



ASX Release

LODGEMENT OF APPENDIX 4E & PRELIMINARY FINAL REPORT

Sydney, Monday 31 August 2015

NuSep Holdings Limited (ASX:NSP) advises the lodgement of Appendix 4E and the Preliminary final report, which are attached.

For further information please contact:

Alison Coutts
Executive Chairman
+61 2 8415 7300
alison.coutts@nusep.com

NuSep Holdings Ltd
30 Richmond Road
Homebush NSW 2140

Postal Address
P.O. Box 2202
Homebush NSW 2140

Contact Details
P +612 8415 7300
F +612 8415 7399

E info@nusep.com
W nusep.com
ABN 33 120 047 556



NuSep Holdings Ltd
ABN 33 120 047 556
Financial Year Ended 30 June 2015
Appendix 4E: Performance Commentary

NuSep has undergone great change, overcoming many challenges over the past year and is now entering a “build” phase. Some of the highlights include:

- Most legacy issues dealt with and company now stabilised;
- A revitalised board and a highly skilled and motivated development team;
- PRIME Biologics Pte Ltd becoming an externally funded investment, resulting from its spin out from NuSep in June 2014;
- A clear, revised strategy with focus on SpermSep and new hydrogel-based polymer membranes; decision to sell the pre-cast gels business;
- Reinvigorated association and new research collaborations with The University of Newcastle on artificial reproduction technology and the University of Melbourne on new hydrogel membranes;
- The reappointment of Professor John Aitken from the University of Newcastle as Chairman of NuSep’s Scientific Advisory team.

Financial Performance

The manufacturing and selling of pre-cast polyacrylamide gels was traditionally the major source of sales for the Company. However, the largest customer of the gel business informed NuSep in February that it would be sourcing products internally from a recent acquisition. NuSep’s board determined that the Company would be best served by focusing on developing its other business units, in particular SpermSep. Accordingly, NuSep decided to exit the pre-cast polyacrylamide gel business and put the business up for sale.

The process for selling the gel business has commenced and a sale is expected to take place before December 2015. Assets and liabilities related to the gel business have been reclassified in the statement of financial position as assets held for sale of \$495,142 and liabilities associated with these assets of \$116,664.

The second largest revenue item after the gels business is from the R&D tax refund. On 21 July 2015, the R&D tax claim for \$328,838 was lodged and subsequently approved by AusIndustry.

The remaining sales revenues relate to diagnostics product sales, which are a mature and small line of business for the Company.

The future direction of the Company will be to invest in high value adding projects. These projects will not be revenue generating for at least two years. The foremost project, SpermSep, received the largest investment totalling \$553,445. This investment is expected to increase in future years, subject to funding availability.

NuSep incurred a \$2,270,346 loss from continuing operations (2014: loss of \$1,036,213). General and Administrative expenses of \$1,509,329 (2014: \$658,055) was the largest expense category and it was also the largest increase in expenses, totalling \$851,274. Most of this additional expense was due to the additional costs that the Company incurred in the extensive ASIC investigation, which is now finished.

NuSep signed an Enforceable Undertaking with ASIC in December 2014 relating to potential contraventions of the Corporations Act 2001 (Cth) (Corporations Act) between 2009 and 2012 over matters primarily concerning governance. The Undertaking noted specifically that the conduct took place prior to 2012 and prior to the appointment of the current board. NuSep published the Undertaking in an ASX announcement on



18 December 2014 and the Enforceable Undertaking is available for viewing on a public register maintained by ASIC.

ASIC ceased its investigation post reporting date, in July 2015. Now that ASIC has ceased its investigation and the major compliance systems are developed and in operation, we expect far reduced General and Administrative expenses in the future.

Other contributors to the loss were increased interest charges on finance costs of \$161,275 and increased foreign exchange losses of \$367,863, mainly triggered by the devaluation of the Australian dollar having an impact on the third party A-Bio debt.

The loss from discontinued operations of \$375,338 relates to the gels business, which includes the results of the US subsidiary, NuSep Inc. The loss from discontinued operations of \$2,805,927 in 2014 includes not only the gels business but also PrIME.

When combined with the exchange translation gain of \$4,596 (2014: loss \$271,826), the total comprehensive loss for the year was \$2,641,088 compared with a loss in 2014 of \$4,113,966.

NuSep's investment in PrIME is held in B class shares. The value of these shares has been maintained at the same cost value as the prior year. More discussion about this is provided in the commentary in the PrIME section which follows.

In the first half of the financial year, the Company converted \$4.2 million debt into equity post the 19 December 2014 Annual General Meeting, thereby strengthening our statement of financial position. Over the whole financial year, the Company decreased outstanding debts with suppliers and tax authorities by \$760,847 using borrowings from related parties. A substantial part of these debts relate to legacy issues. We now have a leaner and more focussed organisation.

The largest current liability is a third party debt to A-Bio Pharma Pte Ltd (A-Bio). A-Bio had developed the Singapore cGMP facility, converting a large floor space of an office building to cGMP manufacturing capability. PrIME took over the space with cGMP fit out after A-Bio decided to vacate. NuSep's agreement to take responsibility for payment of this debt was part of the agreement for spinning out PrIME and obtaining external funding.

Since assuming the debt, interest, at 5% per annum of \$187,596 and the negative effect of foreign exchange currency of \$469,506 have added to its balance, bringing a total of \$4,409,015. The first two instalments, for the amount of \$1,934,236, are included as current debt, with the first instalment payable in March 2016. Should NuSep not pay the debt as it arises, NuSep will lose a pro-rata of its investment in PrIME.

NuSep is currently seeking to sell its investment in PrIME, as announced in April 2015.

The FY 2015 financial performance reflects the largest change in the Company's history, emanating from spinning out the PrIME business. Operating and capital expenditure expenses are now running at a far reduced rate. Further expense reduction is anticipated as the gels business will also be closed, however we expect to incur increasing expenditure in developing the SpermSep business and new membranes.

Business Activities

NuSep has two main areas of internal focus for separating high value biological substances from fluids, utilising its proprietary separation membranes and equipment:

- SpermSep;
- Hydrogel polymer membrane technology development;

In addition, it has an investment in PrIME Biologics Pte Ltd, based in Singapore. PrIME utilises this same core NuSep separation technology as PrIME was part of NuSep until recently.

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NuSep also produces precast polyacrylamide gels and diagnostic products, predominantly for the biological research market. It has put the precast polyacrylamide business up for sale following the decision by its major customer to make its own gels.

SpermSep

Our major internal program, SpermSep, is based on proprietary technology for sorting the most viable sperm from semen samples for human and animal IVF applications. The device has been shown in laboratory testing to separate the viable sperm far more efficiently and with less DNA damage than conventional methods.

In November 2014, NuSep signed a Heads of Agreement with Minitube GmbH, the largest global provider of animal Artificial Reproductive Technologies (ART) products. Minitube is to be the distributor of NuSep's animal ART products. NuSep has an ongoing research program with Minitube, initially focussing on the preparation of frozen bovine semen, a technically challenging project, to process in the SpermSep device. Once sufficient quantities of viable sperm can be retrieved using a special pre-treatment that Nu Sep has devised, prior to treatment in the SpermSep device, *in-vivo* IVF bovine studies can commence in Germany.

The research program with the University of Sydney in sheep (ovine) reproduction has been taken in-house as more internal resources were required to refine the SpermSep testing protocols for the ovine sperm.

Professor John Aitken and his research team at the University of Newcastle are continuing work in the animal ART field, with *in vitro* equine studies and in the oversight of the human IVF *in-vitro* studies at major Australian clinical IVF centres. The first such *in-vitro* study with Monash IVF was announced post reporting date, on 24 August 2015.

Upon completion of the SpermSep clinical trials and the engineering completion of our next-generation clinical grade SpermSep products, we plan to commercialise the product through marketing and distribution arrangements with international distributors.

The valuation of the SpermSep business on the Statement of Financial Position has been held at cost similar to prior year, at \$1,970,567 (2014: \$1,670,576). This is not a market-based valuation and NuSep believes that there is far greater value in this business. NuSep plans to increase expenditure on the development of this business and demonstrate commercial progress in both human and animal IVF trials over the next year.

Membrane Technology Development

As part of the development of clinical grade devices, we will use the new hydrogel membranes we are developing rather than the Company's traditional polyacrylamide membrane technology, as the new membranes will have improved biocompatibility, improved production scalability and lower raw material and production cost of manufacture. NuSep requires further funding to complete development of the new clinical SpermSep product range and the new membranes will be part of this range.

PrIME

In June 2014, NuSep spun off its technology for plasma fractionation by its then subsidiary, PrIME Biologics Pte Ltd in Singapore. PrIME is exclusively developing the human blood plasma separation business with production from its Singapore cGMP manufacturing facility to supply Asian markets with high value proteins including albumin and immunoglobulin.

PrIME is using the technology developed by NuSep which has been shown in laboratory scale tests to be far more efficient and potentially cheaper than current commercial plasma fractionating processes, but has yet to be scaled up.



When NuSep entered the PrIME investment agreement, it resulted in the deconsolidation of PrIME. In late June 2014, PrIME received its first external investment of SGD\$6.4m, principally from Palau Manukan Ventures Labuan Ltd, a Malaysian venture capital fund. The investors received Series A preference shares which have voting control. NuSep, with class B shares, is a passive investor and had a 67.8% shareholding in PrIME on a converted basis as of 30 June 2015.

PrIME Biologics is working towards cGMP accreditation, which will enable it to obtain its next external tranche of funding. It did not pass its initial attempt at cGMP earlier in the year. According to PrIME, there were a number of non-conformances but these were addressable. PrIME is now getting ready for the next attempt, which is expected to occur in the next few months, based on communication from PrIME.

Whilst NuSep considers that the investment has the potential to yield great value to NuSep shareholders in time, its holding value in the Company's statement of financial position has been calculated on a cost basis, which is not a market-based valuation. Internal company analysis has indicated a current valuation to NuSep substantially greater than the SGD\$27 million pre-money value of PrIME paid by the class A investors. Given that the range of reasonable fair value estimates is significant and the probabilities of the various estimates cannot be reasonably assessed at this stage, NuSep is precluded from measuring the investment at fair value.

Board and Management

During the financial year we appointed two new independent directors to our board, which has bolstered the Board's depth and expertise. Michael Graham was appointed upon the resignation of a former non-executive director, Prakash Patel on 10 September 2014 and Mark Gell was subsequently appointed on 17 October 2014.

We have appointed medical devices veteran, Ross Harricks, in a senior Business Development and Engineering Management role on a part time basis. We have also employed Susan Ellingsen as Projects Director.

2016 Outlook

SpermSep: NuSep has started clinical trials in human IVF with Monash IVF and plans to expand to other key IVF sites around Australia. We have developed a regulatory and product development plan for the commercial IVF production system. We are also refining our veterinary system based on the research results with Minitube and University of Newcastle on bovine and equine applications. SpermSep will require extra funding to develop both the human and animal applications.

Membranes: NuSep currently makes membranes for its own use. It will accelerate research into new membranes and applications with its recently signed collaboration partner, the Chemical and Biomolecular Engineering Department at Melbourne University. Apart from being applied to the SpermSep device, the new membranes are also showing early potential in new life sciences market opportunities.

PrIME: The key milestone for PrIME is to obtain cGMP certification and we expect the next attempt at certification within the next few months. The valuation of our investment in PrIME should increase upon cGMP certification.

Overall: Whilst it has been an expensive and time consuming process to spin PrIME out and the ASIC investigation was also arduous and expensive, NuSep has finalised both and is now able to concentrate on its own internal value adding activities.

The major opportunity in the short term is SpermSep for both human and animal IVF. The emerging area is the development of new hydrogel membranes, for both SpermSep and other commercial applications. The



development of SpermSep and new membranes are expected to be value drivers for the company in the foreseeable future, subject to sufficient funding being available. The potential sale of NuSep's investment in PrIME is an additional opportunity with potentially large upside.

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Postal Address
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1. Consolidated Statement of Profit or Loss and Other Comprehensive Income

Continuing operations	For the year ended 30 June 2015 \$	For the year ended 30 June 2014 \$
		Restated
1.1 Revenue		
Revenue from sales or services	190,660	124,466
Cost of sales	(57,994)	(37,592)
Gross profit	132,666	86,874
Grant income	413,491	356,212
Finance income	5,075	2,849
Gain on sales of investments	77,945	-
Marketing	-	(23,574)
General & administration	(1,509,329)	(658,055)
Research & development	(207,706)	(472,373)
Finance cost expense	(682,304)	(521,029)
Impairment reversal	18,331	343,535
Foreign exchange	(518,515)	(150,652)
1.2 Loss before income tax	(2,270,346)	(1,036,213)
1.3 Income tax	-	-
1.4 Loss after tax from continuing operations	(2,270,346)	(1,036,213)
1.5 Discontinued operations		
Loss from discontinued operations net of tax	(375,338)	(2,805,927)
1.6 Net loss for the period	(2,645,684)	(3,842,140)
1.7 Net loss attributable to members of parent	(2,645,684)	(3,842,140)
1.8 Other comprehensive income / (expense) <i>Items that may be reclassified subsequently to profit or loss</i>		
Exchange translation difference	4,596	(271,826)
Total other comprehensive income / (expense) for the year	4,596	(271,826)
1.9 Total comprehensive expense for the year	(2,641,088)	(4,113,966)

Consolidated accumulated losses

	30 June 2015 \$	30 June 2014 \$
1.10 Accumulated losses at the beginning of the financial year	(30,407,086)	(26,564,946)
1.11 Net loss attributable to members (<i>item 1.7</i>)	(2,645,684)	(3,842,140)
1.12 Accumulated losses at end of the financial year	(33,052,770)	(30,407,086)

2. Consolidated Statement of Financial Position

	As at 30 June 2015 \$	As at 30 June 2014 \$
Current assets		
2.1 Cash and cash equivalents	174,785	46,453
2.2 Trade and other receivables	18,872	70,171
2.3 Receivable from a related party	-	163,804
2.4 Inventories	12,376	300,239
2.5 Other current assets	280,196	300,936
2.6 Assets held for sale	495,142	-
2.7 Total current assets	981,371	881,603
Non-current assets		
2.8 Property, plant and equipment	67,642	425,324
2.9 Intangible assets	1,970,567	1,670,576
2.10 Financial assets	3,824,888	4,124,888
2.11 Total non-current assets	5,863,097	6,220,788
2.12 Total assets	6,844,468	7,102,391
Current liabilities		
2.13 Trade & other payables	420,437	1,003,641
2.14 Interest bearing liabilities	2,410,323	479,685
2.15 Non-interest bearing liabilities	175,435	-
2.16 Tax liabilities	(1,436)	176,207
2.17 Short term provisions	138,728	127,399
2.18 Liabilities associated with assets held for sale	116,664	-
2.19 Total current liabilities	3,260,151	1,786,932
Non-current liabilities		
2.20 Interest bearing liabilities	2,785,461	6,236,771
2.21 Long term provisions	52,265	71,536
2.22 Total non-current liabilities	2,837,726	6,308,307
2.23 Total liabilities	6,097,877	8,095,239
2.24 Net (liabilities)/assets	746,591	(992,848)
Equity		
2.25 Issued capital	33,582,742	29,345,275
2.26 Reserves	216,619	68,963
2.27 Accumulated losses	(33,052,770)	(30,407,086)
2.28 Total (deficiency)/equity	746,591	(992,848)

3. Consolidated Statement of Cash Flow

	For the year ended 30 June 2015 \$	For the year ended 30 June 2014 \$
Cash flows from operating activities		Restated
3.1 Receipts from customers	108,850	125,421
3.2 Payments to suppliers and employees	(2,468,082)	(1,857,001)
3.3 Government grants	70,511	55,588
3.4 Finance costs	(61,783)	(18,140)
3.5 Net cash flows used in operating activities	(2,350,504)	(1,694,132)
Cash flows from investing activities		
3.6 Interest receipts	5,077	3,485
3.7 Bank deposit	-	(37,950)
3.8 Proceeds from sale of investment	377,945	-
3.9 Payment for purchases of property, plant and equipment	(18,330)	(61,361)
3.10 Payment for purchases of other non-current assets	(553,445)	(104,945)
3.11 Receipts (payments) relating to discontinued operations	819,510	(722,676)
3.12 Net cash flows from (used in) investing activities	630,757	(923,447)
Cash flows from financing activities		
3.13 Proceeds from issues of securities	-	1,649,006
3.14 Share issue costs	(50,534)	(103,126)
Proceeds from third party loans	228,261	-
3.15 Proceeds from related party borrowings	1,882,683	1,196,710
3.16 Repayment of related party borrowings	(212,331)	(259,500)
3.17 Net cash flows from financing activities	1,848,079	2,483,090
3.18 Net (decrease)/increase in cash held	128,332	(134,489)
3.19 Cash at beginning of year	46,453	180,942
3.20 Cash and cash equivalents at end of year <i>(see reconciliation of cash)</i>	174,785	46,453

<u>Discontinued activities</u>	30 June 2015 \$	30 June 2014 \$
Operating activities	655,706	343,966
Investing activities	163,804	(2,212,634)
Financing activities	-	1,145,992
Total cash flows relating to discontinued activities	819,510	(722,676)

4. Consolidated Statement of Changes in Equity

	Issued capital \$	Foreign currency translation reserve \$	Share options reserve \$	Non-controlling interest \$	Accumulated losses \$	Total equity \$
Balance at 30 June 2013	27,799,395	340,789	247,337	5,167,531	(26,564,946)	6,990,106
Movement						
Loss for the year	-	-	-	-	(3,842,140)	(3,842,140)
Currency translation	-	(271,826)	-	-	-	(271,826)
Total comprehensive income for the year	-	(271,826)	-	-	(3,842,140)	(4,113,966)
Issue of share capital	1,654,120	-	-	-	-	1,654,120
Transaction costs on share issue	(108,240)	-	-	-	-	(108,240)
Employee share option plan	-	-	(247,337)	-	-	(247,337)
Deconsolidated component	-	-	-	(5,167,531)	-	(5,167,531)
Balance at 30 June 2014	29,345,275	68,963	-	-	(30,407,086)	(992,848)

	Issued capital \$	Foreign currency translation reserve \$	Share options reserve \$	Accumulated losses \$	Total equity \$
Balance at 30 June 2014	29,345,275	68,963	-	(30,407,086)	(992,848)
Movement					
Loss for the year	-	-	-	(2,645,684)	(2,645,684)
Currency translation	-	4,596	-	-	4,596
Total comprehensive income for the year	-	4,596	-	(2,645,684)	(2,641,088)
Issue of share capital	4,288,001	-	-	-	4,288,001
Transaction costs on share issue	(50,534)	-	-	-	(50,534)
Share options issued	-	-	143,060	-	143,060
Balance at 30 June 2015	33,582,742	73,559	143,060	(33,052,770)	746,591

5. Reconciliation of cash

Reconciliation of cash at the end of the year (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	30 June 2015 \$	30 June 2014 \$
5.1 Cash on hand and at bank	174,785	46,453
5.2 Total cash at end of period (item 3.20)	174,785	46,453

6. Earnings per security (EPS)

	30 June 2015	30 June 2014
6.1 Basic losses per share	(1.28 cents)	(2.35 cents)
6.2 Weighted average number of ordinary shares used as the denominator in calculating basic earnings per share	205,961,271	163,342,135
6.3 Diluted losses per share	(1.28 cents)	(2.35 cents)

7. NTA backing

	30 June 2015	30 June 2014
7.1 NTA backing per ordinary security	\$(0.01)	\$(0.02)

8. Segment Reporting

Year ended 30 June 2015	Consumable products	Separations	Corporate	Group result
	\$	\$	\$	\$
Revenue from sales or services	110,760	79,900	-	190,660
Income from outside operating activities:				
Grant income	36,906	376,584	-	413,490
Interest income	-	-	5,075	5,075
Other income	-	-	77,945	77,945
Discontinued operation result	800,428	-	-	800,428
Total segment income	948,094	456,484	83,020	1,487,598
Total segment profit/(losses) from continuing operations	89,672	248,778	(2,608,796)	(2,270,346)
Total segment (loss)/profit from discontinued operations	(375,338)	-	-	(375,338)
Total segment (loss)/profit from continuing & discontinued operations	(285,666)	248,778	(2,608,796)	(2,645,684)

Year ended 30 June 2014 - Restated	Consumable products	Separations	Corporate	Group result
	\$	\$	\$	\$
Revenue from sales or services	124,466	-	-	124,466
Income from outside operating activities:				
Grant income	81,065	275,147	-	356,212
Interest income	-	-	2,849	2,849
Discontinued operation result	798,312	-	44,703	843,015
Total segment income	1,003,843	275,147	47,552	1,326,542
Total segment profit/(loss) from continuing operations	106,349	(326,129)	(816,433)	(1,036,213)
Total segment (loss)/profit from discontinued operations	(257,081)	(2,593,549)	44,703	(2,805,927)
Total segment profit/(loss) from continuing & discontinued operations	(150,732)	(2,919,678)	(771,730)	(3,842,140)

Segment assets	Consumable products	Separations	Corporate	Total assets
	\$	\$	\$	\$
Opening balance 1 July 2014	863,841	1,949,859	4,288,691	7,102,391
Additions/disposals/others	(191,506)	397,386	(463,803)	(257,923)
Closing balance 30 June 2015	672,335	2,347,245	3,824,888	6,844,468

Matters subsequent to the end of the financial year

The following events occurred subsequent to the end of the financial year:

- On 21 July 2015 the Company lodged the R&D tax claim for an amount of \$328,838 which was approved by AusIndustry two days later.
- On 23 July 2015 the Company offered to the open market the sale of the interest in Prime Biologics Pte Ltd.
- On 10 August 2015 the Company announced the offer of a share purchase plan at a price of 2.7 cents per share.
- On 10 August 2015 the Company announced the start of an *in-vitro* clinical trial of its SpermSep separation device at the ASX-listed "Monash IVF" in Melbourne.
- On 24 August 2015 the Company announced that it will collaborate with the University of Melbourne, Department of Chemical and Biomolecular Engineering to develop hydrogel membranes with improved bio-compatibility and greater ability to cost-effectively manufacture at large scale.

Annual General Meeting

The annual general meeting will be held as follows:

Place	30 Richmond Road, Homebush West, NSW 2140
Date	Monday 19 th November 2015
Time	TBA
Approximate date the annual report will be available	Monday 12 th October 2015

Compliance statement

- 1 The report has been prepared in accordance with the Corporations Act 2001, the recognition and measurement criteria of Accounting Standards and Urgent Issues Group Interpretations, and complies with other requirements of the law. Accounting Standards, include Australian equivalents to International Financial Reporting Standards "AIFRS". Compliance with AIFRS ensures that the consolidated financial statements and notes of the consolidated entity comply with International Financial Reporting Standards "IFRS".
- 2 This report, and the accounts upon which the report is based, use the same accounting policies.
- 3 This report does give a true and fair view of the matters disclosed.
- 4 This report is based on accounts that are in the process of being audited. Details of any qualifications will follow immediately they are available.
- 6 The entity has a formally constituted Audit Committee.

Signed:

Name: Alison Coutts
 Chairman

Date: 31 August 2015