NuSep
Experts in protein discovery

FOR IMMEDIATE RELEASE

Market Update

Sydney, Australia 27th May 2011 - NuSep (ASX: NSP) Nusep wishes to update the market on its anticipated results for the full year ended 30 June 2011. This market update is based on unaudited management accounts up to 30 April 2011.

2011 Forecast Update

NuSep had previously advised the market that it expected to generate an operational profit of $1.8m for the full year ended 30 June 2011. Based on management actual results to 30 April 2011 NuSep now anticipates the full year results will show a loss of $2.5m. This reforecast is due to four factors:

- $1.3m further investment in NuSep's Singaporean plasma business which has been expensed through NuSep's P&L rather than capitalised;
- $1.2m profit shortfall in the IQ software business;
- $1.1m non operational expenses including amortisation & depreciation; and
- $0.6m of legal expenses relating to recovery of the NxGen funds and protecting the Gels IP.

As a result of these factors the revised 2010/2011 operational profit for NuSep is expected to be:

- $0.5m profit from the Gels & Diagnostic division. This is inline with the original forecast;
- $0.1m profit from the IQ software business.

Business Unit Overview

A brief summary for each of the main business units follows:.

SingaPharm: At the EGM on 28th February 2011 shareholders said they would like to see NuSep maintain a higher percentage ownership of the SingaPharm project. The Board has taken into account this view and looked at how this can be achieved.

IQ Software: Separately, the sales of the IQ software division have been a significant disappointment. In part this is due to the delay of a critical new release, but more to the pricing model that required customers to obtain capital approval for a software package purchase. This is a significant barrier for University users where as consumable purchases of software are common place for our customers. These issues have now been resolved and significantly sales since 1st May have exceeded the previous 3 months combined.

NuSep Holdings Ltd
324 Burns Bay Rd
Lane Cove NSW 2066

Postal Address
P.O. Box 823
Lane Cove NSW 1595

Contact Details
Telephone +61 2 8415 7300
Facsimile +61 2 8415 7399

Email info@nusep.com
Web www.nusep.com
ABN 33 120 047 556

Existing Business: Finally, the strength of the Australian dollar and corresponding US$ conversion rate has had a significant impact on the profitability of our US gel sales. In spite of this there has been growth in overall gel sales since the launch of the new gels line in April 2011. In the meantime the anticipated resolution of the gel litigation against both Thermo and Expedeon will help reduce the ongoing legal costs and enforce our IP position in the US.

Detailed Analysis

Below is a detailed analysis for each of the business units.

SingaPharm

The initial budget for the entire SingaPharm project was S$12m (A$9m). It was initially anticipated that NuSep would bring in outside investors to fund S$8m (A$6m) of this with the balance of S$4m (A$3) coming from NuSep. As a result of this external funding NuSep would have its initial equity reduced to 38%.

The feedback from NuSep's shareholders at the EGM on 28th February 2011 was that NuSep should retain a larger ownership of this project than was initially proposed. As a result we continue to look at ways to maximize NuSep's holding in SingaPharm. In the full year to 30 June 2011 NuSep will have spent over A$1.3m to fund the SingaPharm plasma business. All of this funding has been expensed through NuSep's P&L rather than capitalising it as an investment in the Balance Sheet. This is a more conservative approach, but one that the NuSep Board is comfortable with.

In the meantime, NuSep is evaluating additional non-equity based funding for this project and will keep the market informed as this develops. Since the February 2011 EGM a number of developments have occurred including:

- Completion of the initial design for the Singapore plasma manufacturing facility;
- In order to streamline building and operational costs the facilities in Singapore will now be established in the TechView building in Kaki Bukit in Singapore. This is a larger facility allowing for future expansion and also has more infrastructure reducing the initial set up cost;
- Employed the Director for GMP Operations; and
- Started updating the facility design for the new location.

Since this project was started the EMEA requirements for the IVIG clinical studies have been updated. SingaPharm will now be required to undertake a clinical study of 40 patients over a 12 month period. This has pushed back the timeline of the first commercial sale by six months. In all other respects this project is on schedule.

In response to the establishment of the Singapore facility, NuSep has received requests from other ASEAN governments for the establishment of the PrIME Mini Mill concept in their respective

countries The Company will update the market as these initiatives progress. As part of this marketing effort NuSep is using a push to regional self sufficiency in the plasma therapeutics market. This initiative comes on the heels of the recent WHO report, a copy of which is attached to this market update and the Australian National Blood Authority's Review of the Australian Plasma Fractionation Arrangements see http://www.donateblood.com.au/files/pdfs/Review%20of%20Australia%27s%20plasma%20fractionation%20arrangements%20Dec06.pdf

By continuing to invest directly in this project NuSep has maintained 100% ownership of the SingaPharm investment. In the event that the Company needs to bring in additional equity investment it will be able to do so at a higher valuation as critical milestones have been achieved. Undertaking this investment has placed additional funding needs on NuSep and this has forced the Company to delay other projects including undertaking the SpermSep clinical trial.

IQ Software

When NuSep acquired the IQ software it did so with the expectation that this business would generate approximately US$1.2m in profit in a full year. While the $A/$US exchange rate has negatively impacted on revenue reducing the US$1.2m profit forecast from A$1.3m to A$1m, the real cause for this profit reduction was a lack of sales.

The IQ sales did not occur at the rate forecast because of two factors:

- The late release of the critical software update which was only released on 9th May 2011; and
- The original pricing structure required customers to purchase this software as a capital expenditure item resulting in a long lead time. Since mid May 2011 an annual license fee alternative has been offered bringing the cost within most consumables budget limits of our customers.

Following the launch of the critical update and the new pricing structure, sales have grown significantly. Sales for the month of May exceed the total sales of IQ software for the previous three months and current trends indicate that this increase will continue in the coming months..

Development of the IQ software business is a work in progress. Further work needs to be undertaken on the website together with building the distribution network both in the US and worldwide. Further the IQ software is 'Best in Class' which helps build the value of the NuSep brand.

There are a number of further enhancements and new products that the IQ team are working on. This work is being funded by US Government grants which run until the end of the 2011 calendar year.

It is important to note that the Company was due to make a further payment of 3x the net profit for the year ended 30 June 2011 if the net profit was above $US 500,000. As this is unlikely NuSep will not be making any further payments for the purchase of this business. NuSep has paid a total of $US2m to acquire this business, $US1.5m in cash on acquisition in May 2010 and a further $US500,000 in shares on 31 December 2010.

Existing Business

The existing business includes the Gels, Diagnostics, ProteomeSep and SpermSep. NuSep is pleased to announce that this business is forecast to achieve its overall operational profit projection of $500,000 in spite of a significantly higher $A/$US exchange rate. A number of positive developments have occurred during this financial year which auger well for future profit growth in this division. Balancing this is the two legal cases that NuSep has had to undertake.

Litigation

The NxGen case is progressing albeit slowly. The case is currently due to go to mediation by the end of July 2011. The Company does not expected immediate resolution of this matter. The US IP litigation has however moved on significantly. The company expects to make further announcements shortly. To date costs relating to litigation are approximately $600,000 which is significantly less than the initial estimate of $2m.

Gels

In the first half of this financial year NuSep invested heavily in injection moulding dies to open up the Bio-Rad and Invitrogen dominated gels markets. These markets account for approximately 95% of the total $100m Gels Market. The first of these products were launched in April 2011 and by mid May 2011 direct sales of these products equalled the sales of the existing gel products. While making products that address the two main Gels markets has been critical, the new gel formulations and the 2 minute UV visualisation technology have made NuSep's gels 'Best in Class" and enabled the company to compete on a level playing field in the gels market. The company remains confident that it is on course to meet its stated intention of attaining 10% of the US$60M US market.

Dollar Sales of the Gels in the October and January quarters were down. In part this was artificial, as volume was flat, before the effect of exchange rate was taken into account. The adverse foreign exchange has hidden the overall growth in direct sales of gels which have been particularly strong since the launch of the new gels in April 2011. As an indication of this growth direct sales for the month of May to date were the highest in this financial year.

The quality of the new gels is also apparent from the results of the FaceBook promotion that NuSep ran in April/May 2011. This was the Company's first social media campaign and has generated significant feedback, particularly for the unique UV application of this product. Shareholders are encouraged to review the NuSep FaceBook at http://www.facebook.com/nusepinfo. There are some innovative photos of our gels on the FaceBook page and this campaign has created quite a buzz in the marketplace. The campaign generated a number of new customers and is part of our strategy to establish NuSep as the #1 innovator & 'Best in Class' in the gels market.

Tied to this promotion is the significant website upgrade. The site is being developed as a great resource for our customers and the online store is much improved than the old site. The next iteration of the website will incorporate both the IQ and the Gels in the one shopping cart.

As is probably clear our efforts over the last six months have been focused on generating increased sales revenue. This strategy will continue for the foreseeable future through direct sales and broadening our distributors' network. We remain committed to our objective in achieving a 10% (US$ 6.0M) market share.

Funding the PrIME Mini Mill in Singapore has meant that the SpermSep clinical trials have had to be delayed. While that was a rational decision in February 2011 further development work by Professor John Aitken of the University of Newcastle has demonstrated that the SpermSep technology offers additional clinical advantages which involve sperm immobilisation and the absence of DNA damage. A disposable cartridge was finalised in May 2011 and the final commercial unit should be ready by September 2011. This is an instrument that has been developed by clinicians to meet their needs. Consequently it is important that clinical trials of the SpermSep together with veterinary applications should progress without further delay.

Conclusion

The existing business is on target and the strains of lack of sales with the IQ software products we believe are now behind us. These two divisions are synergistic and sales are growing. Both have 'Best in Class' products with a good pipeline of new products. Further, there are reasonable prospects that sales of the IQ software will continue to grow now that we have the right product and the pricing strategy. In under two months the two new gel products have surpassed the sales of the old product and continue to grow. We believe our goal for a 10% market share remains aggressive but achievable.

Finally, the Board has recently adopted the conclusions of an external Board review. Based on this the Board is looking to bring on three additional skills; Finance, IT and Biotech Industry knowledge. In addition the Board is looking to appoint one of these as an independent Chair. The existing Board is fully supportive of these changes as it believes these changes are necessary in order for NuSep to become an ASX 300 company within the next 5 years.

****ENDS****

For more information please contact:

Contact:
Prakash Patel
Company Secretary
+61 2 8415 7300
prakash.patel@nusep.com

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 ηUView 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 and is expected to undergoing clinical trials later this year.
- **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

About SingaPharm

SingaPharm is a Singapore based biotech company that has developed a disposable procedure for the processing of plasma proteins. SingaPharm is currently a wholly owned subsidiary of NuSep Holdings Limited (ASX: NSP). SingaPharm's process is based on the **Pr**eparative **I**solation by **M**embrane **E**lectrophoresis (PrIME) technology developed by NuSep. PrIME provides disposable modular processing that is 'electronically' driven membrane fractionation.

This process is flexible and modular compared with the large scale inflexible processing facilities of existing fractionators in US and Europe. The process has increased product yield relative to the existing process with increased product safety. The flexible nature of the PrIME technology also provides SingaPharm with access to plasma volumes that previously did not meet the criteria for larger scale processing facilities. Further, SingaPharm's process can produce multiple plasma products in hours compared to days, which is required by the current manufacturers.

WHA63.12 Availability, safety and quality of blood products[1,2]

The Sixty-third World Health Assembly,

Having considered the report on availability, safety and quality of blood products;[3]

Recalling resolution WHA58.13 on blood safety: proposal to establish World Blood Donor Day and preceding related resolutions since resolution WHA28.72 on utilization and supply of human blood and blood products, which urged Member States to promote the full implementation of well-organized, nationally coordinated and sustainable blood programmes with appropriate regulatory systems and to enact effective legislation governing the operation of blood services;

Recognizing that achieving self-sufficiency, unless special circumstances preclude it, in the supply of safe blood components based on voluntary, non-remunerated blood donation, and the security of that supply are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population;

Conscious that plasma-derived medicinal products for the treatment of haemophilia and immune diseases are included in the WHO Model List of Essential Medicines[4] and of the need to facilitate access to these products by developing countries;

Concerned by the unequal access globally to blood products, particularly plasma-derived medicinal products, leaving many patients in need of transfusion and with severe congenital and acquired disorders without adequate treatment;

Aware that a major factor limiting the global availability of plasma-derived medicinal products is an inadequate supply of plasma meeting internationally recognized standards for fractionation;

Bearing in mind that treatment using labile blood components is gradually being included in medical practice in developing countries and that thereby increased quantities of recovered plasma should become available for fractionation into plasma-derived medicinal products to meet their needs;

Concerned that in developing countries blood components separation technology and fractionation capacity are lacking, and that, because of insufficient regulatory controls and failure to implement appropriate practices in blood establishments, plasma from developing countries is often unacceptable for contract fractionation, with considerable wastage of plasma as a result;

Convinced that assuring the suitability of plasma for fractionation requires the establishment of a nationally coordinated and sustainable plasma programme within a properly organized, legally established and regulated national blood programme;

---

[1] For financial and administrative implications for the Secretariat of this resolution, see document EB126/19 Add.1.

[2] The term "blood products" is defined by the Expert Committee on Biological Standardization as follows: "any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products".

[3] Document A63/20.

[4] The WHO Model List of Essential Medicines identifies individual medicines that together could provide safe and effective treatment for most communicable and noncommunicable diseases. This List includes plasma-derived medicinal products, namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide /http://www.who.int/medicines/publications/essentialmedicines/en/index.html).

Recognizing that, as the capacity to collect plasma is limited and would not suffice to produce enough essential medicines to cover global needs, it is essential that all countries have local capacity to collect plasma of acceptable quality and safety from voluntary and unpaid donations in order to meet their needs;

Convinced that fractionation should be set up as close to the source as possible, and that, where national plasma fractionation capacities are lacking, there should be an option for supply of fractionation capacity in other countries, ensuring that the supply of plasma-derived medicinal products can be made available to meet local needs in the country of the plasma supplier;

Recognizing that access to information about strategies to ensure supplies of blood products sufficient to meet demand, effective mechanisms of regulatory oversight, technologies to ensure the quality and safety of blood products, and guidelines on the appropriate clinical use of blood products and the risks of transfusion have become more and more necessary;

Bearing in mind that voluntary and non-remunerated blood donations can contribute to high safety standards for blood and blood components, and being aware that the safety of blood products depends on testing of all donated blood for transfusion-transmissible infections, and correct labelling, storage and transportation of blood products;

Bearing in mind that patient blood management means that before surgery every reasonable measure should be taken to optimize the patient's own blood volume, to minimize the patient's blood loss and to harness and optimize the patient-specific physiological tolerance of anaemia following WHO's guidance for optimal clinical use (the three pillars of patient blood management);[1]

Recognizing that excessive and unnecessary use of transfusions and of plasma-derived medicinal products, unsafe transfusion practices, and errors (particularly at the patient's bedside) seriously compromise patient safety;

Concerned that unsafe and/or poor-quality blood products can render patients vulnerable to avoidable risk if the blood programmes are not subject to the level of control now exercised by experienced national or regional regulatory authorities;

Alarmed that patients in developing countries continue to be exposed to the risk of preventable transfusion-transmitted infections by bloodborne pathogens such as hepatitis B virus, hepatitis C virus and HIV;

Noting the increasing movement across boundaries of blood products and blood safety-related in vitro diagnostic devices, together with their rapid development and introduction into health-care systems of both developed and developing countries;

Recognizing the value of WHO International Biological Reference Preparations (International Standards) for the quality control of blood products and related in vitro diagnostic devices for detection of known and emerging bloodborne pathogens;

Convinced that traceability at all stages of the preparation of blood products, from the donor to the recipient and vice versa, is essential to identify risks, particularly the transmission of pathogens and transfusion reactions, and to monitor the efficacy of corrective measures aiming to minimize such risks;

---

[1] *The clinical use of blood: manual*. Geneva, World Health Organization, 2002.

Convinced that good practices need to be implemented for recruiting voluntary, non-remunerated healthy blood and plasma donors from low-risk donor populations and testing of all donated blood for transfusion-transmissible pathogens, and that the whole chain of processes in the production of blood products, i.e. correct processing, labelling, storage and transportation, needs to be covered by relevant, reliable quality-assurance systems;

Recognizing that stringent regulatory control is vital in assuring the quality and safety of blood products, as well as of related in vitro diagnostic devices, and that special effort is needed to strengthen globally the technical capacity of regulatory authorities to assure the appropriate control worldwide;

Recalling previous resolutions of the Health Assembly that mention the vital need to strengthen blood establishments and ensure the quality, safety and efficacy of blood products,

1. URGES Member States:[1]

(1) to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency, unless special circumstances preclude it;

(2) to take all the necessary steps to update their national regulations on donor assessment and deferral, the collection, testing, processing, storage, transportation and use of blood products, and operation of regulatory authorities in order to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards;

(3) to establish quality systems, for the processing of whole blood and blood components, good manufacturing practices for the production of plasma-derived medicinal products and appropriate regulatory control, including the use of diagnostic devices to prevent transfusion-transmissible diseases with highest sensitivity and specificity;

(4) to build human resource capacity through the provision of initial and continuing training of staff to ensure quality of blood services and blood products;

(5) to enhance the quality of evaluation and regulatory actions in the area of blood products and associated medical devices, including in vitro diagnostic devices;

(6) to establish or strengthen systems for the safe and rational use of blood products and to provide training for all staff involved in clinical transfusion, to implement potential solutions in order to minimize transfusion errors and promote patient safety, to promote the availability of transfusion alternatives including, where appropriate, autologous transfusion and patient blood management;

(7) to ensure the reliability of mechanisms for reporting serious or unexpected adverse reactions to blood and plasma donation and to the receipt of blood components and plasma-derived medicinal products, including transmissions of pathogens;

[1] And, where applicable, regional economic integration organizations.

2. REQUESTS the Director-General:

(1) to guide Member States to meet internationally recognized standards in updating their legislation, national standards and regulations for effective control of the quality and safety of blood products and associated medical devices, including in vitro diagnostics;

(2) to advise and build capacity in Member States on leadership and management of blood supply systems in order to strengthen national coordinated and sustainable blood and plasma programmes by sharing best practices about the organizational structure of blood supply systems in order to increase efficiency and minimize error;

(3) to augment the support offered to Member States for developing and strengthening their national regulatory authorities and control laboratories so as to increase their competence in the control of blood products and associated medical devices, including in vitro diagnostic devices, and to foster the creation of regional collaborative and regulatory networks where necessary and appropriate;

(4) to ensure sustainable development and provision of WHO International Biological Reference Preparations (International Standards) for use in the quality control and regulation of blood products and related in vitro diagnostic devices;

(5) to improve access by developing countries to WHO International Biological Reference Preparations and to the scientific information obtained in their validation in order to assure the appropriate use of these preparations;

(6) to develop, provide and disseminate guidance and technical support to strengthen national coordinated blood and plasma programmes and introduction of blood component separation and plasma fractionation technology, to meet local needs, and promote effective regulatory oversight of blood services and implementation of good manufacturing practices in plasma-fractionation programmes, under the responsibility of regulatory authorities;

(7) to provide guidance, training and support to Member States on safe and rational use of blood products and to support the introduction of transfusion alternatives including, where appropriate, autologous transfusion, safe transfusion practices and patient blood management;

(8) to encourage research into new technologies for producing safe and effective blood substitutes;

(9) to inform regularly, at least every four years, the Health Assembly, through the Executive Board, on actions taken by Member States and other partners to implement this resolution.

(Eighth plenary meeting, 21 May 2010 –
Committee B, second report)