



6 October 2021

Creso Pharma's wholly-owned psychedelics subsidiary continues to make strong progress ahead of its planned clinical trial

Stability testing now underway:

- Halucenex has commenced stability testing work for its GMP grade psilocybin with R&D partner Nucro-Technics
- Stability testing is utilised to determine if the quality of a substance is altered over time by various environmental factors
- Seven and fourteen day testing initiatives now underway with data to be added to Clinical Trial Authorisation documentation prior to submission to Health Canada
- Test work is a pivotal step in Halucenex's USP 61 and USP 62 testing protocol
- Stability testing expected to add to the growing body of evidence for the use of psilocybin, Halucenex's ongoing data capture and IP ahead of phase II clinical trial
- Stability test work is also an important and necessary step for future product commercialisation initiatives
- Results expected to be reported in the coming weeks

Creso Pharma welcomes TGA-commissioned Independent Expert Report on Psilocybin and MDMA:

- TGA report highlights that psychedelic substances could potentially be used to treat treatment-resistant mental illnesses
- Marks a major development in the potential for the TGA to down-schedule psilocybin and MDMA from schedule 9 (prohibited drug) to schedule 8 (controlled drug)
- Full report will now be considered by the Advisory Committee of Medicines Scheduling with a final decision regarding down scheduling expected in December 2021
- Highlights the ongoing shift and acceptance of psychedelic treatments as an alternative therapy to debilitating conditions
- Creso Pharma continues to explore Australian based R&D initiatives with pending and potential favourable regulatory shift set to be the catalyst for local expansion efforts
- Multiple Australian focused research programs currently being explored to capitalise on potential local market opportunity

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 commenced stability testing initiatives for its GMP grade psilocybin. This marks a critical component for the Company's planned phase II clinical trial and future drug development initiatives.

The Company also welcomes a recently released report from the Therapeutic Goods Administration (TGA), evaluating the therapeutic value, benefit and risks associated with the use of psilocybin and



MDMA for the treatment of mental health conditionsⁱ. The report highlights the ongoing shift towards psychedelics in Australia, which Creso Pharma plans to leverage for local expansion initiatives in the near term.

Stability testing underway to progress Clinical Trial Authorisation (CTA) from Health Canada:

The Company is pleased to advise that Halucenex has now commenced stability testing protocols, which will provide additional validation of its GMP grade psilocybin. Testing is underway alongside leading R&D partner Nucro-Technics (refer ASX announcement: 6 May 2021) and will take approximately three weeks to complete.

Stability testing is an important step in drug development and is utilised to determine if the quality of a drug substance or product is altered over time by various environmental factors including light, temperature and humidity.

Halucenex will now test a range of samples over a seven and fourteen-day period to ensure its psilocybin is fit for human consumption. This data will also allow Halucenex to progress its Clinical Trial Authorisation (CTA) with Health Canada, allowing the commencement of the Company's planned phase II clinical trial into the efficacy of psilocybin when used for the treatment of treatment-resistant Post Traumatic Stress Disorder. The data captured from the initiative will also be crucial for future drug and product development initiatives containing Halucenex's GMP grade psilocybin.

The Company expects to update the market upon completion of the testing protocols and subsequent results in the coming weeks.

Creso Pharma and Halucenex welcome TGA-commissioned, independent report on psilocybin and MDMAⁱ:

Both Creso Pharma and Halucenex are pleased to advise that Australia's Therapeutic Goods Administration has released an independent expert panel report which highlights that psychedelic substances could potentially be used to treat treatment-resistant mental illnesses, when used in closely supervised clinical settings, with intensive professional support.

This marks a major development in the potential for the governing body to down-schedule psilocybin and MDMA from schedule 9 (prohibited drug) to schedule 8 (controlled drug), pending a review into the therapeutic value, risks and benefits to public health outcomes for these substances. The current rescheduling consideration follows the 2016 down scheduling of medicinal cannabis from schedule 9 to schedule 8.

The publishing of the report followed a systematic literature review undertaken by an independent panel of experts to review the treatment of mental health conditions and highlights the ongoing shift towards evolutionary therapies.

A final decision by the TGA is expected to occur in early December 2021. Creso Pharma is currently exploring a number of Australian-based R&D and clinical trial initiatives, which it will pursue upon a favourable shift in legislation.

The Company has developed a large body of evidence for the use of psilocybin as an alternative treatment route, which it will leverage to progress opportunities in the local market. Creso Pharma aims to capture a material share of the Australian market as a first-mover, which has the potential to unlock considerable value for shareholders.

**Commentary:**

Non-Executive Chairman, Mr Adam Blumenthal said: *"The recently published report from the TGA highlights the ongoing shift and acceptance towards the use of psychedelic substances as alternative treatment routes and coincides with a pivotal step in the Company's USP 61 and USP 62 testing initiatives.*

"The report highlights that both psilocybin and MDMA have potential therapeutic benefits, when used in the correct setting. We are confident that the data generated through our planned phase II clinical trial will also echo this claim.

"The Management team has been exploring potential opportunities in the Australian market for some time and the TGA's recent announcement validates the potential opportunity that Creso Pharma has at its disposal in Australia, we look forward to its final decision and leveraging this to progress a number of domestic opportunities which have the benefit to unlock considerable value for shareholders."

Halucenex founder and CEO, Bill Fleming said: *"Stability testing is an important part of our USP 61 and USP 62 protocol work, as well as future drug development and one of the final steps that needs to be undertaken to finalise our documentation for Clinical Trial Authorisation.*

"Given the excellent quality of our psilocybin, we anticipate that the Company will witness positive results from the rigorous testing protocols and we expect that the data generated will assist in a number of future initiatives.

"Halucenex continues to make pleasing operational progress, while simultaneously exploring additional opportunities to drive growth. We look forward to providing additional updates on results and as other developments materialise."

-Ends-

Authority and Contact Details

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

For further information, please contact:

Released through:

Ben Jarvis, Six Degrees Investor Relations

Ph: +61 (0) 413 150 448

E: ben.jarvis@sdir.com.au

Investor Enquiries

Creso Pharma Limited

E: info@cresopharma.com

P: +61 (0) 497 571 532

Enquiries can be texted to +61 (0) 497 571 532

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

Creso Pharma offices:

Australia

Suite 5 CPC, 145 Stirling Hwy, Nedlands, WA, 6009

Switzerland

Allmendstrasse 11, 6310 Steinhausen, Schweiz

Canada

59 Payzant Driver, Windsor, Nova Scotia, B0N 2T0

Canada

50 Ivey Ln, Windsor, Nova Scotia, B0N 2T0

About Halucenex Life Science:

Halucenex is a life sciences development company with a focus on researching novel psychedelic compounds, developing and licensing psychedelic compounds for the pharmaceutical and nutraceutical markets, and conducting clinical trials on the medical benefits of psychedelic medicine. Halucenex operates a 6000 sq. ft. medical facility in Windsor, Nova Scotia with 6 treatment rooms and a secure laboratory dedicated to performing psychedelic-assisted psychotherapy and clinical research. Halucenex intends to maintain control over all aspects of the product development process – mycological research, extraction technology, and synthetic formulation as well as drug delivery technologies, psychedelic-assisted psychotherapy and regulatory affairs.
www.halucenex.com

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.

¹ <https://www.tga.gov.au/independent-expert-panel-mdma-and-psilocybin>