



**Clover Corporation Limited**

ABN 85 003 622 866

**ASX ANNOUNCEMENT      25<sup>th</sup> May 2016**

## **Top-line results from the clinical research study, N3RO**

### **- Testing DHA emulsion for improved outcomes in premature infants.**

25 May 2016, Clover Corporation (ASX:CLV), a science-based Bioactives company developing novel nutritional applications of DHA, today announced the release of initial results from the clinical research study called the N3RO trial. Clover has been informed by the responsible researchers at the South Australian Health and Medical Research Institute (SAHMRI), of the first results from the clinical trial, established to test potential benefits of its high DHA emulsion for the health and development of premature infants.

Early indications, as reported by SAHMRI, are that the clinical research study has not met its primary endpoint of a statistically significant 10% reduction in the incidence of bronchopulmonary dysplasia (BPD) a lung condition common in premature babies, when the high DHA treatment was compared with a placebo emulsion. The final results will be available when the full report is compiled, further analysis of these results will determine next steps for the program.

1273 infants born before 29 weeks of gestational age were enrolled in the N3RO trial. A proprietary emulsion high in the omega 3 fatty acid DHA was administered to half of these babies as a component of their nutrition, along with standard treatments currently considered optimal for their successful development. The rest of the group received a placebo emulsion. A variety of parameters indicating the health and development of the treated infants was measured.

The N3RO trial follows on from positive outcomes in a previous Phase II trial named DINO (Docosahexaenoic Acid for the Improvement of Neurodevelopmental Outcome) in which Preterm infants whose diet was supplemented with DHA showed improved cognitive development in girls at 18 months, reduced oxygen requirement at 36 weeks in boys and reduced incidence of hay fever later in their development. The N3RO clinical research study commenced in 2013 after receiving funding support from the National Health and Medical Research Centre and product support from Clover Corporation. The clinical research study has involved hospitals in Australia, New Zealand and Singapore. Over the course of the project Clover Corporation has invested \$1.235M in product development, professional services and people.

"We are clearly disappointed in this early report of the top-line results from the N3RO study. However, we remain committed to better understanding the full data set as we consider potential paths forward for the DHA emulsion product," said Peter Davey, CEO & Managing Director of Clover Corporation. "With strong clinical results from the previous DINO study and high tolerability of the DHA formulation we will continue to seek a viable path forward for the development of DHA emulsions in this and wider clinical applications."

In October 2015 Clover Corporation licensed the development and commercialisation rights of the DHA emulsion product for the treatment of premature babies to Premneo Pharmaceuticals Pty Ltd. This step was taken in anticipation of a positive outcome from the clinical research study, in order to accelerate the market launch of the DHA emulsion product into the Pharmaceutical market. On the basis of the top line result Premneo Pharmaceuticals Pty Ltd has decided to terminate the licence agreement with Clover Corporation.

Clover Corporation's core business remains the manufacture and sale of encapsulated Omega 3 and 6 oils supplied as ingredients into food, pharmaceutical and infant formula products. Increased demand in China and changing regulations in the European Union and China provide opportunities for additional growth in the future. This will be supported by the commencement of commercial production of encapsulated products at the New Zealand spray drying facility in which Clover has invested \$1m over the past 18 months.

At the January half year, sales revenue had shown grown to \$19.9 million, an increase of 24% compared with the same period in the previous year. This was a result of both Clover securing additional customers and growing global demand for infant formula. As indicated at the time these results were released, orders have continued to grow and will be reflected in a stronger second half for the 2016 financial year, ending July 31st. The DHA emulsion product was not expected to provide a material return to Clover Corporation in the near term as product registration, manufacturing and distribution would have begun in earnest on a successful result.

**For further information, please contact:**

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**About Clover Corporation Limited**

Clover Corporation is an Australian company listed on the Australian Stock Exchange (ASX:CLV). Clover has evolved from being a research and development, manufacturing and marketing company to one concentrating on forming strategic relationships focused on technology, new product development and commercialisation.

Clover's superior microencapsulation technology enables nutritional oils, such as tuna, fish, algal and fungal oils, to be added to infant formula, foods and beverages. Developed through extensive research and development, our proprietary technologies protect those sensitive oils from oxidation, allowing them to be incorporated into a range of applications. All of our ingredients reach the highest standards of purity, stability and performance, allowing customers to deliver and maximise nutritional benefits to consumers of their products.

For more information about Clover visit [www.clovercorp.com.au](http://www.clovercorp.com.au)