



ASX Announcement

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## **Creso continues to fast-track commercialisation with binding LOI for new human and animal health cannabinoid-rich nutraceutical products**

### **Highlights:**

- **Creso secures binding LOI with high-tech Swiss food and pharma development company, Domaco, Dr. med Aufdermaur AG.**
- **Domaco is a leading European producer of innovative products for global pharmaceutical and food companies such as Blackmores, Bayer, Danone, Angelini and others and is an own-label manufacturer specialising in buccal delivery technologies.**
- **LOI is for the development, manufacture and commercialisation of two new second-generation cannabinoid-rich nutraceutical products using fast-acting buccal absorption delivery technologies for human health, complementing Creso's first-generation products in development.**
- **Agreement also includes the development of a new animal health nutraceutical product for companion animals with an innovative delivery technology.**
- **The two new human nutraceutical products will target the management of anxiety and stress and bone metabolism disorders, specifically osteoporosis and osteoarthritis.**
- **The animal product will target several conditions including behavioral-based disorders, chronic pain, inflammation, arthritis and metabolic conditions such as diabetes in companion animals.**
- **Commercialisation will be in collaboration with commercial partners targeting Switzerland, key European countries, Latin America and Australia.**

**Creso Pharma Limited** (ASX:CPH, the "Company") is pleased to announce that it has signed a binding Letter Of Intent (LOI) with Swiss-based food and pharma development company, Domaco, Dr. med Aufdermaur AG (Domaco), for the development and commercialisation of new cannabinoid-rich nutraceutical products for human and animal health.

Under the agreement, the two parties will work together on the development, manufacture and commercialisation of two human health cannabinoid-rich nutraceutical products: one for the management of anxiety and stress and one for the management of bone metabolism disorders (osteoporosis and osteoarthritis). They will also develop one animal health nutraceutical product for companion animals.

Nutraceuticals are naturally nutrient-rich pharma-grade standardised food or dietary supplements that you eat or drink in order to strengthen and maintain good physical and mental health.



## **About the products**

The two new products for human health are Creso's second-generation cannabinoid-rich nutraceuticals for anxiety and stress and bone metabolism and complement Creso's first-generation nutraceutical products based on the INNutri Soft Gums™ technology. While the first-generation product aims to up-regulate the endocannabinoid system and relieve symptoms, the new products complement the first-generation nutraceuticals by providing a faster mode of action.

The new animal health product follows the two proprietary-formulation animal feed CBD-based nutraceutical products for companion animals, which received EU registration earlier this year.

The new human products will use new buccal delivery technology systems allowing absorption via the rich blood vessels in the mouth, ensuring high absorption and enhanced bioavailability of the full plant hemp extract and its cannabinoids, and will also be standardised in doses and formulations.

The animal product will use a novel formulation adapted for veterinary use, intended for companion animals, specifically dogs and horses.

### ***The human stress and anxiety product***

Creso's new second-generation nutraceutical product for anxiety and stress offers a fast-acting innovative alternative therapeutic option designed to enhance improved mental focus and stress reduction while avoiding the gastrointestinal side effects and addiction dependency found with many alternative therapies.

#### *Clinical rationale*

The hypothalamic–pituitary–adrenal axis (HPA axis) is a major neuroendocrine system that controls reactions to stress and regulates many body processes, including digestion, the immune system, mood and emotions, sexuality and energy storage and expenditure. Stress activates the HPA axis and triggers a hormonal cascade involved in mood disorders, including anxiety.

The endocannabinoid system and CBD in particular, modulates the HPA axis and mediates the response to stress. Balancing the endocannabinoid system is pivotal in generating healthy stress responses (as opposed to an overcompensated one) - mitigating excessive fear, anxiety, and panic that can accumulate with dysfunctional responses to stress.

In various preclinical animal models, CBD has been shown to reduce stress-induced anxiety responses. In initial human experiments, CBD has been shown to reduce subjective anxiety in patients with social anxiety disorder.

### ***The bone metabolism product***

Osteoporosis and osteoarthritis are degenerative bone diseases. Osteoporosis is the most common bone disease, resulting from an imbalance in normal bone remodeling and is a chronic condition. It leads to loss of bone mineral content and mass, structural abnormalities, bone weakening, increased risk of fracture and poor healing. Osteoarthritis is a result of trauma, infection, and/or age (wear and tear), and leads to stiffness, chronic and often severe pain, and limited mobility, primarily in the hands, feet, hips and spine.



Current treatments are anti-inflammatory drugs, pain medication, and joint replacement with many potential side effects (stomach ulcers, increased risks of blood clots, cardiac problems). Creso's new first-generation nutraceutical product for bone metabolism is designed to offer an innovative alternative therapeutic option to support the regulation of bone metabolism and bone health while avoiding gastrointestinal and cardiac side effects found with many alternative therapies.

### *Clinical rationale*

Current evidence suggests that exogenous CBD may offer a new and safe approach to manage the conditions and complications of osteoporosis and osteoarthritis and possibly other bone diseases and their complications. Cannabinoid receptors have been shown to be vital for the regulation of bone metabolism and bone health by helping to maintain the balance between osteoclasts and osteoblasts.

In animal models of osteoporosis and osteoarthritis, CBD has been shown to prevent bone loss and stimulate bone formation, as well as to promote maturation of collagen, improve fracture healing, and reduce inflammatory processes. Experience in humans suggests that CBD has a good safety profile.

### ***The veterinary product***

The new veterinary nutraceutical product will target a range of conditions including behavioral-based disorders (such as anxiety linked to separation, loud noise, travel, crowds), chronic pain, inflammation, arthritis, and metabolic conditions such as diabetes. These are very common ailments afflicting companion animals. It will enhance and enrich the lives of pets, and consequently, their owners.

The number of treatment options available to veterinarians are limited, and available treatments are often human therapies that are poorly adapted to animals. This new animal health nutraceutical product will be specifically formulated for various companion animal segments, and contain very low THC (the psychoactive component of cannabis) at levels below legal thresholds.

### **Market opportunity**

Both the human and animal health markets are important markets for Creso:

- The anxiety and stress markets were worth approximately \$US3.5 billion in 2015<sup>1</sup>.
- The global osteoporosis market is expected to reach approximately \$US14.3 billion by 2021, growing at a CAGR of around 4.0% between 2016 and 2021<sup>2</sup>.
- The osteoarthritis market was valued at \$US5.132 billion in 2015, and is expected to reach \$US5.896 billion by 2022<sup>3</sup>.
- The veterinary health market is estimated to be worth \$US39.7 billion by 2021<sup>4</sup>.

<sup>1</sup> Source: IMS Health, MIDAS, December 2015.

<sup>2</sup> Source: Zion Market Research: <https://globenewswire.com/news-release/2016/11/14/889630/0/en/Global-Osteoporosis-Drugs-Market-will-reach-USD-around-14-30-Billion-by-2021-Zion-Market-Research.html>

<sup>3</sup> Source: Credence Research: <http://www.biopharmadive.com/press-release/20160511-forecast-report-global-osteoarthritis-treatment-market-size-share-growt/>

<sup>4</sup> Source: Mordor Intelligence, [https://www.mordorintelligence.com/industry-reports/global-veterinary-animal-healthcare-market-industry?gclid=Cj0KEQjwhbzABRDHw\\_i4q6fxoLIBEiQANZKGW4D-M9PWyi7pnUEiajZ9YB0ZbK-f90LaU9pfumyAl8caArjj8P8HAQ](https://www.mordorintelligence.com/industry-reports/global-veterinary-animal-healthcare-market-industry?gclid=Cj0KEQjwhbzABRDHw_i4q6fxoLIBEiQANZKGW4D-M9PWyi7pnUEiajZ9YB0ZbK-f90LaU9pfumyAl8caArjj8P8HAQ)



### **LOI development timeline**

Under the terms of the LOI, Domaco will develop the products using Creso's full-plant CBD hemp extracts. The development will include full formulation and analytics development, production of lab samples, pilot batches, and validation batches for stability testing. Domaco will manufacture and package the products and Creso will pay a manufacturing fee on a cost of goods sold basis. Creso will retain full ownership and IP rights of the developed end products.

Commercialisation of the end products will be in collaboration with commercial partners targeting Switzerland, key European countries, Latin America and Australia.

Domaco will also have the option to sell the products as Creso's distributor or third party.

The Company expects to have the new second-generation human anxiety and stress nutraceutical product in this new delivery technology available for sale in 1H2018, and the first-generation nutraceutical product for osteoporosis and osteoarthritis in 1H2019. The animal product in the new delivery technology is expected to be launched in 1H2018.

"Creso continues to make significant progress in broadening the pipeline with innovative nutraceutical products derived from CBD full-plant hemp extracts for both human and animal health. This LOI, with a Swiss leader in the development and manufacturing of food and pharma products, is another key milestone to establishing our leadership position in the field of hemp and cannabis derived therapeutics," said Creso Pharma Group CEO and Co-Founder, Dr. Miri Halperin Wernli.

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### **About Creso Pharma**

Creso Pharma brings pharmaceutical expertise and methodological rigour to the world of medical cannabis and strives for the highest quality in its products. It is the leader in cannabidiol (CBD) innovation and develops cannabis- and hemp-derived therapeutic-grade CBD nutraceuticals and medical cannabis products with wide patient reach for human and animal health. Creso uses GMP development and manufacturing standards for its products as a reference of quality excellence with initial product registrations in Switzerland. It has worldwide rights for a number of unique and proprietary innovative delivery technologies which enhance the bioavailability and absorption of cannabinoids. The Company is already generating revenues via its subsidiary, Hemp-Industries.

### **About Domaco, Dr. med Aufdermaur AG**

Domaco, Dr. med Aufdermaur AG is a Swiss-based food and pharma development company that owns the rights to a number of innovative delivery systems used to administer active ingredients through galenic forms which is a way of preparing and compounding medicines in order to optimise their absorption.