



**ASX Release**

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**NUSEP INVESTOR PRESENTATION**

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*Sydney, Tuesday 11 August 2015*

NuSep Holdings Limited (**ASX:NSP, Company or Nusep**) is providing an updated investor presentation focussing on its SpermSep business and with details on the clinical trial being undertaken at Monash IVF.

An article about NuSep was recently published in Forge Magazine. A copy of the article is available on the Company's website through the link:

<http://www.nusep.com.au/ressources/fichiers/b744c5b2d9e8.pdf>

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# **Transforming IVF and Biological Separations**



**Presentation by Executive Chairman Alison Coutts  
August 2015**

# NuSep (ASX:NSP) key facts

|                            |  |
|----------------------------|--|
| <b>No. shares</b>          | 237,606,002  |
| <b>Market Cap.</b>         | \$7.1 million (@3 cps)   |
| <b>No. of shareholders</b> | Approx. 900  |
| <b>Top holdings</b>        | <ul style="list-style-type: none"> <li>• Top : 38.9%*</li> <li>• Top 5: 45.7%</li> </ul> |



# Why Invest In NuSep?

- **NuSep has unique proprietary technology in biological separations**
  - Proven to work
  - Two current applications: human plasma (through investment in PrIME, which is externally funded) and sperm separation
  - Multiple unique benefits over incumbent technology
- **SpermSep**
  - Entered human IVF *in-vitro* clinical trial with Monash IVF
  - Planning animal IVF clinical trials with our animal fertility collaborator, MiniTube in Germany
  - Large, fast-growing global market
  - Close to having a commercial device for sale
  - Relatively small funding required
- **Capital is required for: -**
  - Funding of multi-centre clinical trials
  - Development and market launch of production SpermSep system
  - New membrane development

# NuSep's Unique Technology

To our knowledge, no other company has

- a **proven proprietary** method for separating cells\* (eg sperm cells)
- using a **membrane** that can precisely control pore size (for size separation)
- that can be combined with **electrophoresis technology** (for charge separation)
- in a way that can be scaled up to provide **commercial quantities** of product.

NuSep's majority-owned investment, PrIME Biologics Pte Ltd, is focused on separating proteins from human blood plasma using the same core technology developed by NuSep

# Human IVF

# Male Infertility

## A factor in nearly 50% of human IVF cases

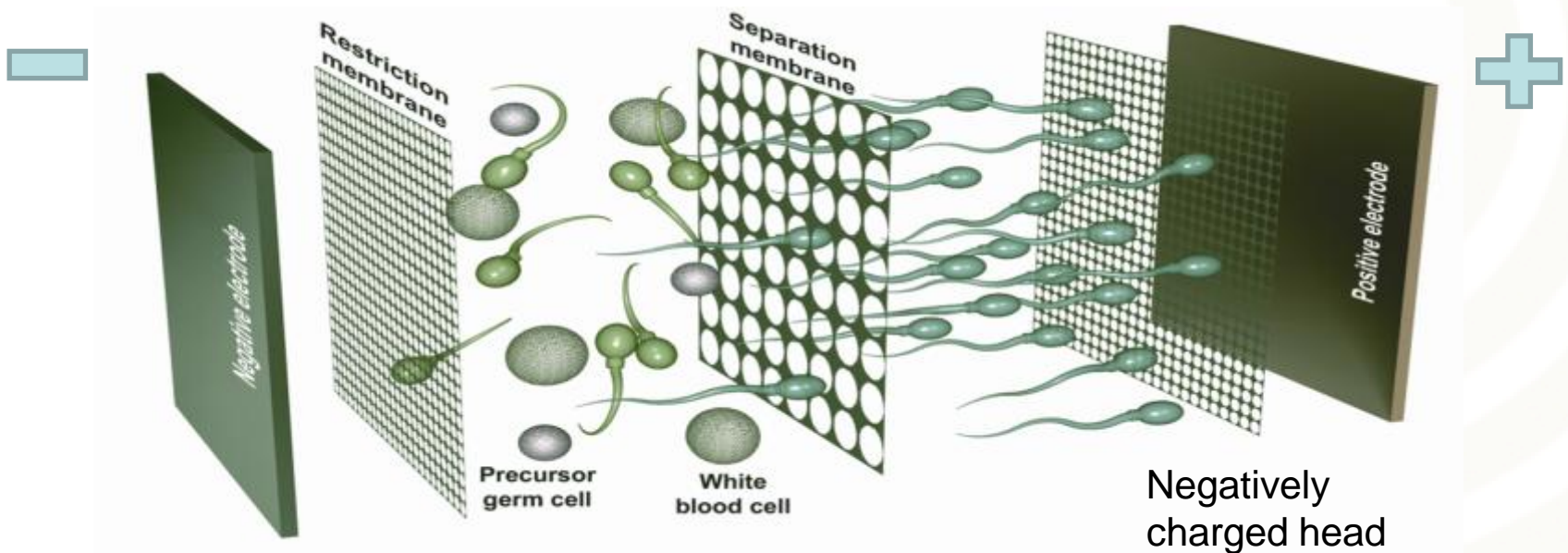
- highly prevalent
- increasing for the past few decades
  - Environmental and lifestyle factors?
- a factor in > 45% of infertile couples
- affects ~1/3 of men over 40
- strongly linked with chronic disease eg cardiovascular disease & diabetes

**Sperm **quality**, rather than **quantity**, is the issue**

# We Separate the Best Sperm

... by size ( with our membranes) & charge ( using electric field)

- The best sperm have a negative charge



# A Large and Expanding Human IVF Market

|  |                           |  |
|--|---------------------------|--|
| <b>Couples with fertility issues:</b> ~50m             |                           | Australian couples seeking IVF:<br>1 in 6**  |
| <b>Global IVF clinic business:</b>                     |                           |  |
| Cycles/year  | ~15 m                     | 570K in Australia (2010)   |
| IVF babies/year  | ~350,000                  | 10,500 in Australia (2010)   |
| Numbers of IVF clinics                                 | ~3,000                    | Australia: Dominated by 5-6 companies<br>EU is largest market<br>Asia is fastest growing |
| <b>IVF market size:</b><br>- 2012<br>- 2020 (forecast) | US\$ 9.3 b<br>US \$21.6 b | Australia: AUD\$470m   |
| <b>Cost to patient per cycle</b>                       | ~US\$1.5K<br>~US\$30K     | India<br>USA   |

Sources: Vitrolife 2013 Annual Report, Cooper/Origio investor Report, Jun 2012

\*\* Industry interviews

# DNA Damage

## Caused by most common sperm preparation methods

- **Birth defects** are about **double in IVF** compared with conventional conception.
- **Density Gradient Centrifuge (DGC)** is most common IVF method & involves two damaging steps for sperm cells.

- |                            |   |
|----------------------------|---|
| 1. <b>Centrifuging</b>     | Spinning creates damaging shear forces  |
| 2. <b>Separation media</b> | Oxidative damage arises as the separation media - contains trace heavy metals, including copper |



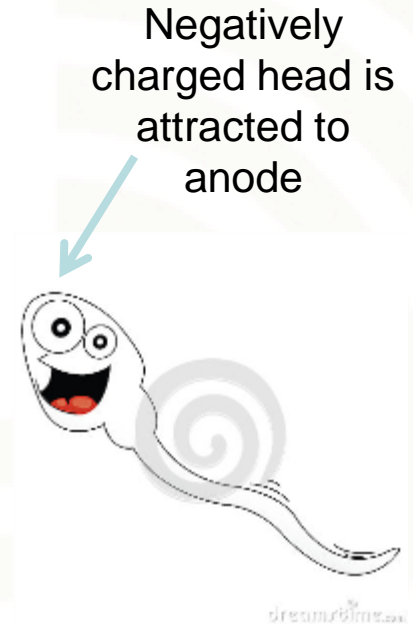
Increased risk:

- Infertility
- Premature birth/ birth defects
- Later onset of disease & disability eg cancers, deafness, mental illness, metabolic diseases, immunity issues etc

» Swim-up method also damages DNA

# Spermsep Commercial Solution to Key Male Infertility Issues

- **Highly selective of healthy sperm**
  - The highly negatively charged sperm are the 'healthier'
  - First to reach the (positive) anode through the separation membrane, leaving the less viable sperm behind
- **Far less damaging for sperm**
  - Sperm from our technology have significantly less DNA damage than from DGC method
- **Cheaper, quicker, more convenient process**
  - Automated instrument
  - disposable processing cartridges
  - quick (5 mins/sample vs 40 mins/sample),
  - much less manual lab tech time



# SpermSep Clinical Trial Programs: Human IVF

- Already has resulted in 4 live, normal births at Sydney IVF and Westmead Hospital in 2006/7
- The Company's focus changed to plasma separation over the intervening years until the plasma business was spun out as PRIME Biololgics Pte Ltd in mid 2014
- Under a new board and management, the company's strategic direction was refocussed on SpermSep,
- *In-vitro* trials at the first clinical centre, Monash IVF, have just started, under the leadership of Prof John Aitken, Uni Newcastle,
- Prof Aitken was responsible for originally proving that NuSep's core technology could successfully process sperm samples
- There is no cost to NuSep, apart from supplying the machine and consumables
- Expected duration of the trial: 6 months



# SpermSep Human *in-vitro* Clinical Trial protocol

- To determine how well the SpermSep device can isolate sperm from three challenging sources where viable sperm recovery is difficult: -
  - From a biopsy from the testes and epididymis
  - From cryo-stored (frozen) ejaculates;
  - From seriously compromised samples with very low sperm count.
- Sperm number, motility (ability to swim) and DNA damage analysis on snap frozen material will be analysed against conventional sperm preparation methods.
- The SpermSep device's efficiency in handling multiple samples in a busy clinical setting will also be analysed
  - Processing improvements in busy clinics, typically handling 20 samples a day, are becoming increasingly important
  - The present sperm preparation methods require time consuming laboratory steps including multiple washings and centrifuging.
  - Previous tests have shown that the SpermSep device can separate viable sperm from a sample in less than five minutes against the current methods of around 30 minutes.

# **Animal IVF and AI (Artificial Insemination)**



# Animal Artificial Reproduction

## A Large Market

- **Artificial insemination\* (AI) dominates the assisted animal reproduction market**
  - USA
    - ~90 %of the nation's dairy cows
    - 70-75% of commercial swine production
  - Europe
    - ~90% of pigs and dairy cows
  - AI in other species
    - Non-thoroughbred horses (AI is illegal with thoroughbreds for racing)
    - Goats, camels, zoos, greyhounds, endangered species, etc
    - **Although still niche, IVF is rapidly gaining traction**
    - NuSep is initially concentrating on animal IVF as it is high margin and well suited to NuSep's technology

# SpermSep Will Focus on Reproduction in Elite Animals and Where Sperm Quality is an Issue

- SpermSep is being trialled in cows with partner MiniTube Germany and equine work is continuing with University of Newcastle
- MiniTube are the largest provider of AI equipment globally and also undertake preeminent research in Animal Reproduction

|     |  <b>Cow IVF</b>  |  <b>Horse IVF</b>   |
|-----|---|--|
| Aim | <ul style="list-style-type: none"><li>▪ Provide a new method of preparing frozen bovine semen</li><li>▪ Implant multiple embryos in “foster” cows to produce multiple births (not the usual one per year)</li></ul> | <ul style="list-style-type: none"><li>• Improve ability to rapidly separate the most viable sperm*</li><li>• To successfully implant embryos with high quality sperm</li></ul> |

\*equine semen is poor as it has not been traditionally selected for reproduction quality.

# Membrane Separation Technologies

- New polymer membranes are being developed which have the potential to replace present polyacrylamide membranes
- It would have major advantages in bio-compatibility, raw material cost, sterilisation ability and scale up
- It could have wide application across the bio-separation industry

# PrIME

- Independent Singapore-based investment spun out of NuSep in mid 2014
- NuSep presently holds 68% in B class shares and is attempting to sell those shares to fund its other operations
- Has a production facility in Singapore and is seeking cGMP accreditation
- Is using the core NuSep technology to separate immunoglobulins and albumin from blood plasma in partnership with G. E. Healthcare
- Technology has been proven at bench scale to work using NuSep's device and membranes

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