

NuSep Holdings Limited

(ASX: NSP)

Bioseparation Specialists



28 May 2014

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NuSep Corporate Statistics

- Number of shares on issue: **171,259,376**
- Market Capitalisation: **\$13.4 million** (@ 7.8 cents per share)
- No. of shareholders: **935**
- Top 5 holdings: **32%**
- Top 20 holdings: **64%**

Share Price/Liquidity last 6 months



Biological Separations from NuSep's Technology

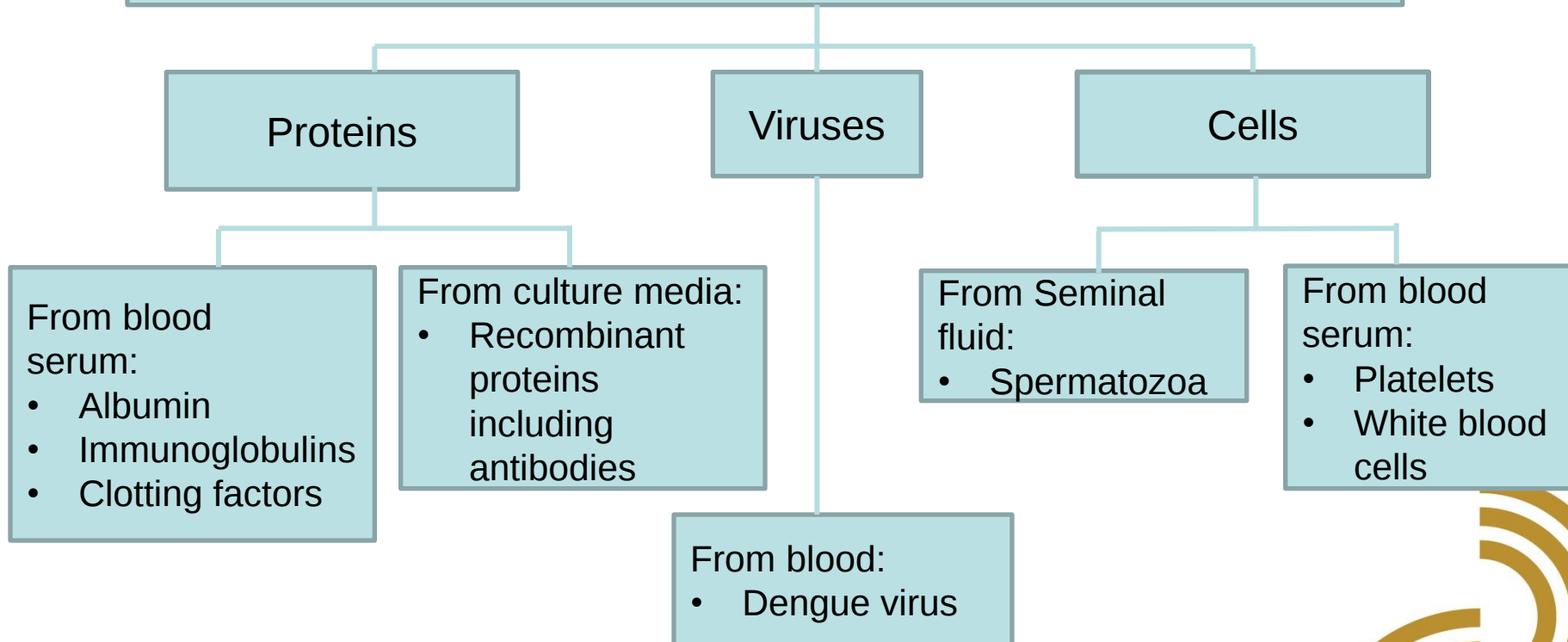
- NuSep has developed a unique technology for biological separations called PrIME *
- It utilises proprietary polymer-based membranes and the application of an electric field (electrophoresis)
- It can separate large molecules such as proteins from blood plasma
- It can also separate viruses and even individual cells such as spermatozoa

*PrIME = “Preparative Isolation by Membrane Electrophoresis”

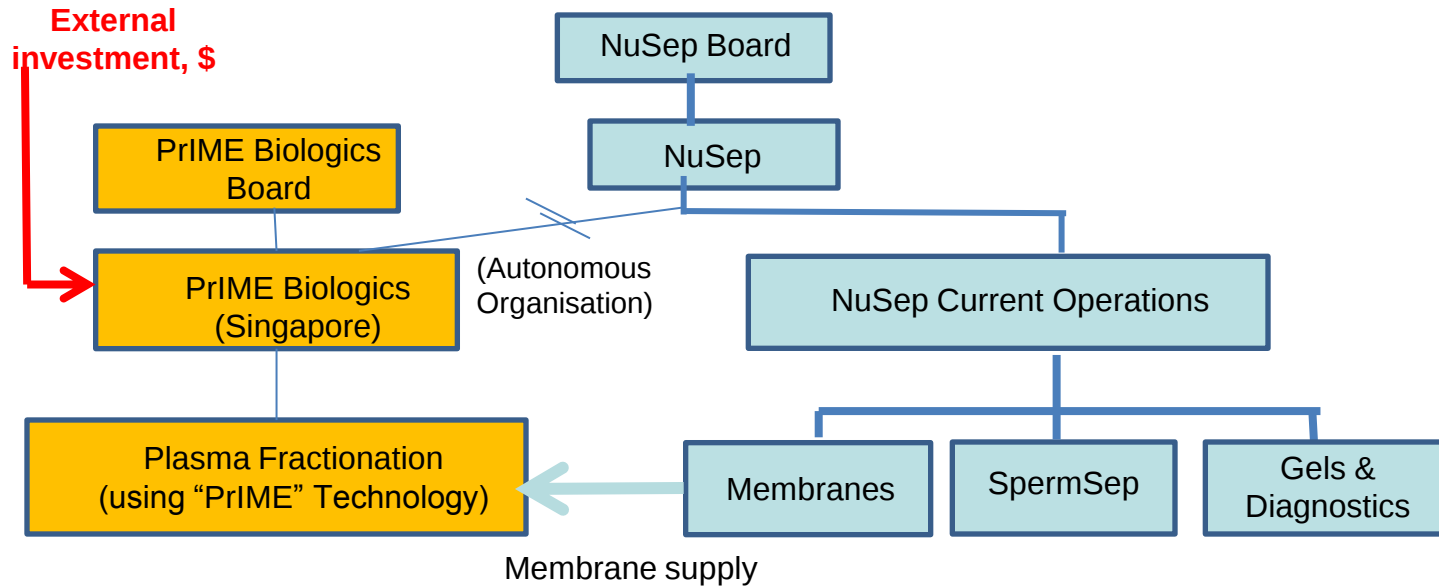


NuSep can separate a wide variety of biological entities

Examples of Biological Separations using NSP's technology

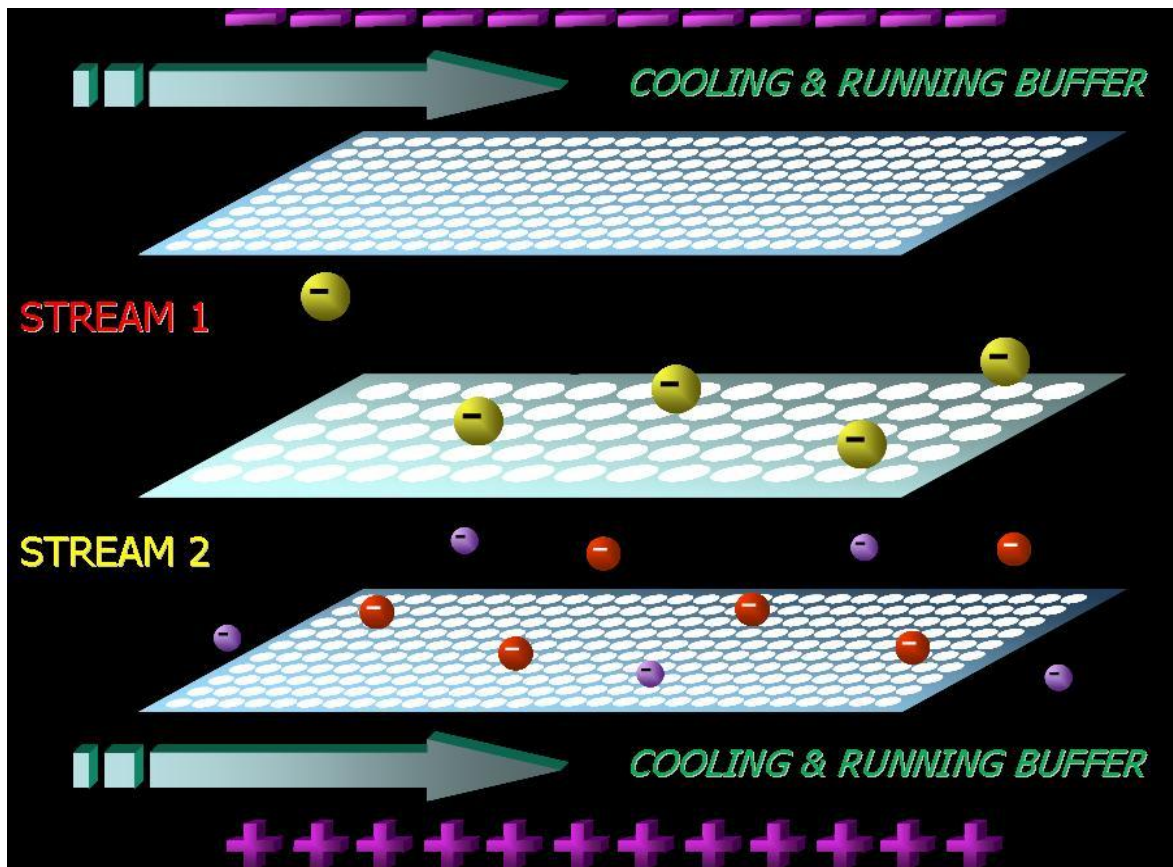


NuSep Organisation



Note: PrIME Biologics is the autonomous NuSep Subsidiary whereas "PrIME" is the name of NuSep's proprietary technology.

The PrIME Technology: separates by size and charge

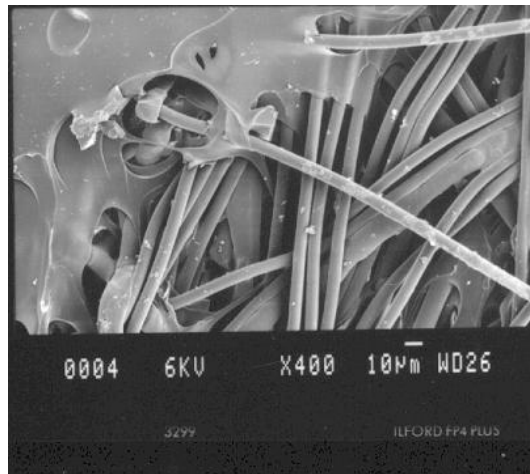


PrIME charge and size based separation



NuSep's Proprietary Membranes

- NuSep will sell its proprietary membranes and other equipment and consumables for plasma fractionation to PRIME
- NuSep will make initial batches of membranes using current practices but will also scale up and automate the process over time



Nusep's Proprietary Membrane: Interior Cross Section (x400)



NuSep has developed multiple devices for specific separation applications



BF400



CS10



Pilot scale GF100



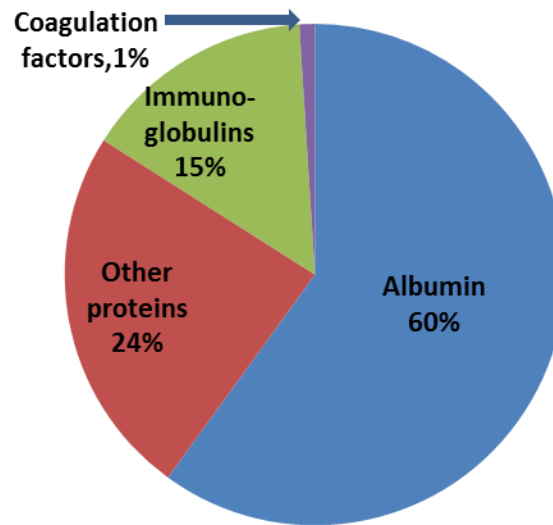
Advantages of PrIME technology over chromatography in plasma fractionation

- **Substantially cheaper**
 - has very low maintenance costs due to disposable cartridges which decrease the potential for viral contamination
 - processes in one rather than two steps yet provides 95% end product purity
 - requires minimal capital investment for scale up
- **Quicker**
 - takes hours rather than days
- **More flexible and easy to use**
 - Cartridges are stackable and can process from 10 to 10,000 litres
 - Modular components enable rapid expansion and addition to other process equipment
 - Small space requirement



Prevalence and Uses of Plasma Proteins

Prevalence of proteins in plasma



Common uses of plasma proteins

Protein	Common uses
Albumin	Shock, burns, respiratory distress syndrome, cardiopulmonary bypass surgery
IVIG	Primary immunodeficiency diseases, autoimmune diseases
Coagulation factors	Bleeding disorders, haemophilia A&B, von Willebrand disease

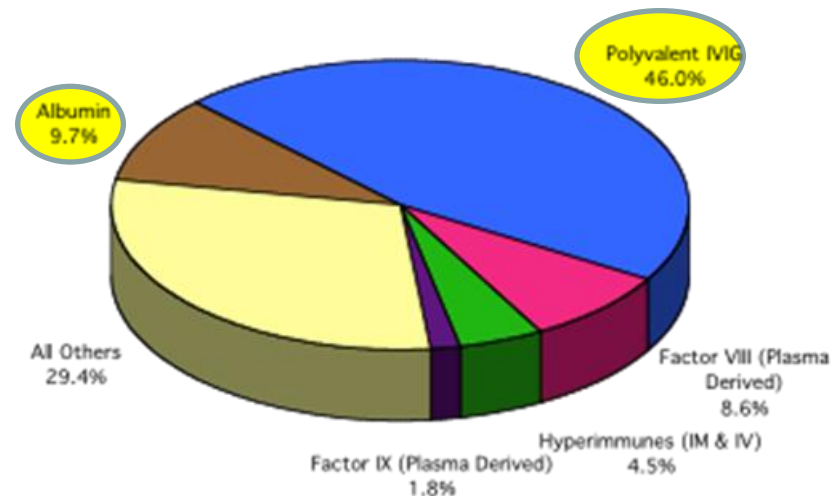


The largest revenue plasma products are IVIG and albumin

THE WORLDWIDE PLASMA FRACTIONS MARKET BY PRODUCT - 2008

WITHOUT RECOMBINANT FACTORS

Total Market \$11,778.8 Million



Plasma Fractionation Market Dynamics

- **Global market size: Approx US\$11.8 B**
- **Market is dominated by 4 players:**
 - **Baxter, CSL, Grifols and Octapharma**
 - **Secondary players include Kedrion and Biotest.**
- **Most use chromatography for high value products such as immunoglobulins and clotting factors**
- **Current chromatography plasma fractionation is capital intensive, inflexible and high cost**
- **Current fractionators focus on US and EU markets; Asia is underserved**

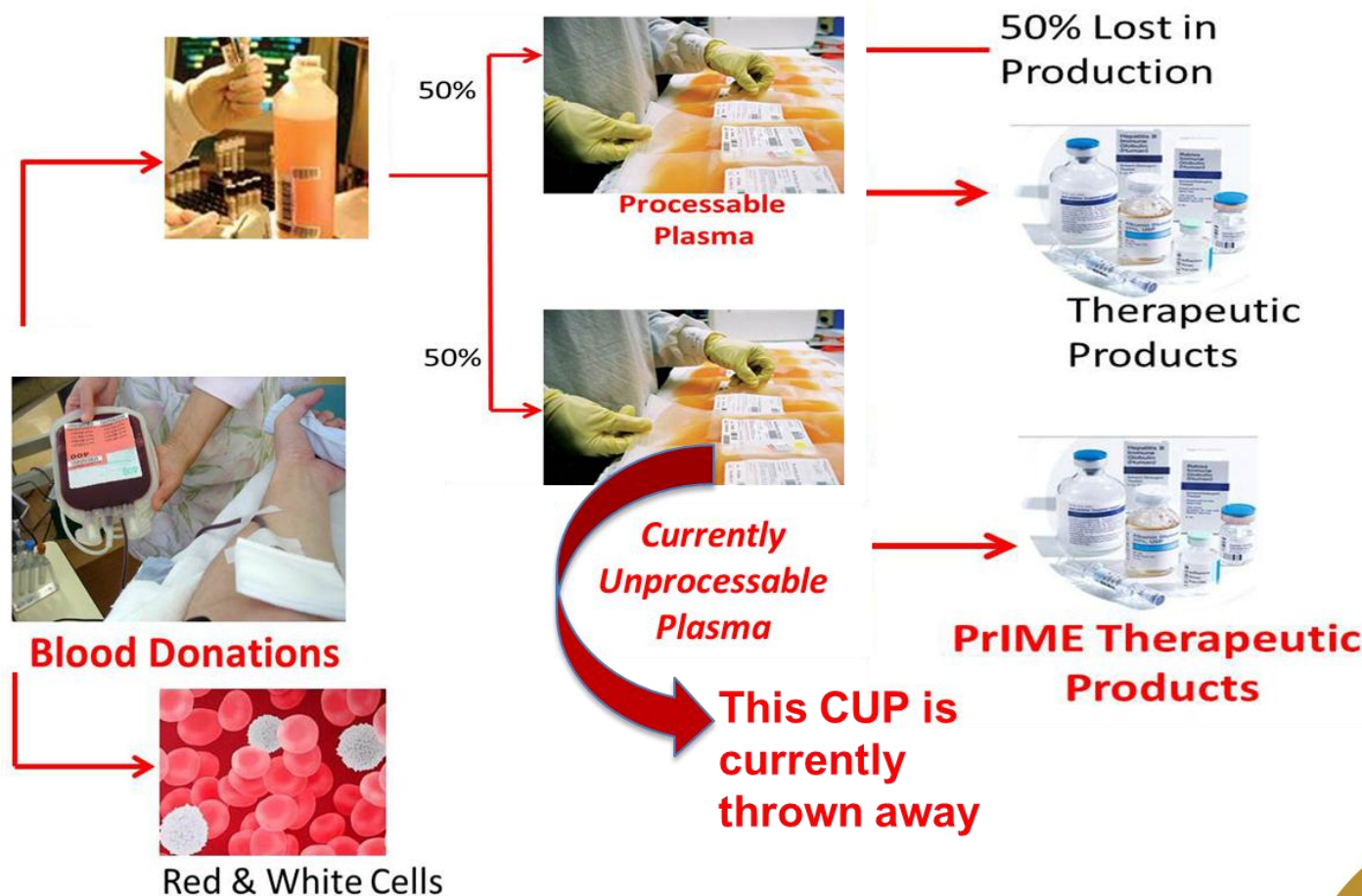


Target Asian Market

- **Estimated Asian sales: US\$1.8B**
 - Asia is a high growth market, with variable supply and high pricing
- **External Processing of Asian-sourced plasma is limited due to regulatory barriers**
 - Concern about viral contamination of existing fractionation lines
- **Over 50% of all plasma collected in most Asian countries is wasted**
- **PRIME can process this waste plasma, or “Currently Unprocessable Plasma” (CUP)**
 - Uses disposable cartridges and processes in small, flexible volumes
- **Use of CUP provides a major raw material cost advantage**



PriME can process the 50% of plasma that is currently discarded



cGMP Facility in Singapore

- A cGMP facility is required to produce human grade pharmaceuticals
- PrIME's cGMP facility in Singapore will be used to produce valuable protein products from blood plasma fractionation
 - Initially: albumin, immunoglobulins and clotting factors
 - Later: other high value products
- The facility will centrally process “CUP” blood plasma sourced from Asian countries



cGMP Singapore Facility for PrIME Biologics' Plasma Separation



200L Bioreactor, Harvest and Permeate Tank



Plant Corridor



Product Registration Process in Singapore

cGMP Approval	Manufacture Clinical Products	Start Clinical Trial	Apply for Registration	Product Registration
Start up equipment	Make 3 production batches	Truncated clinical trial □	Write up trial results □ □ □	
Lodge application	QC batches	40 patients over 12 months	Submit to HSA	
Undertake audit	Ship to clinical trial sites	Endpoint, same as existing products	Respond to HSA questions	
Write up processes	Start stability testing		Receive HSA approval	



External Investment into PrIME Biologics

- The major investor, Xeraya Capital Labuan, is a sovereign Malaysian private equity fund that invests in life sciences
- Xeraya undertook rigorous due diligence, including witnessing the successful performance trials of PrIME's equipment, prior to executing the deal
- Xeraya is investing up to SGD\$15m into PrIME Biologics Pte Ltd and Singapore-based private equity fund, JP Asia Prime Capital will co-invest up to SGD\$1m with Xeraya on the same terms, with an option to invest up to a further SGD\$4m
 - Investment is to be in four tranches against completion of pre-set milestones
 - Initial tranche of SGD\$6.4m will be received on first milestone completion
- Xeraya and JP Capital will hold class A shares which have preferential rights
- They will also receive a fixed cumulative preferential dividend at 10% pa
- NuSep's ordinary shares will convert to class B shares with limited rights, which is typical for venture capital-backed deals of this nature
- The pre-money valuation (pre investment) of PrIME is SGD\$27m



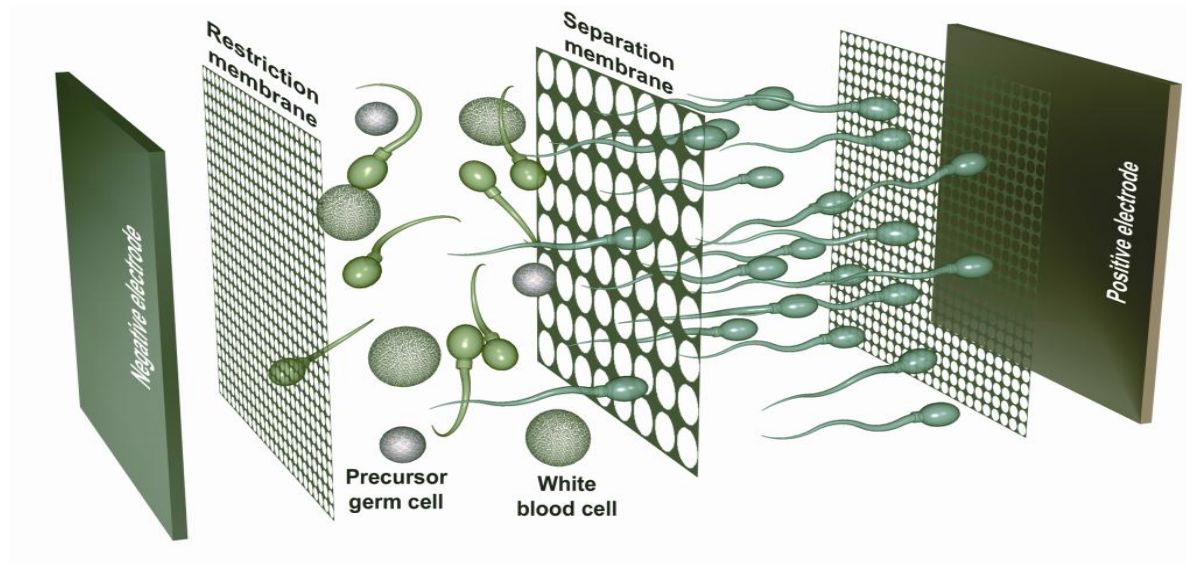
Benefits to NuSep Shareholders

- The deal provides external validation of the core technology by a specialist life science Malaysian sovereign fund, Xeraya
- Xeraya not only provides the funding, without any reliance on NuSep's shareholders, but also specialist expertise
- This deal enables the technology to be developed with minimum dilution to NuSep shareholders
- Post the full investment of SGD\$16m, NuSep's 60% holding of PrIME provides a value of SGD\$27m to NuSep
- NuSep is contracted to supply membranes and equipment to PrIME which will provide ongoing revenue to NuSep
- NuSep can focus on other lines of business eg SpermSep



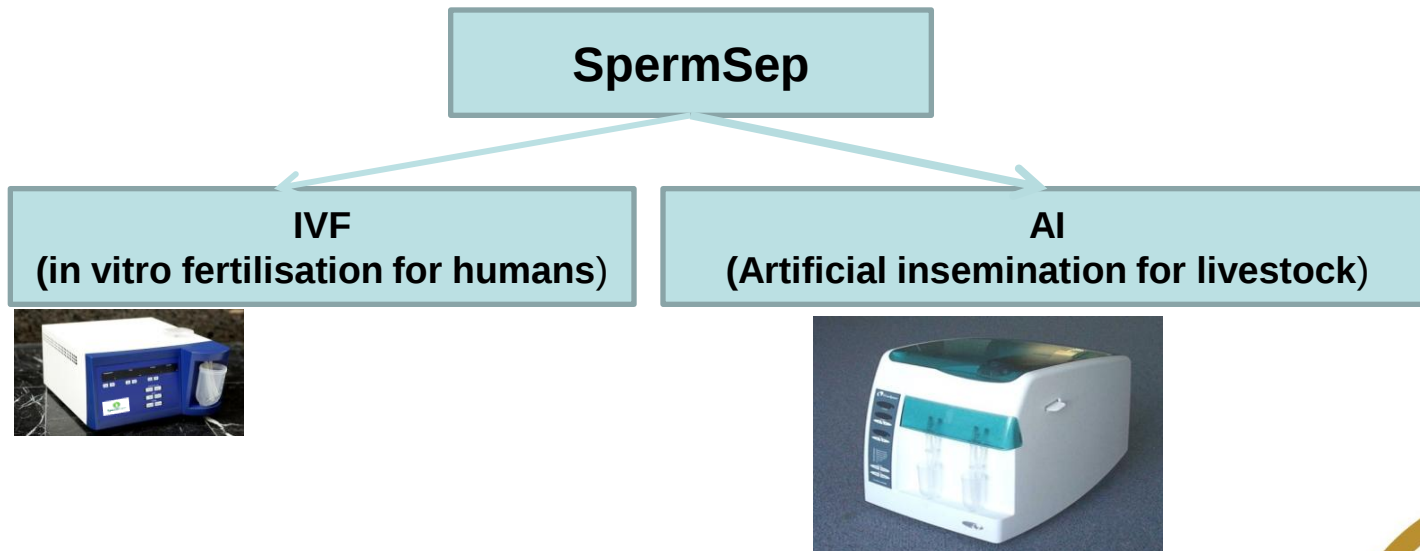
SpermSep:

Separation of the most viable sperm from sperm samples



SpermSep

- SpermSep is a NuSep Division undertaking work in ART (Assisted Reproductive Technologies)
- It selects samples of the healthiest, most viable sperm cells from sperm samples
- SpermSep services both the IVF and AI markets



Adverse Effects of Current Sperm Preparation Methods

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



SpermSep Benefits

- Deals with the increasing problem of male infertility
 - Male infertility is increasing
 - It is a factor in more than 45% of ART cycles.
 - Quality rather than quantity of sperm is the key issue
- Selective of healthy sperm
 - The highly negatively charged, highly motile healthy sperm swim fast to the anode and separate from the less viable sperm
- Far less damaging on sperm
 - University of Newcastle researchers have shown sperm produced from our technology have significantly less DNA damage than sperm provided from current techniques
- Cheaper - about half the cost
- Quicker
 - takes 5 minutes to process a sample v 30 minutes for the current centrifuge and “swim up” technique
- More convenient
 - disposable cartridges, less labour intensive



SpermSep's Ability to Satisfy AI Market Need

- Although AI increases the usefulness of superior sires by vastly increasing their reproduction rate, it is a relatively expensive process
- Faster, less complex, more efficient 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
 - decreased cost
 - simplicity of use



Human Assisted Reproduction Technologies (ART) Market Dynamics

- 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 ART market
 - ~1.5 million ART cycles/yr worldwide.
 - ~ 350,000 ART babies born /yr.
 - > 2,500 ART clinics worldwide.
 - Europe has largest activity; strongest market growth is in Asia
- Sales
 - ART sales ~\$US3bn in US, \$A170 m in Australia
 - ART consumables sales were ~\$223M in 2011
 - ~90% of ART consumables market is divided among a few key companies which dominate supply for both human and veterinary sectors.



Veterinary Assisted Reproduction Technologies (ART)

Market Dynamics

- **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 markets exist**
 - goats, camels, zoos etc



Stage of SpermSep Project

- **We have demonstrated our technology works in human IVF**
 - It has resulted in a number of successful IVF births – including for a couple unable to conceive with IVF
 - We have demonstrated it can select the most viable sperm with least genetic damage
- **We have demonstrated it can be applied in veterinary Artificial Insemination through research at Newcastle University**
- **We are ready to supply prototype SpermSep systems to human and veterinary sectors to complete clinical validation studies**



Next Steps for SpermSep

- **We are ready to supply our prototype SpermSep systems into extensive human and veterinary trials**
- **Subject to obtaining sufficient funding, we are planning the following**
 - **Veterinary**
 - **Complete Stage 1 clinical trials (late-Yr1)**
 - **Market launch internationally (late-Yr2-3)**
 - **Human**
 - **Complete 6-site stage 1 clinical trials to validate multiple clinical applications and support regulatory filings (end-Yr1)**
 - **Develop Production system; instrument & cartridges (end-Yr1)**
 - **Start international Research market roll out (mid-Yr2) and revenue**
 - **Complete regulatory approvals (end-Yr2)**
 - **Clinical market launch (start Yr2-3)**



Next Steps for SpermSep (cont'd)

	IVF	AI
Next Studies	Capture data from 5-6 leading IVF centres	Demonstration studies on horse sperm with Uni of Newcastle
Aim	• Conduct multiple clinical validation studies in leading IVF clinics • Increase key opinion leader support	• Demonstrate advantages of SpermSep technology in horses • Move to other livestock later
Anticipated cost	Estimated total investment to SpermSep cash flow breakeven is approximately \$7 million	

