm

- Cryopreserving (freezing) is frequently used
  - for donor sperm, sperm retrieved from testicular biopsies, poor quality samples\* and from men who cannot provide sperm to coincide with the IVF procedure or who wish to preserve sperm before they undergo chemotherapy or radiotherapy
- Cryopreservation severely impacts sperm motility and vitality and leads to more DNA damage, especially when centrifuging is used for processing post freezing
- Current sperm preparation methods (DGC and Swim up) do not resuscitate cryopreserved sperm well
- Initial testing with Felix™ on cryopreserved semen samples against DGC and Swim up techniques has demonstrated its superiority in retrieving higher yields and higher quality sperm

## New cryopreservation media

- No advances in cryopreservation media for past 50 years
- Memphis is working on new, improved formulations

\*eg high DNA fragmentation, low sperm count, low motility

# 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 30/06/21) | Peters Investments (27%)<br>Mr Andrew Goodall (22.4%)<br>Ms Alison Coutts (10.1%) |

MEM 12mth Share Price



Source: ASX website

## Board of Directors

### Alison Coutts – Executive Chairman



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 and executive management, currently with Memphasys Ltd. Formerly Chair of CSIRO's Health Sector Advisory Council and was a co-founder and director of eG Capital.

### 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. For the past two decades, he has worked as CEO for three leading international Australian technology companies focussed 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.

### Shane Hartwig – Non-Executive Director



Mr Hartwig has over twenty five years' experience in the finance industry both nationally and internationally with exposure to both the debt and equity capital markets. He is a Certified Practising Accountant and Chartered Company Secretary and founder of Peloton Advisory corporate advisory firm.

# Memphasys Investment Highlights

- Addressing major global human and animal reproductive markets
- First commercial sales of Felix™ device
- Key collaborations with
  - University of Newcastle research team, led by Global Fertility Expert, Professor John Aitken and
  - Clinical industry partner, Monash IVF
- Expanding portfolio of highly prospective new products to meet unfulfilled market needs in humans and in high-value animals



better technology, more life



# Thank you

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