18 July 2022

Creso Pharma's wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. making progress ahead of its planned Phase II clinical trials

Highlights:

- **Following strong inbound interest, Halucenex has made the strategic decision to broaden the scope of its planned phase II clinical trial and apply for a further amendment to its Clinical Trial Authorisation ("CTA") from Health Canada**
- **If granted, the updated CTA will allow Halucenex to include cohorts using Selective Serotonin Reuptake Inhibitors and not require patients to cease using prescribed medications a week prior to trial commencement**
- **A broadened CTA would provide Halucenex with additional trial data, allow a larger spectrum of patients and valuable insight into how psilocybin interacts with other medications**
- **Appointment of KGK Science Inc. ("KGK") as contract research organisation provides additional expertise in a more cost effective manner**
- **KGK is a premium full service research organisation dedicated to providing clinical trial research that meets the highest quality standards**
- **Doctor of medicine and neurologist Dr Gosia Eve Phillips, MD, DABPN appointed as Principal Investigator**
- **Dr Phillips is an esteemed medical professional and has educational training from the University of Massachusetts Medical School, Columbia University and Harvard University**
- **Final submissions to ethics review board made and are now pending ethics approval**

Creso Pharma Limited (ASX:CPH, OTC:COPHF, FRA:1X8) ('Creso Pharma' or 'the Company') is pleased to advise that wholly-owned, Canadian based psychedelics company, Halucenex Life Sciences Inc. ("Halucenex") has executed on a number of milestones making progress ahead of its planned phase II clinical trials to test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD).

Application for amendments to Clinical Trial Authorisation ("CTA") from Health Canada:

Following a material number of enquiries from potential trial participants, Halucenex has made the strategic decision to apply for amendments to its currently approved CTA (refer ASX announcement: 28 February 2022) to include cohorts that are currently utilising Selective Serotonin Reuptake Inhibitors (SSRIs) and not require potential patients to stop using prescribed medications for a week prior to the potential Phase II trials' commencement.

The decision comes following ongoing engagement with potential patients, veterans affairs groups and the general public and will broaden the scope of the planned clinical trials. It will also provide Halucenex with additional data on how psilocybin interacts when used in combination with other medication commonly used by PTSD sufferers.

The Company anticipates that the receipt of an amended CTA should occur shortly, and subject to ethics approval, this will allow Halucenex to complete patient recruitment initiatives and begin administering first dosages.

Appointment of KGK Science Inc. as contract research organisation:

Following an ongoing review of service providers, Halucenex has also engaged leading research organisation, KGK Science Inc. ("KGK") to assist with clinical trial initiatives. As a premium full-service contract research organisation, KGK is dedicated to providing clinical trial research that meets the highest quality standards. Led by a team of scientific research and regulatory experts, KGK combines cutting-edge clinical science with industry expertise to design clinical trials and claim substantiation strategies customised to meet the needs of clients.

The Company has made the decision to appoint KGK following a review of clinical trial service providers. KGK will replace previously appointed investigator True North Clinical Research (refer ASX announcement: 17 March 2021), due to the group's expertise in pharmaceuticals and natural health products and cost effectiveness.

Under its research services agreement with Halucenex, KGK will perform research services, including the development of the clinical trial protocol, preparations towards the Phase II clinical trials, data management and validation, statistical analysis and drafting of the final report ("Services"), for which the total set compensation payable to KGK by Halucenex will be CAD$339,440. The term of the Agreement will run until KGK has completed all services contemplated under the Agreement ("Expiry"), unless KGK terminates the Services at any time by providing Halucenex with 30 days of notice before the Expiry.

Dr Gosia Eve Phillips, MD, DABPN appointed as Principal Investigator:

Dr Phillips is a doctor of medicine and certified neurologist. She earned her Doctor of Medicine in 2001 and has also undertaken various educational practises through the University of Massachusetts Medical School, Columbia University and the Beth Israel Deaconess Medical Centre, Harvard University. Dr Phillips' certifications include a licentiate of the Medical Council of Canada, a Diplomate, American Board of Psychiatry and Neurology, as well as a Diplomate, American Board of psychiatry and Neurology (subspecialty sleep medicine).

She has been recognised through the receipt of a number of awards including The Nickols Award, Department of Neurology, University of Massachusetts, The Practice-Based Learning Award, Department of Neurology, University of Massachusetts and The Professional Competency Award, Department of Neurology, University of Massachusetts.

As Principal Investigator, Dr Phillips will assist the Company as the physician leading the conduct of the clinical trial at the study site. Halucenex will leverage her extensive experience and background during additional trial preparation initiatives, throughout the trial and following to progress potential research or cooperative grants with government bodies and other large pharmaceutical companies.

Final submissions made to Ethics Review Board:

Halucenex has also successfully lodged its final submissions with the Ethics Review Board, on which an outcome is expected shortly. Ethics approval is a key component to the research process, which protects both patients and researchers during the initiative. The approval would be a major milestone for the Company and is expected to assist any future R&D initiatives undertaken by Halucenex in the ongoing use of psilocybin across various conditions.

Commentary:

Halucenex CEO and Founder Mr Bill Fleming said: *"In the recent months, Halucenex has made considerable progress towards the commencement of what has the potential to be a ground-breaking research initiative. We have been completely inundated from several groups regarding potential participation in the study, highlighting the demand for an alternative treatment solution to pharmacological interventions. Further, by lodging an application to extend the scope of our CTA, we are expecting benefits from the additional data that the broadened scope will provide, including observing how psilocybin interacts with other medication being used as treatment for PTSD.*

"We are confident that the appointment of both KGK and Dr Phillips will also be beneficial for the Company. KGK has extensive experience with pharmaceutical drug testing and development and provides a much more cost effective service offering. The appointment of someone as esteemed as Dr Phillips is also a great development for Halucenex. We look forward to working with both parties in the coming weeks.

"The Board and management will continue working with the independent ethics board and Health Canada for final approvals and expect additional updates to materialise shortly."

-Ends-

Authority and Contact Details

This announcement has been authorised for release by the Disclosure Committee of the Board of Directors of Creso Pharma Limited.

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About Creso Pharma

Creso Pharma Limited (ASX:CPH) brings the best of cannabis to better the lives of people and animals. It brings pharmaceutical expertise and methodological rigor to the cannabis world and strives for the highest quality in its products. It develops cannabis and hemp derived therapeutic, nutraceutical, and life style products with wide patient and consumer reach for human and animal health.

Creso Pharma uses GMP (Good Manufacturing Practice) 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. To learn more please visit: www.cresopharma.com

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About KGK Science Inc.

KGK Science Inc. provides high-quality clinical research trials and expert regulatory support for the nutraceutical, cannabis and hemp industries. For over 22 years, KGK has successfully helped hundreds of companies with custom designed clinical trials and claim substantiation strategies to move products efficiently into global markets. During this period, KGK has participated in 350+ clinical trials across 40+ indications, and collected over 10 million data points.

Forward Looking statements

This announcement contains forward-looking statements with respect to Creso and its respective operations, strategy, investments, financial performance and condition. These statements generally can be identified by use of forward-looking words such as "may", "will", "expect", "estimate", "anticipate", "intends", "believe" or "continue" or the negative thereof or similar variations. The actual results and performance of Creso could differ materially from those expressed or implied by such statements. Such statements are qualified in their entirety by the inherent risks and uncertainties surrounding future expectations. Some important factors that could cause actual results to differ materially from expectations include, among other things, general economic and market factors, competition and government regulation.

The cautionary statements qualify all forward-looking statements attributable to Creso and persons acting on its behalf. Unless otherwise stated, all forward-looking statements speak only as of the date of this announcement and Creso has no obligation to up-date such statements, except to the extent required by applicable laws.