



FOR IMMEDIATE RELEASE

NuSep Announces Commencement of Clinical Trials for the Sperm Sorter

SYDNEY, AUSTRALIA – 6th June 2007 – NuSep Ltd (ASX: NSP) announced today that initial clinical trials for the Sperm Sorter had commenced at the Westmead Hospital in Sydney.

The Sperm Sorter separation device is based on the patented Gradiflow^{®1} technology. The device separates sperm from human semen, an essential pre-requisite to Assisted Reproductive Technologies including IVF, Inter-Uterine Insemination (IUI) and Intra Cytoplasmic Sperm Injection (ICSI) procedures. The Sperm Sorter is based on research that links DNA damaged sperm with poor fertilisation rates in assisted reproduction procedures. Research by the University of Newcastle has confirmed the potential of using the Sperm Sorter to separate high quality sperm from a sample of semen. This feature is of particular value to the ART market.

The Sperm Sorter is supported by the Australian Government's *Commercial Ready* program having been awarded a \$2.2 million grant for research and commercialisation activities.

The purpose of the clinical trial currently underway is to determine the efficacy and safety of the Sperm Sorter as a sperm preparation technique for IVF treatment. The sperm samples will be collected by Westmead Hospital and, together with resulting fertilisation rates, will be analysed against specific clinical trial criteria. It is anticipated that this initial trial will be completed by December 2007. Additional clinical studies will be directed to the performance of the Sperm Sorter in processing additional patient samples for ICSI and IUI procedures².

Prior to formal clinical studies, ethical approval was received to use the Sperm Sorter in treating a couple who were unable to conceive using other sperm preparation methods. The couple then successfully conceived and gave birth to a healthy baby girl. In order to bring this product to market NuSep must complete a series of clinical trials. These are required for obtaining regulatory approval of the Sperm Sorter.

Mr John Manus, CEO of NuSep announced "The clinical trial at Westmead is an exciting and significant development as the company progresses towards the commercialisation of the Sperm Sorter. Demonstration of clinical performance represents the last phase prior to commercialisation."

The current clinical trials are being conducted at Westmead Fertility Centre, located within Westmead Hospital. This clinical trial will involve between 20 and 30 patients who will undergo

¹ Gradiflow[®] is a registered trade mark of Life Therapeutics Limited.

² **Definitions –**

ART (Assisted Reproductive Technology) defines all treatment that includes in vitro handling of human eggs (oocyte), sperm or embryos for the purpose of establishing a pregnancy.

ICSI (Intracytoplasmic sperm injection) involves micromanipulation techniques whereby a single sperm is injected directly into the mature egg. The procedure increases the possibility of fertilization in cases of low sperm number, quality or function.

IUI (Intra-Uterine Insemination) is a method of introducing a quantity of washed sperm directly into the uterus to enhance the chances of fertilization. The purpose of IUI is to increase the number of sperm that reach the uterus, consequently improving the chance of fertilization.

IVF (In Vitro Fertilization) involves combining an egg with sperm in a laboratory cell-culture plate. If the egg fertilizes and begins cell division, the resulting embryo is transferred to the uterus where it may implant in the uterine lining and further develop.

both the existing sperm preparation procedure as well as the Sperm Sorter procedure. Patient enrolment has already begun and a number of procedures have been undertaken.

About NuSep Limited

NuSep is an Australian BioSeparations company based in Frenchs Forest, Sydney. NuSep manufactures and markets a range of products to BioSeparations customers located worldwide through distribution and sales centres located in Australia, the USA and Europe. NuSep is listed on the Australian Stock Exchange where its shares trade under the code "NSP".

NuSep currently operates across three product groups, each addressing BioSeparations customers, utilising patented technology and leveraging the company's global distribution network. The three product groups are as follows:

1. **Gels** – NuSep offers two ranges of electrophoresis pre-cast gels: **iGels**, innovative gels including long-life gels and gels with solid well dividers; and **NuBlu**, high quality gels at an every day price together with associated consumables.
2. **Gradiflow® Instruments** – NuSep has developed two unique laboratory separation devices based on Gradiflow® technology. The first to be released in early 2008 is a proteomics instrument that can separate a biological sample into eight fractions. The second instrument will be applied to sperm separation required for fertility treatments such as IVF. Development of this product is supported by the Australian Government's Commercial Ready program.
3. **Biological Products** – in May 2007, the company began manufacturing research grade reagents purified from human and animal plasma. The first product release is a human IgG product.

For more information about NuSep please visit the company's website www.NuSep.com

About the Westmead Fertility Centre

Westmead Fertility Centre is based at Westmead Hospital, one of Sydney's leading University teaching hospitals and is one of Sydney's largest fully-independent infertility clinics. The Westmead Fertility Centre has a strong emphasis on medical research and the training of dedicated infertility specialists. Westmead Hospital is one of a select group of infertility teaching centres that are accredited by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists for sub-specialty training in infertility.

Enquiries/additional information:

Prakash Patel
Company Secretary
NuSep Limited
(02) 8977 9000

-Ends-

Background Information on the Sperm Sorter

What is the Sperm Sorter and how does it work?

The Sperm Sorter differentiates normal sperm (with normal sperm motility, vitality, functionality, morphology and minimal level of DNA damage) from defective sperm (high level of DNA damage), cell debris and other contaminating materials in human semen. The instrument uses Gradiflow[®] separation principles which employ a combination of molecular charge, generated by the choice of suitable buffer pH; membranes with a selected pore size; and the applied potential from two electrodes, to separate target molecules on the basis of their charge and/or size.

Based on the hypothesis that there is a positive correlation between the functional and genetic integrity of human sperm and their overall surface charge, targeted healthy sperm cells can be isolated according to their unique electric mobility. The native separation conditions also allow healthy sperm to maintain their physiological functions.

During a Sperm Sorter run, sperm cells are negatively charged when exposed to the chosen buffer. The sperm is then attracted to the positive electrode. As illustrated, the chosen membranes allow the relatively small sperm cells to migrate towards the positive electrode where as other larger contaminating factors, such as blood cells or germ cells are restricted. The net result is an enrichment of purified, normal sperm cells.

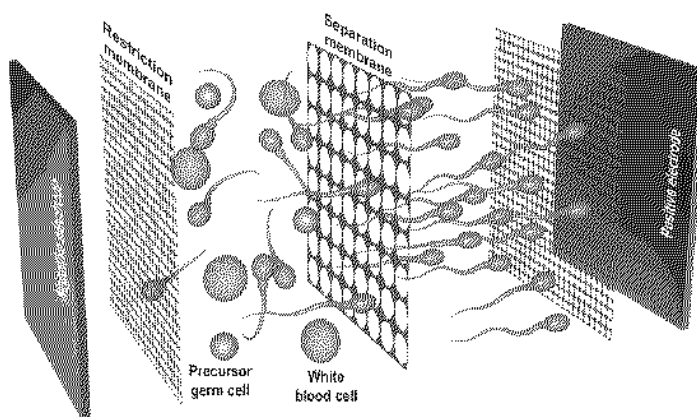


Figure 1: The separation of healthy sperm cells from contaminating factors in semen inside a Sperm Sorter separation cartridge.

The membranes are encased in a separation cartridge (not shown). The central separation membrane acts as a sieve allowing the small, negatively charged sperm cells to migrate from the semen sample into the purified fraction whilst retarding the migration of larger contaminants. It is sandwiched between two restriction membranes which act as a barrier to all sample components ensuring they are retained within the cartridge.

Pre-Clinical Results

Pre-clinical studies by the University of Newcastle ARC Centre of Excellence in Biotechnology and Development, under the direction of Professor John Aitken, indicated that the cell separation device compared well with existing sperm separation techniques. In particular, the results demonstrate a unique ability to separate sperm with less DNA damage. This feature is very significant in treating infertility patients as DNA damage in the male germ line is associated with poor fertilisation rates, implantation and/or pregnancy problems and abnormalities in the

offspring. While conventional sperm preparation techniques are efficient at producing fractions of motile sperm, there is no technology available that can actively sort DNA damaged sperm.

ART Market Information

IUI is a highly accessible and relatively cheap service. It is often the first point of call for couples seeking fertility treatment. IVF is more of a 'niche' product. Although it is widely offered in western countries it is expensive at a cost between \$5000 and \$15,000 per treatment. In Australia the average cost of an IVF cycle is around \$6000. According to the Biomedical Business International newsletter, infertility care is a \$2 billion-a-year **business**³. NuSep estimates that the Sperm Sorter addresses an A\$19 million section of this market.



Figure 2: Above is the Sperm Sorter prototype. This instrument was used for the pre-clinical studies.

³ As quoted in PEDIATRICS Vol. 93 No. 3 March 1994, pp. 403