Transforming IVF

NuSep

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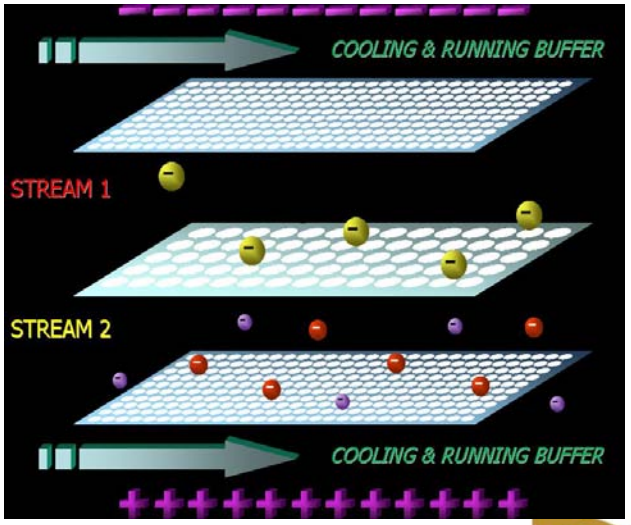
NuSep's technology selects high value proteins & cells based on size and charge

- NuSep (ASX: NSP) separates high value proteins and cells from fluids
- We use proprietary membranes (for size separation) and an electric field (for charge separation)
- We can separate proteins from blood serum* and the best sperm from a semen sample
- NuSep has proven that its technology works and is now engaged in commercialising applications.



* Performed through our majority owned investment, PrIME Biologics Pte Ltd

Why is NuSep Technology Unique?

To our knowledge, no other company has

- a **proven proprietary** method for separating cells, viruses and proteins
- using a **membrane platform technology** that can precisely control pore size (for size separation)
- that can be combine with **electrophoresis technology** (for charge separation)
- in a way that can be scaled up to provide **commercial quantities** of product.

NuSep has technological advantages across multiple applications

Application	Current Methodology	NuSep's Technological Advantages			
		Cheaper	Faster	Easier	Other
IVF (human & animal)	Density gradient centrifugation (DGC)	✓	✓	✓	• Less damage to sperm • Extracts 'best' 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		✓	✓		

NuSep has multiple separation systems

BF400

CS10

Pilot scale GF100

NuSep has developed multiple devices for specific separation applications

Current Program Status

- **PrIME Biologics Pte Ltd, Singapore: NuSep's autonomous, majority owned investment**
  - Is preparing to commercially produce albumin and immunoglobulins from human blood serum
  - PrIME is focussed on the underserved Asian plasma market
- **SpermSep: Nusep's most advanced internal program**
  - Has established human IVF benefits & has produced successful human births
  - Is preparing for further trials in major IVF Australian centres to demonstrate additional benefits over present practices
  - Has trials underway in animal IVF and artificial insemination
- **New Membranes:**
  - Additionally, NuSep is developing new membranes for other commercial opportunities.

PrIME Biologics Pte Ltd Update

- Investment by Xeraya Capital Labuan, a Malaysian biotech-focussed venture capital fund and J P Capital, Singapore
- Valuation prior to initial external investment: SGD$27m
- Current major shareholdings:

Shareholder	Share class	%	Investment to date (SGD $m)
Xeraya & JP Capital	A (= control)	24.3	8.7
NuSep	B (non-voting)	72.6*	
Other (individuals)	B (non-voting)	3.1	

- Next major milestone, cGMP certification for the Singaporean production facility, anticipated by Q2 2015

* Based on completion of ~S$2.7m investment by JP Capital under the S$4m option agreement.

NB: NuSep's share would be diluted to 55% if Xeraya and JP Capital jointly invested to SGD$19m, their maximum combined commitment on achievement of milestones by PrIME

SpermSep Addresses Male Infertility

- NuSep's SpermSep devices select the healthiest, most viable sperm cells from semen samples – quickly, cheaply, and with reduced sperm damage
- Current IVF processing is a multi-stage, expensive, hands-on process performed by lab technicians; SpermSep will provide the first dedicated sperm selection device for the IVF industry.

SpermSep

IVF
(for humans and animals)

Artificial Insemination (AI)
(for animals)

Male Infertility is highly prevalent - and increases with age

- **Male infertility is highly prevalent**
  - is a factor in > 45% of infertile couples
  - ~5% of Australian men are infertile
- **Has been increasing over the past few decades**
- **Fertility issues are more common in older men**
  - Affects ~1/3 of men over 40
- **There are also strong links between infertility and chronic disease**
  eg cardiovascular disease, diabetes

Sperm quality, rather than quantity, is the issue

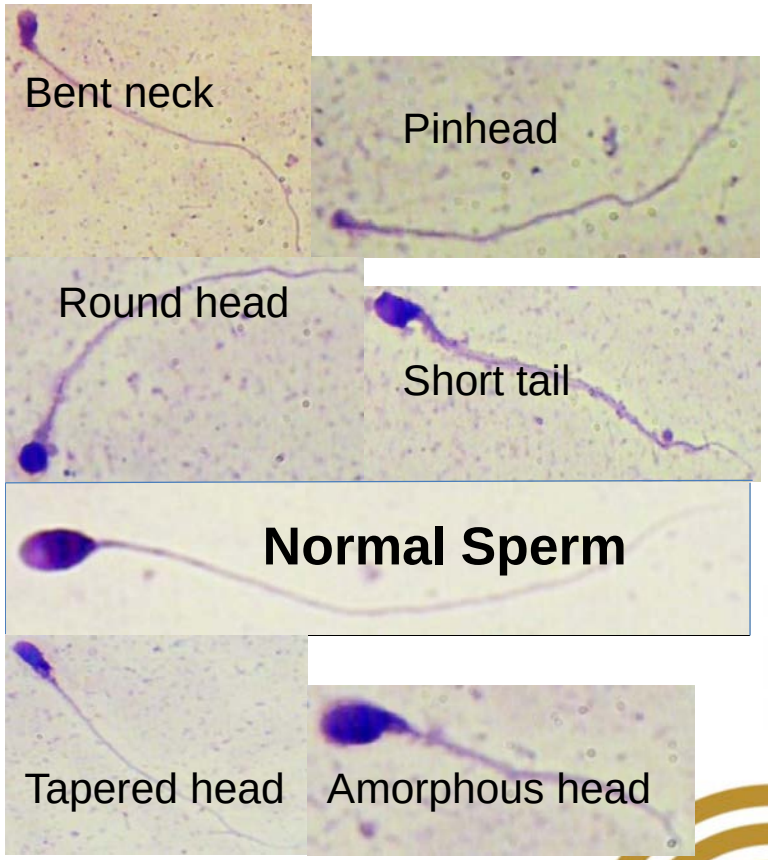
A typical semen sample contains many abnormal sperm

- which the SpermSep process eliminates

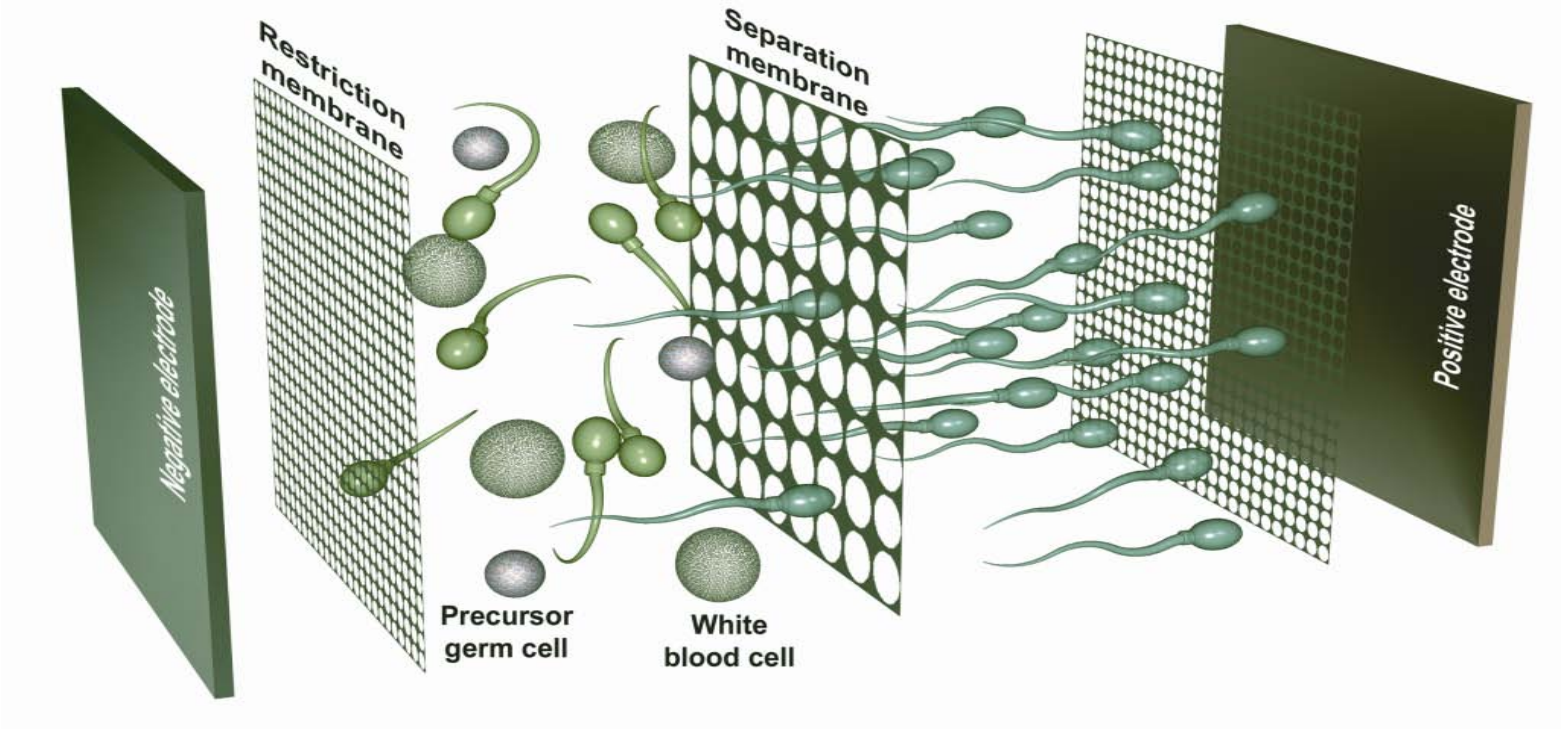
Examples of sperm abnormalities:

- double head or tail
- a short tail
- a tiny pinhead
- a bent neck
- a mis-shapen head eg round or tapered instead of oval
- damaged DNA

These factors affect their ability to move, to break the egg and/ or create a normal conception



SpermSep works by separating the most viable sperm from semen samples

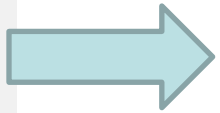


Current sperm preparation methods have disadvantages

Density Gradient Centrifuge (DGC) method:

- **Is the most common sperm preparation method used,**
- **It involves two damaging steps for sperm cells**

1. **Centrifugation**	Spinning creates damaging shear forces
2. **Culturing**	Oxidative damage arises from the culture media - contains trace heavy metals, including copper



Increased risk:

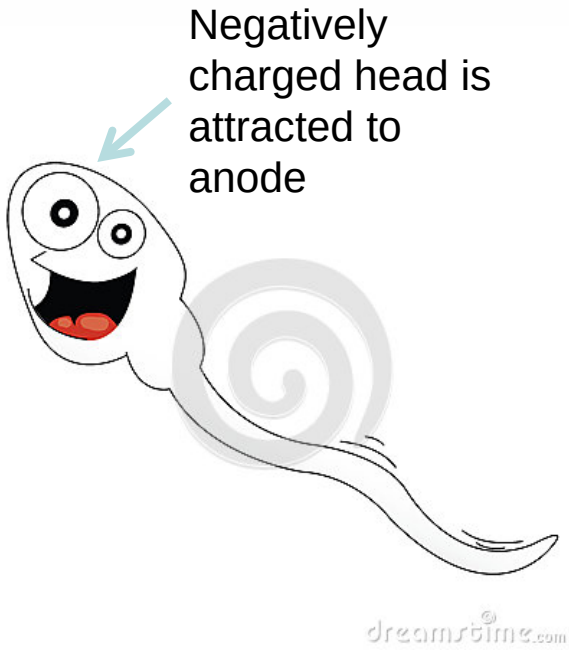
- Infertility
- Premature birth/ birth defects
- Later onset of disease & disability eg cancers, deafness, mental illness, metabolic diseases, immunity issues etc

Current artificial fertilisation processes (IVF and ICSI) use DNA-damaged sperm from DGC

Traditional IVF **(in vitro fertilisation)**	**ICSI** **(intra cytoplasmic sperm injection)**
• Multiple sperm swim to the ovum. • The first sperm to penetrate the ovum fertilises it.	• Used when male fertility is an issue. • A single sperm is inserted into the ovum. • Sperm is selected on appearance (morphology) and motility (ability to swim), not intact DNA.
	

Spermsep has a 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



Small human IVF clinical trials completed - we have demonstrated proof of concept

- Prof John Aitken (Newcastle University) has published several papers in leading reproduction journals on the clinical benefits of SpermSep.
- These *in vitro* trials documented the improved sperm selection and reduced DNA-damage using the SpermSep method.
- Limited *in vivo* trials using SpermSep at Sydney IVF and Westmead Fertility Centre have demonstrated successful births
  - Couples had been unsuccessful with IVF
  - The trial showed there was no issue with safety, however the SpermSep machines now need to be upgraded to approved clinical devices.

The Human IVF market is large and expanding

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

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

Human IVF consumable market is significantly smaller - but still substantial

Market size	US $450 million pa
Industry growth rate	12% pa
	Driven by expansion in emerging markets, especially China
Consumables cost/ IVF cycle (global average)	~US $300

SpermSep Prices, Margins

- Device price is anticipated to be ~$15,000, though free of charge if customer commits to long term consumables supply contract.
- Single-use sterile SpermSep consumable pack price for human IVF is anticipated to be $75-100.
- Product margins >75%.

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

Animal artificial reproduction market is large

- **Artificial insemination* (AI) dominates**
- **IVF is used for elite, high value animals; rapidly expanding as emerging countries improve herd genetics**
- **AI market:**
  - USA
    - ~66%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

*sperm directly inserted into uterus

SpermSep in Animal IVF

- IVF is used for elite, high value animals
- Although still a niche market, it is rapidly expanding to improve herd genetics

  eg IVF is being used by Shanghai Dairy (4th largest in China) to assist in growing the number of elite milking cows from 60,000 to 230,000 over the next 5 years
- NuSep is trialling bovine IVF (with Minitube Germany), and general animal reproduction in horses* (with Uni. Newcastle) and sheep (with Uni. Sydney)



*Artificial reproduction is banned in thoroughbred horses but can be used in other horses

SpermSep Clinical Trial Programs

Human IVF

- Multi-centre *in-vitro* clinical trial at 4 leading IVF centres in Australia
- Aims to broaden validated IVF indications by testing on key categories of male infertility
- Begins Mar15, expected completion by Sept.

Animal IVF (and subsequently AI)

- Successful results to date from *in vitro* trials at Uni Newcastle (horses) and Uni Sydney (sheep)
- IVF bovine trials at Ludwig Maxmillian University (Munich) to commence in Q1’15.

Estimated cost to SpermSep business cash flow breakeven: ~A$6 million.

Competitors

- SpermSep's competitor - in both human and animal IVF - is the DGC technique.
- DGC uses standard lab centrifuges, plus consumables
- SpermSep will be the first dedicated system for preparing sperm samples for artificial reproduction.

The major equipment & consumables suppliers:

- Human *(Jun 2012)***:**
  - *Origio/Cooper* 32%, *Vitrolife* (23%), *Cook* (16%), *Irvine* (11%) *Sage/Cooper* (7%).
- Animal:
  - The global market leader is Minitube (Germany), NuSep's SpermSep distributor

IP, Patents, Protection

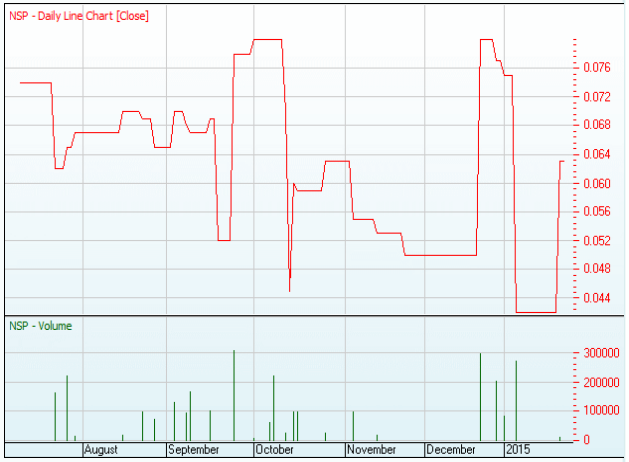
- **NuSep has patents and know how on its core separation IP and the SpermSep application.**
- **NuSep has a license to all the Prime Biologics IP for use in fields outside human plasma separation.**
- **The University of Newcastle (UN) has licensed to NuSep its patents and IP on the SpermSep application**
  - Key UN patent is granted in Australia, USA, UK and Germany
  - UN will receive a small royalty on SpermSep sales
  - UN is also engaged in ongoing funded research with NuSep in the assisted reproduction field

NuSep's Board

	Qualifications	Experience
Alison Coutts (Exec Chairman)	B.E (Chem), MBA, Grad Dip Biotech	Engineering project management, strategy consulting, executive search, financial services and capital markets, technology commercialisation, governance, listed board & senior management experience
Andrew Goodall (Non-Exec director)		International commercial property management, founding and management of successful small business. Major shareholder.
Michael Graham (Non-Exec director)	B.A, Dip Mgt	Company secretarial, global marketing communications, governance, technology commercialisation, founding and management of high tech start up, experienced board member
Mark Gell (Non-Exec director)	B.Ec, MBA, Member AICD	Capital markets, investor relations and senior management within large corporates, consulting, commercialisation of new ventures, governance, experienced board member

NuSep Shareholding Structure

Number of shares on issue	237,606,002
Past 6 month share price range	4.3 – 8.0 cents
Market Capitalisation	$19 million (@8.0 cents/shr) $15.4 million (@6.5 cents/shr)
No. of shareholders	941
Top holdings	• Top : 38.9%* • Top 5: 45.7%%



*Goodall & related parties

NuSep Key Financials

- **The balance sheet has improved post the 19 Dec'14 AGM**
  - Over $4 million in debt has been converted to equity
  - The Net Asset position is now positive at ~$2 million
  - Current Assets also now exceed Current Liabilities by $0.45 million
- **The main liability, $4.4 million, is the debt on PrIME's Singapore production facility, which NuSep agreed to adopt as part of the agreement to spin out PrIME**
  - This debt is repayable starting in March 2016 and is required to be paid for NuSep to maintain its investment in PrIME
- **Cash on hand end Jan: ~$400K**
- **Cash burn per month:**
  - $150K min;
  - $260K pm max (with all growth programs covered)

Funding Requirement – 2015

Use of Funds		$’000
Product Development		
	Commercial IVF system	$700
	Membranes	$230
SpermSep Clinical Trials		$220
Market Development		$300
Corporate		$800
Working capital		$150
		$2,400

Additional operational funding required 2016 & 2017:
$3.9m (excludes debt repayment)

SpermSep Project Launch Milestones

NUSEP - PROJECT MILESTONES & COSTS	FY15		FY16				FY17	
	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q
SPERMSEP								
To First | To First Revenues								
SpermSep commercial system devt (m/c, consumables)								
Regulatory prep, filing & approval *CE*								
FDA								
Clinical Trials *Aust*								
International								
SpermSep Production set up and Production build								
First shipments *Human IVF - research*								
Human IVF - clinical								
Animal AI								
MEMBRANES								
New Apps Development/Validation								
App A research, protoype, develop IP								
App B research, protoype, develop IP,								
App C research, protoype, develop IP,								

Summary

- **NuSep has unique proprietary technology in biological separations**
  - Proven to work
  - Two major applications: human plasma (through investment in PrIME) and sperm separation
  - Multiple unique benefits over incumbent technology
- **SpermSep**
  - Entering clinical trials, in human IVF and animal (initially IVF)
  - Large fast-growing global market
  - International distribution partnership in place for animal fertility
- **Further Capital Required for**
  - Funding of multi-centre clinical trials
  - Development and market launch of production SpermSep system
  - Development of new membranes