



FOR IMMEDIATE RELEASE

## PrIME completes first three trial production runs of Albumin in Singapore GMP Facility

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**Sydney, Australia** 8<sup>th</sup> January 2013–NuSep (ASX:NSP) wishes to advise the market that staff at its Singapore subsidiary PrIME Biologics has successfully completed three trial production runs of Human Albumin using its pilot production unit in its Singapore current Good Manufacturing Practise (cGMP) production facility. These trial production runs were completed in a cGMP environment using human plasma kindly provided by the Health Sciences Authority (HSA) of Singapore in association with Defence Medical and Environmental Research Institute. Scientists from the HSA and the Defence Science Organisation (DSO) viewed the 3<sup>rd</sup> Human Albumin PrIME production run while visiting PrIME Biologics cGMP production facility in Singapore. A report on these 3 trial production runs has been submitted to the HSA.

These initial trial runs of Human Albumin represent a major milestone as it is the first time that the PrIME process has ever been operated in a cGMP facility. It is also the first trial production run using the pilot scale PrIME plant since it was transported to Singapore. Since the pilot scale PrIME unit was shipped to Singapore in October 2012, the PrIME Biologics personnel have been restarting the cGMP facility which had not been active for several years. The pilot scale PrIME unit was activated in early December 2012 and was operational from initial start up. This also validates the robustness of the PrIME process, an important feature as this process will be replicated throughout Asia.

PrIME's Executive Chairman Dr Hari Nair said, "This is the first time that the facility has been used to fractionate plasma at the GMP level and it showed that our PrIME technology can be used in a demanding production environment to produce therapeutic grade Human Plasma." PrIME's Managing Director John Manusu added, "This production run helps us prepare for the cGMP certification required to produce our first batch of therapeutic plasma products for the clinical trials anticipated to start later this year."

PrIME will undertake further replications of this initial trial run before preparing to complete further trial production fractionation runs of Human IVIG. Ultimately, PrIME Biologics intends to undertake production of Albumin, IVIG, FVIII and FIX from human plasma in its Singapore cGMP facility.

Finally, as previously advised, NuSep will seek shareholder approval to spinout PrIME Biologics once it has received the necessary approvals from ASIC & ASX.

**\*\*ENDS\*\***

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**About NuSep**

NuSep (ASX: NSP) is a publicly listed life sciences company that sells products into the global BioSeparations market. NuSep recently acquired BioInquire which developed the ProteoIQ software enabling NuSep to offer a total Proteomics solution from **Fraction to Function**. The company has offices in both Sydney Australia and Atlanta, USA.

With a 30 year heritage in biological separations, NuSep has forged a world class reputation for its innovative yet simple biological separation techniques including the world's first IVF sperm separation device. In short NuSep has redefined the BioSeparations market through innovation and simplification.

NuSep's world renowned research team has developed an extensive portfolio of patented products. In all, NuSep currently manufactures, distributes and sells 55 products to customers in the USA, Europe, Asia and Australia.

NuSep Products:

-  **Gels** – NuSep manufactures and sells precast gels including the innovative nUView Gels, which can be visualised 2 minutes after use.
-  **Separation Instruments** – NuSep has developed two unique biological separation instruments. The ProteomeSep was released in 2009 and can separate biological samples into 8 fractions for use in the proteomic market. The SpermSep separates sperm for fertility treatments such as IVF.
-  **Proteomics Software** – NuSep offers the unique ProteoIQ software for the analysis of complex mass spec samples. This software is also designed to identify bio markers.
-  **Biological Products** – NuSep supplies research grade biological products manufactured using its unique separation technologies. These products include human IgG and Albumin.

For more information about NuSep please visit the company's website [www.NuSep.com](http://www.NuSep.com)

**About PrIME Biologics Pte Ltd**

PrIME Biologics is a Singapore based biotech company that has developed a disposable therapeutic plasma manufacturing process based on NuSep's PrIME Technology. NuSep has a 90% shareholding in PrIME Biologics. PrIME Biologics process is based on the **P**reparative **I**solation by **M**embrane **E**lectrophoresis (PrIME) technology developed by NuSep. PrIME provides disposable modular processing that is 'electronically' driven membrane fractionation.

The PrIME process increases product yields to over 90% relative to the existing process 50% while increasing product safety. The PrIME has been shown to remove virus, bacteria, endotoxins and prions which cause 'Mad Cow Disease'. Further, PrIME Biologics process can produce multiple plasma products in hours compared to days, which is required by the current manufacturers.

The initial application for the PrIME process will be the *Currently Unprocessable Plasma* which represents approximately 50% of all the plasma collected in many Asian countries.