



8 November 2021

Creso Pharma's wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. receives positive USP 61 and USP 62 results, completing major step towards phase II clinical trial

Highlights:

- **Halucenex completes all USP 61 and USP 62 testing requirements and secures positive lab test results for psilocybin active pharmaceutical ingredient ("API") – API is now deemed safe for human consumption ahead of phase II clinical trial**
- **Favourable test results highlighted superior concentration of between 98.6% and 99.8% in GMP grade psilocybin with minor impurity levels**
- **Successful test results validate Halucenex's relationship with Canada's only synthetic psilocybin manufacturer – Company has ample supply to progress clinical trials**
- **Seven and 14-day stability testing protocols completed – results further outline superior quality of psilocybin API**
- **Additional 30-day stability testing to commence shortly – positive results from the 30-day stability testing would allow Halucenex to progress international opportunities with its psilocybin API**
- **Multiple international R&D opportunities are being explored prior to receipt of additional stability testing results**
- **Positive test results allow Halucenex to progress Clinical Trial Authorisation ("CTA") filing with Health Canada – expected to be lodged within weeks**
- **CTA allows for commencement of planned phase II clinical trial to test efficacy of psilocybin API on treatment resistant Post Traumatic Stress Disorder ("PTSD")**
- **Clinical trial expected to commence during Q2 CY2022 with ethics approval and patient recruitment initiatives to occur during Q1 CY2022**
- **Access to the PTSD therapeutics sector is a potential major market opportunity for Creso Pharma with the sector expected to grow to US\$10.5Bn in value by 2025ⁱ**

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 completed all USP 61 and USP 62 testing requirements and received exceptional results from laboratory testing initiatives which highlight the superior quality of Halucenex's psilocybin API.

The completion of testing and subsequent, favourable results marks a major milestone in the commencement of the Company's planned phase II clinical trial to test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD).

The USP 61 test provides enumeration of mesophilic bacteria and fungi that may grow under aerobic conditions. This test provides the total number of aerobic organisms, yeast, and mould present within



a sample. The sample is typically diluted, plated, and then incubated with results used to determine whether or not compounds can be used for human testing.

A USP 62 test evaluates a product for the presence or absence of potential pathogens. USP 62 tests are necessary for cosmetic and personal products to determine that any microorganisms that may be present in a product are not specific pathogenic microorganisms of particular concern if found in a consumer product.

Testing was undertaken alongside leading R&D partner Nucro-Technics (refer ASX announcement: 6 May 2021) and highlighted that Halucenex's psilocybin API samples showed a concentration range of between 98.6% and 99.8%, highlighting the minimal impurity and superior quality. Halucenex also completed both seven and 14-day stability testing of samples, further highlighting the product's high grade. Importantly, the results deem the Company's products safe for human consumption.

Halucenex can now progress the final steps in lodging its Clinical Trial Authorisation (CTA) with Health Canada. Halucenex expects to file this with Health Canada before the end of November 2021, which will be subject to a 30-day review by the regulating body. Receipt of the CTA will allow Halucenex to progress its planned phase II clinical trial by Q2 CY2022.

The Company's clinical trial will test the use of psilocybin on treatment resistant PTSD and is expected to provide access to a number of opportunities in the PTSD therapeutics sector, which is estimated to be valued at US\$10.5Bn by 2025¹.

The proposed phase II clinical trial is designed to be a single-arm, open-lab trial that will ultimately determine the feasibility of future trials of psilocybin in this indication. It is planned that 18 to 20 individuals (over 18 years old) that suffer from treatment resistant PTSD will be enrolled in the trial. Additional work towards trial design and ethics approval is well progressed, in collaboration with Acadia University (refer ASX announcement: 20 September 2021).

Commentary:

Halucenex CEO and Founder Mr Bill Fleming, added: *"We are very pleased to have achieved such outstanding testing results. These highlight the significantly high grade and concentration of our GMP grade psilocybin samples, which is another key competitive advantage for Halucenex and the Creso Pharma group of companies.*

"We will now finalise our CTA and submit to Health Canada in the coming weeks. Clinical Trial Authorisation is the final piece in the commencement of our planned initiatives, which will unlock a number of substantial opportunities for the Company.

"Following the 30-day review from Health Canada and potential CTA grant, we will be able to commence the ethics approval and patient recruitment process. Sadly, treatment resistant PTSD is widespread, so we anticipate that patient recruitment will be seamless and finalised during Q1 CY2022, ahead of trial commencement shortly thereafter. Additional work is underway across product development and clinical trial design and we look forward to updating shareholders regularly over the coming months."

Non-executive Chairman, Mr Adam Blumenthal said: *"The completion of this test work highlights a significant advancement in our efforts to commence the planned phase II clinical trial. The results highlight that the Company's product is stable and safe for human consumption and will make up a large part of our CTA.*



“Halucenex has made very pleasing progress since becoming part of the Creso Pharma group and we look forward to working alongside Bill and his team as it begins to scale operations ahead of the clinical trial. This is a major opportunity for Creso Pharma to become a market leader in the psychedelics sector.”

Correction to ASX release dated 4 November 2021:

The Company wishes to make the following correction to the Company’s ASX announcement dated 4 November 2021. The announcement stated that recently appointed strategic consultant Hon. Dr Brian Walker MLC was a director of Mind Medicine Australia. Creso Pharma advises that Dr Walker does not hold a position on the Board of Mind Medicine Australia.

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Authority and Contact Details

This announcement has been authorised for release by 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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Forward Looking statements

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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 Credence Research PTSD Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026