

NuSep

(ASX: NSP)

Transforming IVF



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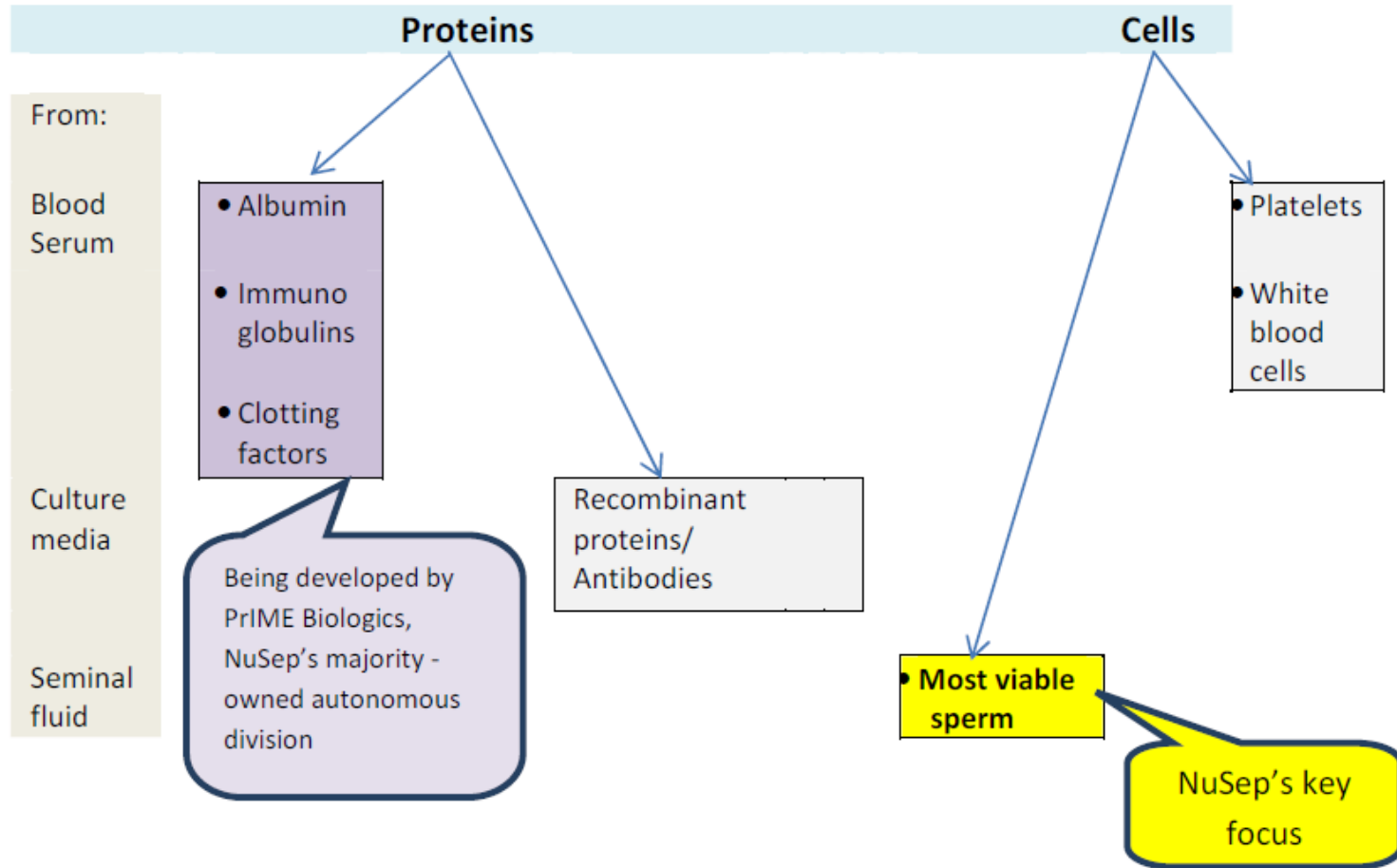
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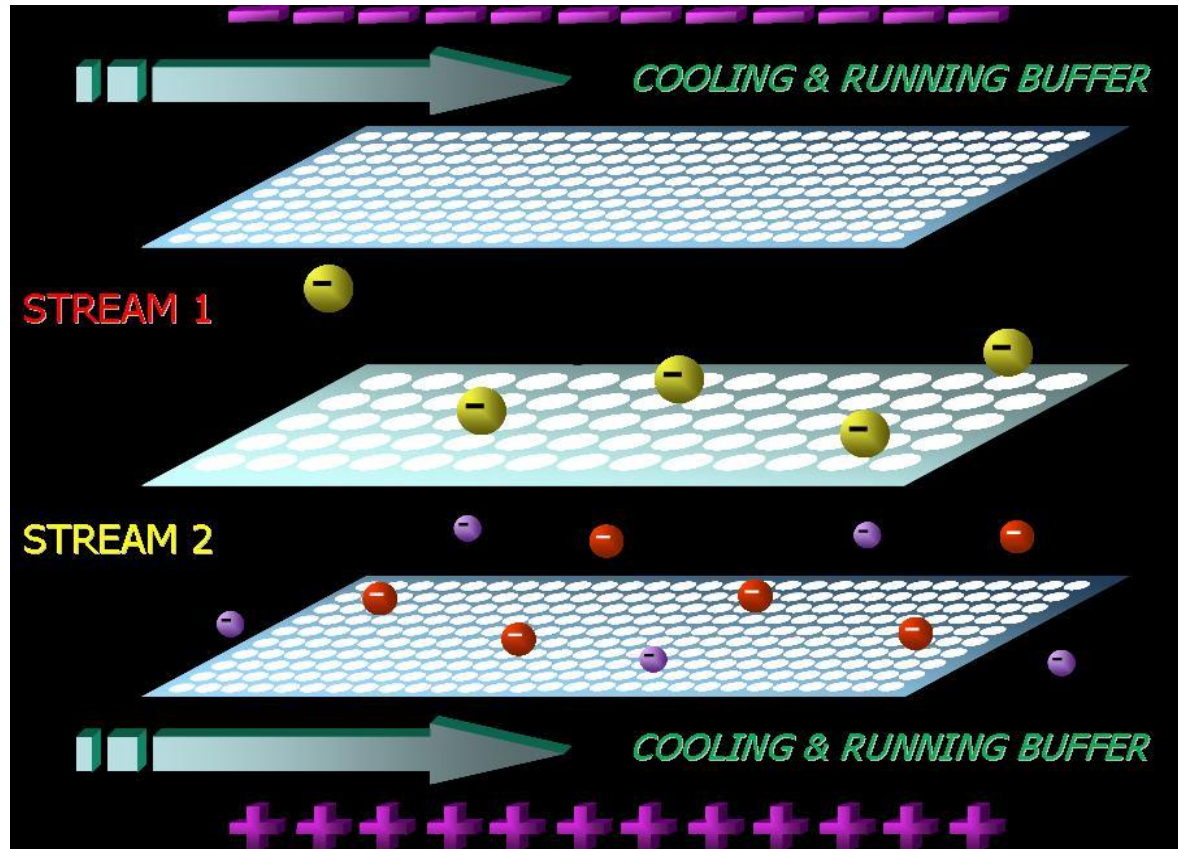
What Does NuSep Do?

- Utilises proprietary polymer-based membranes and an electric field (electrophoresis) for separating high value biological substances from fluids.
- Our technology can separate large molecules such as proteins, whole organisms such as viruses and individual cells such as spermatozoa.
- Now commercialising the technology, which has been proven to work.
- Most advanced application, for spermatozoa (SpermSep), has potential use in human IVF and in IVF and Artificial Insemination in animals.
 - 1st commercial product, for animal fertility, is in clinical trials
 - Next product will be validated in further human IVF *in-vitro* trials starting in the new year
- Also developing new membranes and animal fertility diagnostics.

NuSep technology can separate an array of high value biological entities



Separates By Size & Charge



NuSep charge and size based separation

Why Is NuSep Technology Unique?

To our knowledge, no other group:

- has a **proven** method for separating cells, viruses and proteins.
- can provide **commercial quantities** of product using a **combination of membranes** (for size separation) and **electrophoresis** (for charge separation).

NuSep Advantages By Application

Application	Current Methodology	NuSep's Technological Advantages			
		Cheaper	Faster	Easier	Other
IVF (human & animal)	Density gradient centrifugation (DGC)	✓	✓	✓	• Less damage to sperm • Selects most viable sperm
Plasma fractionation	Concentration/fractionation + chromatography	✓	✓		• More flexible: can process 10 – 10,000 litres. • Higher yield & purity, hence less chromatography steps required
Recombinant protein purification		✓	✓		

Commercialising The Technology

- NuSep has developed multiple devices for specific separation applications.



Pilot scale GF100



CS10



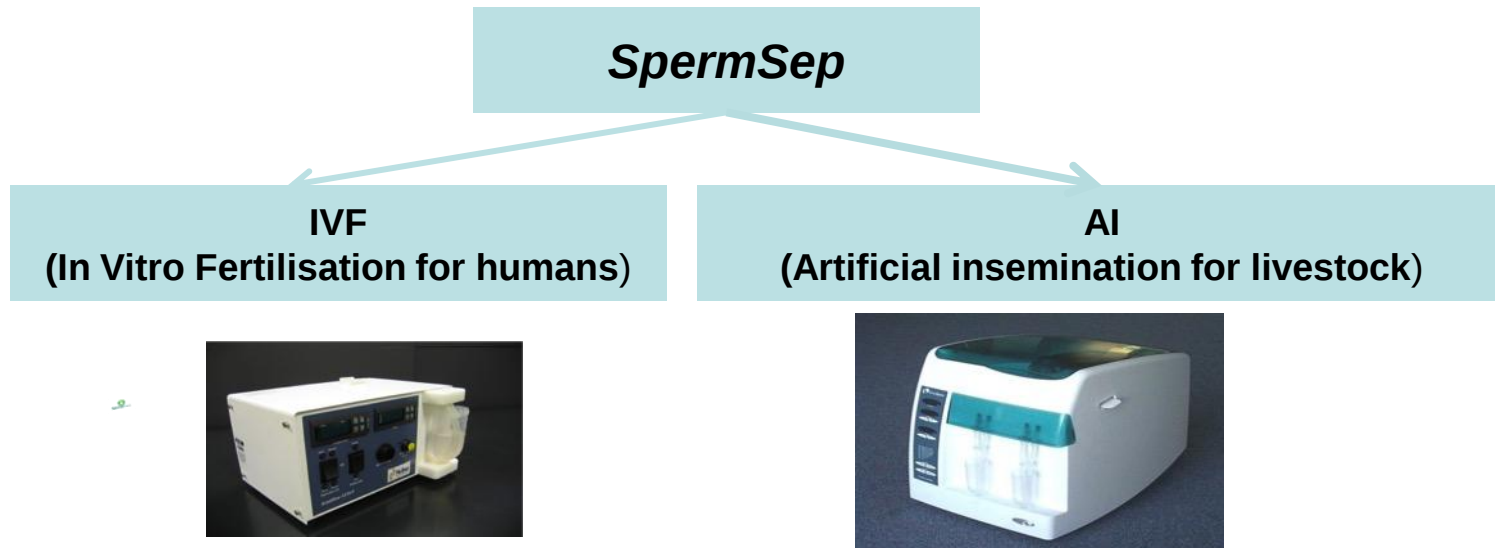
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Medium Term Strategic Focus

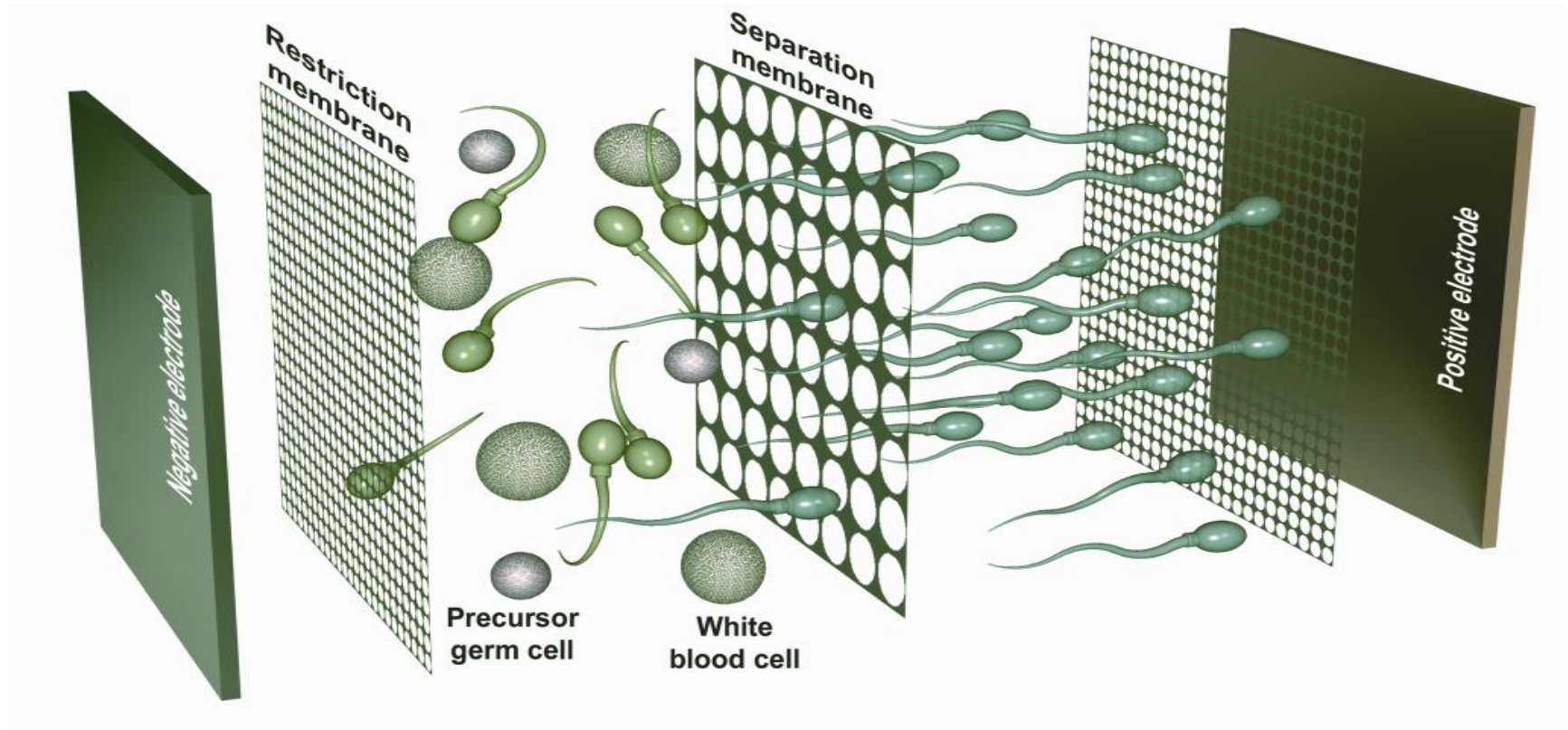
SpermSep

What Is SpermSep?

- SpermSep is a NuSep business working in Assisted Reproduction Technologies (ART).
- It selects samples of the healthiest, most viable sperm cells from semen samples.
- SpermSep services both the human IVF and the animal ART sectors.



How SpermSep Works



SpermSep Addresses Current Problems

- **Current IVF and AI sperm selection methods involve two damaging steps to the sperm cells:**
 - centrifugation - applies damaging shear forces;
 - culturing in a media containing trace heavy metals, particularly copper - leads to oxidative damage to DNA
- **DNA-damage to the sperm cells increases the risk of**
 - infertility
 - birth defects
 - cancers and neurological diseases developing later

SpermSep Benefits

- ✓ **Addresses the increasing problem of male infertility**
 - Male infertility is a factor in more than 45% of infertile couples
 - Quality, rather than quantity, of sperm is the key issue
- ✓ **Highly selective of healthy sperm**
 - Highly negatively charged, highly motile healthy sperm swim fast to the anode through the separation membrane and separate from the less viable sperm
- ✓ **Far less damaging on sperm**
 - Sperm produced from our technology have significantly less DNA damage than sperm provided from current techniques (DGC)
- ✓ **Cheaper & quicker to process semen sample and collect best sperm for IVF/ICSI**
- ✓ **More convenient**
 - Disposable processing cartridges, less labour intensive

SpermSep For Animal AI Market Needs

- SpermSep has the same IVF advantages in the small but growing animal IVF market.
- Applications in high-volume routine animal AI are being researched with our Animal AI development partner, the world's biggest supplier of animal AI products.
- High throughput, less complex, more robust processes, with cheaper equipment and consumables, are required.
- SpermSep's technology meets these needs:
 - decreased DNA damage
 - greater likelihood of successful insemination, healthy births, true progeny genetics
 - reduced cost
 - simplicity of use

Human Assisted Reproduction Technology (ART) Market

- **Dominant technologies:**
 - IVF and ICSI (single sperm for single egg)
 - ICSI is overtaking IVF as preferred method
 - Male fertility is driven by quality not quantity of sperm
- **Size of human ART market:**
 - ~1.5 million ART cycles/yr worldwide
 - ~ 350,000 ART babies born /yr in > 3,000 ART clinics w'wide
 - Europe has largest activity; Asia has strongest growth
- **Sales:**
 - ART sales ~\$US3bn in US, \$A170m in Australia
 - ART consumables sales were ~\$223m in 2011
 - ~90% of ART consumables market is divided among a few companies for both human and veterinary sectors.

Animal Assisted Reproduction Technology (ART) Market

- **Artificial insemination (AI) dominates (sperm directly inserted into uterus)**
 - IVF only used for very high value animals
- **USA:**
 - ~ 66% of the nation's dairy cows are bred by AI
 - 70-75% of commercial swine production is from AI
- **EU:**
 - ~90% of pigs and dairy cows are produced by AI
- **Horses**
 - AI & IVF is illegal with thoroughbreds for the racing industry; must use live stallions
 - Extensive AI/IVF is used for other types of horses
- **Regional and niche AI markets exist**
 - goats, camels, zoos, etc

Current Status of SpermSep

- Research SpermSep devices for human and animal use developed and in use.
- Human IVF benefits of SpermSep demonstrated:
 - Separates the most viable sperm with least DNA genetic damage (Newcastle Uni evaluation program & publications)
 - Multi-centre clinical trial at 3 leading IVF centres in Australia beginning Jan 15 to broaden indications for use.
- Animal AI benefits being documented in trials at Newcastle University and in Germany.
- Development of 2nd-generation production systems for human clinical and animal production use to commence on completion of fund raising.

SpermSep 3 Year Plan



- Complete Stage 1 veterinary clinical trials (late-Yr1)
- Complete 3-site Stage 2 human clinical trials (end-Yr1)

- Develop human prodn system; instrument & cartridges (mid-Yr2)
- Start international human IVF research market roll-out (mid-Yr2) and revenue
- International veterinary market launch (late-Yr2)
- Complete regulatory approvals for human IVF (late-Yr2)
- Clinical market launch for human IVF (start Yr2-3)

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Next Steps for SpermSep

	Human IVF	Animal IVF and AI
Next Studies	Capture data from 3 leading IVF centres – extending indications for use	Demonstration studies on horses with Uni of Newcastle & in Germany (bulls)
Aim	• Conduct multiple clinical validation studies in leading IVF clinics • Increase key opinion leader support	• Demonstrate advantages of SpermSep technology in stallions & bulls • Move to other livestock later
Anticipated cost	Estimated total investment to SpermSep cash flow breakeven is approximately \$7 million	

Summary

- **NuSep has unique proprietary technology in the biological separations market**
 - Already commercialised areas of the technology
- **Medium term focus on SpermSep**
 - Entering clinical trials
 - Large global market
 - International distribution agreements in place (AI)
- **Seeking Capital**
 - Funding of clinical trials