

INVESTOR PRESENTATION 2023

Memphasys Limited (ASX: MEM) April 2023

Better technology, more life





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This presentation provides indicative timelines for various product development and commercialisation activities. These timelines are based on best current estimates, which are subject to change.





Memphasys Limited (ASX: MEM) is an emerging small-cap reproductive biotechnology company.

Founded in its value proposition 'better technology, more life', MEM's primary aim is to grow long-term value for its shareholders through the development and commercialisation of novel reproduction and fertility solutions for humans and animals.



MEM's value proposition is underpinned by strong fundamentals



Strong pipeline of unique, potentially company-making products, driven by a clear market demand and offering distinct advantages over current industry practice



World-class product R&D led by internationally-recognised leader in reproductive medicine, Laureate Professor John Aitken



Comprehensive 'pathway to market' strategy for each product



Board and management with requisite skills / experience in health, medtech, product development and commercialisation to deliver strategic objectives



Robust Pipeline of Core Products including devices, media & in vitro diagnostic solutions

	FELIX™ System	ROSA	AI-Port
OVERVIEW	The patented Felix [™] System is MEM's first commercial product. It automatically separates high-quality sperm with least DNA damage from raw semen for use in IVF procedures. It takes 6 minutes compared with current practices, which take 30-40 minutes.	ROSA, a novel Rapid Oxidative Stress Assay, is a unique rapid diagnostic (provisional patent) that measures oxidative stress in samples of bodily fluid. Oxidative stress is a leading cause of infertility & of serious complications during pregnancy.	AI-Port is a proprietary device comprising a novel medium to store & transport semen at ambient temperatures for use in artificial insemination (AI). The sperm remains viable for up to 3-4 days without requiring the use of cryopreservation, which is damaging to sperm.
INITIAL TARGET MARKET SECTORS	Specialist IVF & andrology clinics	Early sales: Clinical fertility researchers Later sales: Males / females with potential fertility issues, & pregnant females	Premium beef cattle bred with AI
ESTIMATED ACCESSIBLE MARKET	~A\$617 million ¹	A\$2.3 billion (top 5 markets)	A\$2.4 billion (top 5 markets)
DEVELOPMENT STAGE	Initial clinical adoption in early target markets. Clinical trials in domestic & international markets	Production prototypes under development for field validation & regulatory clinical trials	Production prototypes under development for field trials

1 Total annual potential market for the Felix[™] System that MEM could be accessing as sales opportunities within the next five years. Reference: Allied Market Research Global IVF Services Market 2019; "The Infertility Trap: Why Life Choices Impact Your Fertility & Why We Must Act Now" – Cambridge University Press, 5 May 2022



Financial Snapshot as at 3 April 2023

	KEY DATA ¹	A\$		
	Share price	0.018		
	Shares on issue	959.5M		
	Market capitalisation	17.2M		
(F)	Cash & cash equivalents ²	2.1M		

OWNERSHIP STRUCTURE ¹	%
Peters Investments	27.2
A Goodall	19.6
A Coutts	8.8
Тор 20	55.6

CONVERTIBLE NOTES	
Peters Investments	3M (at A\$3M face value & maturity at 31 December 2023)

Strategic Priority FY23 – FY25: Accelerate Commercialisation

BUILD BUSINESS IN LINE WITH INCREASED COMMERCIALISATION ACTIVITIES

CORPORATE		
PEOPLE	Business	Recruitment Recent recruitments: Business Development & Sales Director; Operations Director¹ For recruitment before 2Q CY 2023: Engineering Manager
	Research & Development (R&D)	Further develop R&D pipeline with University of Newcastle (UoN) R&D Group including current product extensions & innovations

PROGRESS PRODUCT DEVELOPMENT & REGULATORY ENGAGEMENT

PRODUCT		
HUMAN	Felix™ System	Grow business, initially focusing on the largest and/or early target human reproduction markets – Japan, China, India & Canada
	Felix™ Plus	Develop next generation of the Felix™ Plus System with aim of optimising product performance & decreasing cost of production
	ROSA	Finalise design/build of production system, followed by completion of field validation. Target research market for early sales & pass regulatory process to enable sales for clinical applications
ANIMAL	Al-Port	Complete April field trial; if successful, undertake further field trials followed by completion of design/build of production system



Advantages of the Felix[™] device over current sperm preparation processes for IVF

FELIX™ SYSTEM

VERSUS DENSITY GRADIENT CENTRIFUGATION (DGC)

One step, automated, desk-top console with disposable, single use cartridges

- Delivers consistent & repeatable high-quality results
- Less chance of operator error

Six minute process

Selects sperm with low DNA damage & low oxidative stress

Capable of processing wide variety of semen samples, not just from good quality samples ie viscous, low sperm count, poor motility, highly-damaged DNA

Premium product

 Indicative pricing is in mid-range between lab-based techniques (DGC and Swim-up) & other commercially available sperm separation products



Multi-step 30-40 min laboratory process

More variable results

Potential to cause DNA damage with centrifuging

DGC unable to identify sperm with less DNA damage & oxidative stress

Felix™ produces better quality sperm from frozen/thawed semen than DGC (used with cancer patients & sperm banks)

CURRENT SPERM SELECTION PROCESSES

Indicative labour & equipment cost A\$100 in Australia / US\$100 in US

VERSUS SWIM-UP

Multi-step 30-40 min laboratory process

- Potential for more variable results
- Requires high level of operator expertise

Swim-Up underperforms against Felix[™] with poor semen samples

- Felix[™] produces better quality sperm from frozen/thawed semen than Swim-Up (used with cancer patients & sperm banks)
- Swim-Up performs equally against Felix™ using healthy semen samples

Indicative labour & equipment cost A\$100 in Australia / US\$100 in US

Zymot is a semi-automated, commercially available product that utilises a Swim-Up process

- Priced at top of market
- Underperforms with poor semen samples; performs best with healthy samples
- Still requires operator expertise
- 30-40 min process



Potential Felix[™] global market opportunity exceeds A\$630 million^{1, 2}

GLOBAL GROWTH RATES IN HUMAN REPRODUCTION ARE ACCELERATING

- 2-6%: Europe (mature market)
- 6 8%: US, Australia & NZ
- 12 15%: Japan, China, India & Canada

INFERTILITY RATES ARE ACCELERATING BUT THE PROBLEM REMAINS

- 1 in 6 couples have fertility issues
- Male issues contribute to couple infertility in approximately 50% of cases
- Sperm counts halved globally in last 30 years
- No fundamental change in how sperm is processed in IVF clinics in over 40 years

CURRENT IVF SUCCESS RATES LOW AND COSTLY

- Live birth rate per fresh embryo transfer is still low in Australia at 24.6%; similar rates in other jurisdictions
- Cost: A\$11,500 A\$21,000 IVF per cycle in developed countries & approximately \$3,000 - \$6,000 in developing countries



2 ART in Australia and NZ, Oct 2022, UNSW, Sydney - in collaboration with Fertility Society of Australia



¹ Total annual potential market for the Felix[™] System that MEM could be accessing as sales opportunities within the next five years. Reference: Allied Market Research Global IVF Services Market 2019 & "The Infertility Trap: Why Life Choices Impact Your Fertility & Why We Must Act Now" – Robert John Aitken, Cambridge University Press, 5 May 2022

Progress to date: global engagement with key opinion leaders and some early sales

KEY OPINION LEADERS (KOLS)

15 KOLs in clinical assessments of Felix[™] globally

Prof John Aitken as principal investigator

KOLs are generating early clinical data on Felix™ for:

- publications & presentations
- commercialisation process in complex regulated markets requiring clinical trial data ahead of regulatory submissions
- potential sales in early target markets ie Japan, Canada
 MEM conducting regulatory clinical trial with Monash IVF
- Initial (blinded) results encouraging
- ⁻ Trials provide clinical data for EU, Australia & other regulatory filings
- Early low participation rates pushed trial completion into 2023 as a result of stringent entry criteria

Participation now building due to initiatives introduced to boost numbers
 Felix[™] registered and/or cleared for sale in NZ, Canada & Japan

 Sales in Japan focused on private sector following introduction of new IVF reimbursement regime in 2022

INITIAL Felix[™] SALES

- Initial & repeat sales made to Indian KOL in 2022
- First baby born using Felix[™] in India; many ongoing pregnancies
- Subsequent regulatory changes temporarily suspended sales to India.
 - MEM actively planning to manufacture in India to expedite the regulatory clearance of Felix[™] & to decrease COGS

KOLS ARE RECOGNISED AS THE ESTEEMED PRACTITIONERS OF THE GLOBAL IVF SECTOR & KEY REFERENCE POINTS FOR THE WIDER IVF COMMUNITY ON INDUSTRY INNOVATION & LEADERSHIP TRADITIONALLY 'FIRST BUYERS' OF NEW PRODUCTS





Felix[™] endorsed by leading global IVF clinics

PUBLICATION OF PEER REVIEWED RESEARCH OF FELIX[™] SYSTEM BY KEY OPINION LEADERS (KOL's) IN GLOBALLY SIGNIFICANT JOURNALS

SPERMATOZOA ISOLATION WITH FELIX™ OUTPERFORMS CONVENTIONAL DENSITY GRADIENT CENTRIFUGATION PREPARATION IN SELECTING CELLS WITH LOW DNA DAMAGE

- Published 11 January 2023 by the American Society of Andrology & the European Academy of Andrology in leading medical magazine, Andrology, which specialises in male reproductive & urological issues
- Conducted by renowned French genetics reproduction & development lab (GReD), supported by the University Clermont Auvergne (UCA), & led by Professor Joel Drevet, an international leader in mammalian andrology (the KOL) and a global expert in oxidative damage
- Paper concluded: Felix[™] "significantly improved" sperm fractions with higher motility & less oxidative and DNA damage¹

"Outperforms DGC" "These improved sperm parameters, along with the fact that the Felix™ (System) separation process is very fast and highly standardised, should be of great interest to the assisted reproduction technologies industry".

Excerpts from GReD paper titled "Spermatozoa isolation with Felix™ outperforms conventional density gradient centrifugation preparation in selecting cells with low DNA damage"

A COMPARISON BETWEEN THE FELIX™ ELECTROPHORETIC SYSTEM OF SPERM ISOLATION AND CONVENTIONAL DENSITY GRADIENT CENTRIFUGATION: A MULTI-CENTRE ANALYSIS

- Published 14 December 2022 in the Journal of Assisted Reproduction and Genetics by group of five, highlyesteemed international ART Centres in Australia, India, Sweden, US and China²
 Study compared the quality of sperm populations isolated by Felix™ & DGC in
- terms of processing time, sperm concentration, motility, vitality, & DNA integrity as assessed by three methods: SCSA, Halo, & TUNEL.
- Paper concluded: "Felix™ is a positive technical development capable of isolating suspensions of highly motile spermatozoa exhibiting low levels of DNA damage in a fraction of the time taken by conventional procedures such as DGC".

1 A "sperm fraction" is the sperm that is separated from the original amount of sperm

2 The team comprised Farnaz Shapouri, Tara Mahendran, Mirudhubashini Govindarajan, Philip Xie, Olena Kocur, Gianpiero D. Palermo, Hassan W. Bakos, Aisling Ahlström, Gunilla Caisander, Bo Xu, Shun Bai, Sarah Lambourne R John Aitken. John



Pathway to market CY 2023 – 2025



PRELIMINARY ESTIMATED DATES IN EARLY TARGET MARKETS

Country	Completion of clinical trials for local regulatory filings	Felix™ regulatory clearance
JAPAN	Not required for regulatory filings ¹	Not required – able to sell in Japan ¹
INDIA	Q1 CY2024	Q2 CY 2024
CHINA	Q4 CY 2023 (if 'fast track' cleared – April 23)	Q2 CY2024 (if 'fast track' cleared – April 23)

CLINICAL TRIALS, EARLY SALES & REGULATORY FILING PLANS

- 1. China (in collaboration with MEM's Chinese partner, Diagens Biotechnology)
 - Submitted application for 'fast track' clearance
 - Establish local clinical trials for regulatory filing

2. India

- Make regulatory filing & seek regulatory clearance
- Commence manufacturing Felix[™] in India for local market
 - Potential to significantly reduce costs & expedite access to market

3. Australia, EU & US

- File results of MVF clinical study with AU & EU regulators
 - Regulatory approval enables commercial sale of Felix™ in Australia & EU
 - Supports Felix™ registration in other jurisdictions ie Asia Pacific, Middle East
- Plan clinical trials in US based on FDA's pre-submission meeting feedback; FDA approval enables commercial sale of Felix™ in US

EARLY SALES & MARKET LAUNCHES

- 1. Continue to build Felix[™] profile
 - Increased industry speaker engagements & trade show participation
 - Ongoing publishing of papers & market updates on Felix[™] trial results
- 2. Make direct sales to KOLs in early markets
- 3. In high reg markets, make direct sales to KOLs once regulatory clearance received
- 4. Appoint distributors to accelerate sales using these KOL seed sites



ROSA (Rapid Oxidative Stress Assay)

Rapid, sensitive, accurate and novel point-of-care diagnostic test to measure oxidative stress

OXIDATIVE STRESS IS A SERIOUS IMBALANCE BETWEEN REACTIVE OXYGEN SPECIES & ANTIOXIDANT PROTECTION WITHIN THE BODY. THE IMBALANCE INCREASES WITH AGE AND IS A MAJOR UNDERLYING FACTOR IN MANY CHRONIC ILLNESSES AND SERIOUS DISEASES.





ROSA (Rapid Oxidative Stress Assay)

Addresses diagnostic void in global fertility market

OXIDATIVE STRESS IS A MAJOR CONTRIBUTOR TO HUMAN INFERTILITY

- A known pre-cursor to sperm DNA damage, a leading cause of male infertility
- Major contributor to lack of conception, still births, recurrent pregnancy loss, pre-term labour & birth, sudden newborn death & miscarriage
- ⁻ Linked to pre-eclampsia & placental failure during pregnancy

MARKET OPPORTUNITY

SHORT-TERM FOCUS

1 Reproductive science research market

- Make ROSA available for researchers
- Enables improved, cost effective, rapid & accurate assay for researchers to study effects of oxidative stress ie on placenta, foetal death, pre-eclampsia, infertility etc
- No regulatory hurdles: shortest 'pathway to market'

MEDIUM TO LONGER-TERM FOCUS

2 Human fertility clinical market

- Class 2 IVD (In Vitro Diagnostic) classification for human application
 Must clear stringent regulatory requirements prior to sale for human use
- Male & female fertility testing & monitoring of pregnant women
 - For fertility assessments at IVF clinics & GP/urologist/ obstetrician facilities
 - For clinicians to assess & monitor risks during pregnancy & make early interventions

Potential broader / long-term market opportunities as diagnostic to assess & monitor

- Human
- Serious inflammatory conditions & diseases
- Appropriate anti-oxidant dosage to deter toxic user over-dosing in the more than A\$4.7 billion² global antioxidant supplements therapy market
- Animal
 - Pregnant mares & stud stallions throughout mating season
 - Wellness preparedness checks for performance horses
- Source: NIH Clinical Intervention in Aging, 2018; 13: 757-772. Oxidative stress, aging and diseases (2020 data) NIH website
- 2 Market size estimated by: number IVF cycles in each market pa; X by average number of cycles used; X by ROSA's likely use during a cycle; X by anticipated price per test





ROSA (Rapid Oxidative Stress Assay)

Pathway to market CY 2023 – 2025 (indicative)



EPRODUCTIVE BIOTECHNOLOG

AI-Port

Potential to revolutionise storage & transport of bull semen at ambient temperature to improve bovine pregnancy rates

AI-PORT AIMS TO SUBSTANTIALLY IMPROVE PREGNANCY RATES WITH EASIER-TO-USE TECHNOLOGY



PROCESS

Sample collected

Al-Port is used in the



field or breeding centre to isolate motile sperm (plus could provide a rapid sperm assay)



Motile sperm is loaded in straws with MEM proprietary longlife media



Al is performed at user site using fresh AI-Port straws

Al-Port

The AI-Port System combines the use of a proprietary sperm separation system with a novel medium

Fresh bull semen is collected in the field and processed through AI-Port

The harvested sperm is stored / shipped at ambient temperature for up to 3-4 days for use in AI procedures at user sites

- Using fresh semen results in up to a 20% improvement in pregnancy rates compared to use of frozen semen
- Industry sources have stated a 5% increased pregnancy rate would make a substantial positive difference¹
- AI-Port has potential to significantly improve rate of genetic gain in the herd

CURRENT AI PREGNANCY RATES OF 40% OR LESS ARE COMMON FOLLOWING A SINGLE AI DOSE

CURRENT PRACTICE VERSUS

Bull semen samples are generally frozen to extend shelf-life for long-distance transport & to allow insemination in remote locations

- Freezing semen causes significant damage to sperm cells
- only 40-50% of sperm survive which can decrease pregnancy rates
- Lower fertility rates are costly for farmers, especially those dependent on replenishing stock numbers

Chilled semen with extender medium is an alternative to freezing but has major limitations and is therefore not commonly used

- Must be used within 24 36 hours of semen collection
- Technically challenging



Sample collected







Addition of semen extender, chilling at 4°C overnight



Straws loaded with diluted semen and frozen in liquid nitrogen



Al performed using thawed straws



Al-Port

Potential to disrupt a substantial international market

AI USED EXTENSIVELY & INCREASINGLY IN ANIMAL BREEDING GLOBALLY

- AI provides substantial economic & animal welfare benefits
 - Fastest way to improve genetic gain across cattle herds
 - Introduces heritable traits without transporting live animals
- Value of global animal artificial insemination market in 2022 estimated at A\$6.1 billion¹

GLOBAL ANIMAL AI REVENUE EXPECTED TO RISE 6.5% pa BY 2030 TO MORE THAN A\$10.3 BILLION $^{\rm 1}$

BOVINE GLOBAL AI ANIMAL MARKET

- Dairy bovine is the largest AI market & is a high volume, commodity
 - Used by more than 90% of market
- Beef bovine (non-dairy) AI is used by less than 15% of market in Australia, however addressable global market size is nearly A\$2.4 billion¹
 - Brazil leads market using nearly 22 million¹ doses per annum
 - Al in beef bovine is used at the top end of the market where high prices are paid for elite genetics ie wagyu beef
- Opportunity also exists for niche elite dairy cattle breeding using AI at ambient temperature





¹ Extracted from multiple sources: Grandview Research – Veterinary AI Market Size, share and trends, analysis report by animal type – 2017 – 2030 - <u>https://www.grandviewresearch.com/industry-analysis/veterinary-artificial-insemination-market;</u> United States Department of Agriculture – Foreign Agricultural Service 2021 (Report No: BR2021-0010); "World Statistics for Artificial Insemination in Cattle; Statista – "Capturing the Value of Artificial Insemination in Commercial Herds"; "Artificial Insemination – Current & Future Trends"

² As percentage of global total doses

AI-Port Pathway to market 2023 – 2025 (indicative)

VERFICATION & VALIDATION

- 1. Al-Port prototype & medium ready for April field trial
 - AI-Port to undergo ongoing optimisation & will require scale up to process 10 30 ml of extended semen (current prototype processes 1 ml)
- 2. Recruit KOLs from elite Australian beef bovine stud farms (done)
- 3. Commence AI trials in commercial beef herds in Upper Hunter region (initial trial in April 2023)

GO-TO-MARKET PRODUCT

1. Subject to successful field trial, develop 'Go-to-Market' product

CLINICAL TRIALS, EARLY SALES & REGULATORY FILINGS

- 1. Commence clinical trials with 'Go-to-Market' product (projected for 2Q CY 2023)
- 2. Provide clinical data required for product registrations & regulatory filings with APVMA (Australian Pesticides & Veterinary Medicines Authority) in Australia

POTENTIAL MARKET LAUNCH

- 1. Australia (projected for (projected for 4Q CY 2023 /1Q CY 2024)
- 2. Early target markets ie NZ, Brazil & Argentina (projected for 4Q CY 2023 /1Q CY 2024)
- 3. Other developed markets ie US, Japan & EU (projected for 1Q CY 2024)





CORPORATE

Board & Executive Team

BOARD





Alison Coutts

Managing Director

& CEO

Robert Cooke Non-Executive Chairman

Et.



Paul Wright Non-Executive Director

Andrew Goodall Non-Executive Director

BALANCED MATRIX OF SKILLS / EXPERIENCE

STRATEGY

- Highly-strategic & results-focused approach
- Strong entrepreneurial skills in building high-growth, technology-based businesses

LEADERSHIP

- Executive leadership of publicly-listed / privatelyowned healthcare companies
- Leadership in development, manufacturing & marketing of novel medical devices & diagnostic instruments

RESEARCH & DEVELOPMENT

- Acknowledged global leadership in reproductive biotechnology
- John Aitken ranked world #1 in cell biology of spermatozoa & germ cells¹

BUSINESS DEVELOPMENT & COMMERCIALISATION

- Established track record in medical technology industry
- Specialised in commercialisation process & hands on 'go-to-market' experience
- Extensive regulatory expertise

EXECUTIVE TEAM





John Aitken Laureate Professor & Director Research

Pablo Neyertz Director Finance





David Ali Director Business Development

li Hassan Bakos iness Director ent Operations²



Tony Poulson Clinical Trials &

KOL Management



Ross Harricks Product Development



2 Appointment effective 24 April 2023



APPENDIX



better technology, more life





Felix[™] PATENTS & TRADEMARKS

PATENTS

MEMPHASYS REFERENCE	APPLICANT	COUNTRY	TITLE	CASE STATUS	EXPIRY
Cell Separation	Memphasys Limited	US	Cell Separation	Granted (3 Jan 2012)	14-Jul-26
Electrophoresis Separation (CN)	Memphasys Limited	China	Electrophoresis Device	Granted (30 Aug 2022)	20-Oct-37
Electrophoresis Separation (JP)	Memphasys Limited	Japan	Electrophoresis Device	Granted (30 Jun 2022)	20-Oct-37
Electrophoresis Separation (US)	Memphasys Limited	US	Electrophoresis Device	Granted (11 Oct 2022)	09-Jul-38
Electrophoresis Sperm Separation (CN)	Memphasys Limited	China	Sperm separation by electrophoresis	Granted (24 Aug 2021)	20-Oct-37
Electrophoresis Sperm Separation (JP)	Memphasys Limited	Japan	Sperm separation by electrophoresis	Granted (13 Apr 2022)	20-Oct-37
Electrophoresis Sperm Separation (US)	Memphasys Limited	US	Sperm separation by electrophoresis	Granted (16 Mar 2021)	20-Oct-37
Membrane (US)	Memphasys Limited	US	Biocompatible Polymeric Membranes	Granted (30 Mar 2021)	15-Aug-37
Newcastle Uni (AU)	The University of Newcastle Research	Australia	Sperm cell separation by	Granted (20 Sep 2007)	07-Oct-24
	Associates Limited ¹		electrophoresis		
Newcastle Uni (UK)	The University of Newcastle Research	UK	Sperm cell separation by	Granted (4 Mar 2009)	07-Oct-24
	Associates Limited ¹		electrophoresis		
Newcastle Uni (US)	The University of Newcastle Research	US	Sperm cell separation by	Granted (28 Feb 2012)	01-Feb-27
	Associates Limited ¹		electrophoresis		

TRADEMARKS

The Felix™ System trademark is registered in Australia, United States, United Kingdom, European Union, India, Japan and Canada

¹ MEM has sole & irrevocable, perpetual license for commercial use of patent under its core 2016 licensing agreement with the UoN under which it pays a small royalty to the University on net sales.



Felix™ How it works



ALLOWS ION TRANSFER BUT BLOCKS SPERM PASSAGE

MATURE, NEGATIVELY CHARGED SPERM HARVESTED AFTER 6 MINS



AI-Port

In vitro tests at UoN indicate AI-Port could greatly improve current practice



