Transforming IVF

NuSep

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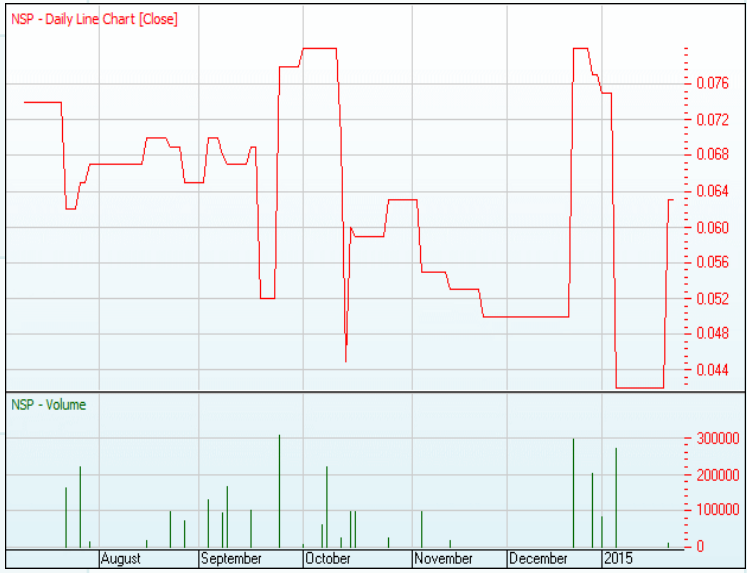
NuSep (ASX:NSP) is an ASX-listed medical device company in IVF

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

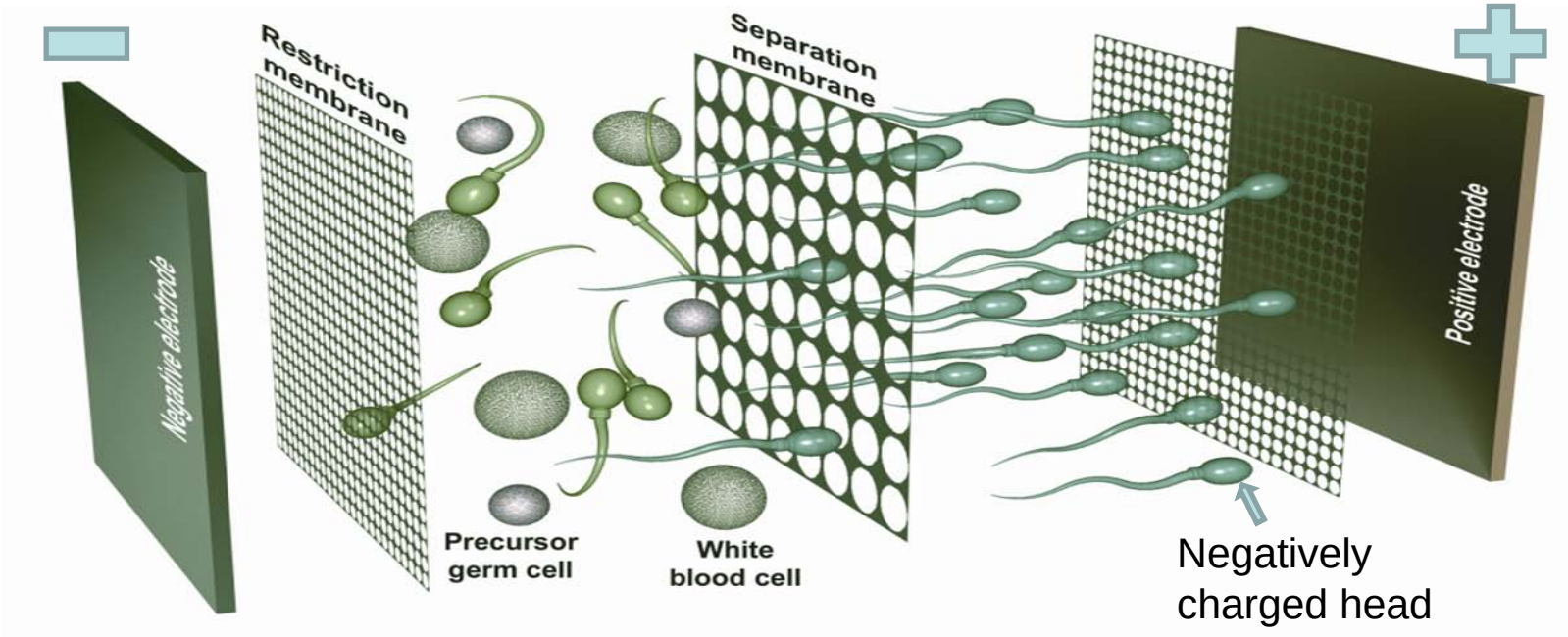


*Goodall & related parties

We separate the best sperm for IVF

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

•The best sperm have a negative charge



Why is NuSep Technology Unique?

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.

* Our spinoff investment, PrIME, can separate proteins from blood serum using the same core technology.

We have demonstrated that our “SpermSep” technology works

- **We have documented improved sperm selection and reduced DNA-damage with independent *in vitro* trials**
  - Prof John Aitken (Pro Vice-Chancellor of the Faculty of Health and Medicine, Newcastle University) has published several papers in leading reproduction journals on SpermSep’s clinical benefits
- **Small *in vivo* trials 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
- **The SpermSep machines now need to be upgraded to approved clinical devices**

NuSep has multiple separation systems

BF400

CS10

Pilot scale GF100

NuSep has developed multiple devices for specific separation applications

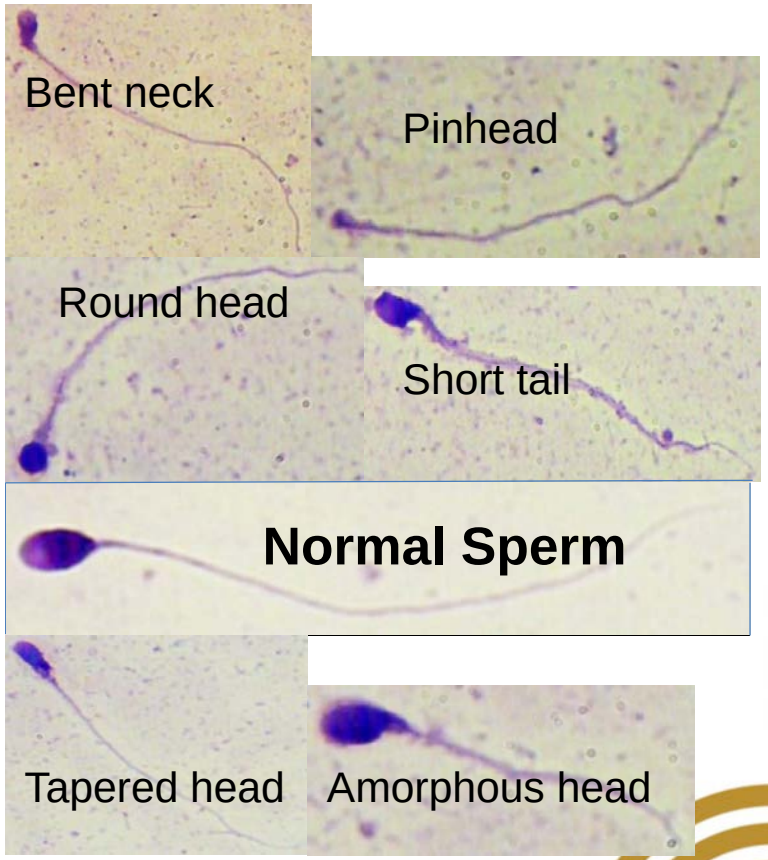
A typical semen sample contains many abnormal sperm

- 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



Most common sperm preparation methods, cause DNA damage

- **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.**

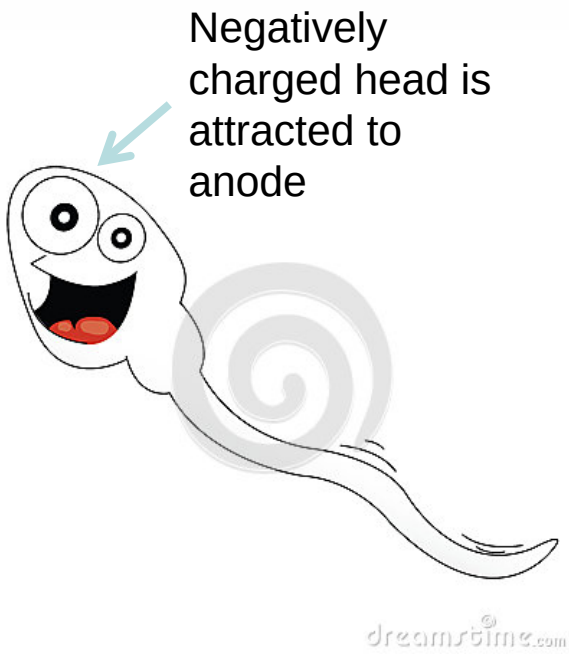
1.	**Centrifuging**	Spinning creates damaging shear forces
2.	**Separation media**	Oxidative damage arises as the separation media - contains trace heavy metals, including copper

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 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



Male Infertility: a factor in nearly 50% of IVF cases

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

Sperm quality, rather than quantity, is the issue

The Human IVF market is large and expanding

Couples with fertility issues: ~50m **Australian couples seeking IVF: 1 in 6****		
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

*** Industry interviews*

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 could disrupt current practices and create a new demand

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

Upcoming SpermSep Human IVF Clinical Trial

- ***In-vitro* trial at 4 leading Australian IVF centres**
- **Protocols will be developed by NuSep, University of Newcastle (Prof John Aitken) and the participating IVF centres**
- **Aims: to test the ability of SpermSep to retrieve viable sperm against traditional DGC approach for cases of**
  - very low sperm count
  - poor sperm quality
  - testicular or prostate damage
- **Expected duration: Mar ’15 - Sept ’15**

NB: Whilst this trial is running, we will be developing a new clinical grade device which will be used in the next set of clinical trials.

Competitors

- **SpermSep's major competitor is the DGC technique**.
  - DGC uses standard lab centrifuges, plus consumables
- **SpermSep will be the first dedicated system for preparing sperm samples for IVF**
- **Our challenge is to establish SpermSep as the industry standard method of sperm preparation**
- **To do this we must**
  - Enrol IVF Key Opinion Leaders (KOLs) to co-develop and run tests on SpermSep vs the standard DGC process (about to occur)
  - Based on new successful *in-vitro* clinical trials, have the KOLs publish papers in leading journals about the advantages of SpermSep

IP, Patents, IP Protection

- **NuSep has patents and know how on its core separation IP and the SpermSep application.**
- **NuSep has a license to all of 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

*PrIME, NuSep's majority-owned investment, was spun out in mid 2014 and is focused on separating proteins from human blood plasma.

It was valued by the external investor at SGD $27 million before SD$6+ million was externally invested.

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

Funding Requirement – 2015

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

Cash on hand end Jan: Cash burn per month: ▪ $150K min; ▪ $260K pm max (with all growth programs covered)	~$400K

SpermSep Project Launch Milestones

NUSEP - PROJECT MILESTONES & COSTS	FY15		FY16				FY17	
	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q
SPERMSEP								
To First ǀ 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,								

Why you should buy shares in NuSep

- **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 human IVF clinical trials
  - Large fast-growing global market
  - Also applicable to animal fertility
- **Further Capital Required for**
  - Funding of multi-centre clinical trials
  - Development and market launch of production SpermSep system
  - Development of new membranes