



17 March 2021

## **Halucenex Life Sciences Inc. appoints True North Clinical Research as lead investigator for Phase II Clinical Trial**

### **Highlights**

- **Phase II Clinical Trial will test the efficacy of psilocybin on the treatment of treatment resistant Post Traumatic Stress Disorder (PTSD) in veterans and first responders**
- **True North is a leading research provider with strong ties to the veteran community**
- **Halucenex to leverage True North's extensive experience, established research team and facilities to progress trial initiatives**
- **Trial expected to commence in June 2021 with results anticipated during H2 CY2021**
- **PTSD therapeutics market is expected to grow to US\$10.5Bn by 2025<sup>i</sup> - highlighting a major opportunity for Creso Pharma and Halucenex**
- **Halucenex CEO Bill Fleming to replace Dr Miri Halperin Wernli as a director of Creso Pharma upon completion of the transaction.**

**Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company')** is pleased to advise that target acquisition company, Halucenex Life Sciences ("Halucenex"), has appointed True North Clinical Research ("True North") as the principal investigator for its proposed Phase II Clinical Trial which will test the efficacy of psilocybin for the treatment of treatment resistant Post Traumatic Stress Disorder ("PTSD") in veterans and first responders.

Halucenex, which is set to become part of the Creso Pharma Group (refer ASX announcement: 15 March 2021), is a life sciences development company focused on researching, developing and licencing novel psychedelic molecules for the global pharmaceutical and nutraceutical markets.

True North is a leader in R&D, focused on implementing industry best practises and providing the highest quality of care during clinical trial initiatives. The group has a team of highly qualified research staff and all work undertaken adheres to stringent regulatory guidelines. True North also has strong ties to the Canadian armed forces and veterans, which will be imperative to the trial.

As lead investigators, True North will provide clinical oversight into the trial, assist with facilitation of compliancy with the Nova Scotia Ethics Committee, undertake patient recruitment initiatives, conduct the trial, monitoring, data capture and compilation of results and ensure follow up measures are taken to ensure participant safety.

Halucenex chose to engage True North because its locations are geographically favourable for participants, its team of over 30 clinicians have considerable experience in providing patient care and the group's CEO Dr Mark Johnson has considerable experience with the Armed Forces, developed over a 20-year career as a psychiatrist with various military organisations.

The trial is a Phase II, single-arm, open-label trial to determine the efficacy and safety of psilocybin in subjects with treatment-resistant PTSD, and ultimately to determine the feasibility of future trials of psilocybin in this indication. Approximately 18 to 20 subjects (18 years or older) with treatment-



resistant PTSD will be enrolled into the trial, which will be conducted at one study site. Halucenex expects to recruit between 18 to 20 patients, who will be treated with two oral doses of psilocybin separated by 7 days, with a 10mg micro dose of psilocybin to be administered in the clinic on Day 7 and a follow up macro dose of 25 mg to be administered in the clinic on Day 14. Following treatment on each day, subjects will be closely monitored in the clinic by the study monitors during the hallucinogenic period. Safety assessments will be conducted including incidents of adverse events and vital signs. At 6 to 7 hours post-dosing, subjects will be assessed using patient ratings of subjective intensity of psilocybin's effects. Subjects will also complete the patient verbal rating of the intensity of the subjective effects. One day after each treatment, on Day 8 and Day 15, subjects will return to the clinic for efficacy and safety assessments.

Follow-up visits will be conducted at the clinic on Day 22 (End of Treatment), and via telephone visits on Day 36, and Month 3 (approximately Day 90) and Month 6 (approximately Day 180; optional) for efficacy and safety assessments.

Patient identification criteria has already begun, with the trial expected to commence in June 2021, subject to a Clinical Trial Authorisation Permit ("CTA Permit") being awarded by Health Canada. Halucenex intends to lodge the required documentation to obtain the CTA Permit by the end of April 2021. Initial results are expected within the first months of trial commencement.

#### Acquisition update:

Creso Pharma's Board and management team continue to progress a number of initiatives to ensure the seamless integration of Halucenex into the Creso Pharma Group. As part of the acquisition, the Company advises that Director Dr Miri Halperin Wernli will resign today and will be replaced by Halucenex Founder and CEO Bill Fleming who is proposed to join the Creso Board as a non-executive director upon completion of the transaction.

Creso Pharma would like to take this opportunity to thank Dr Halperin Wernli for her service and contribution to the Company. Dr Halperin Wernli was instrumental in building the Company's very experienced management team with the necessary commercial and technical expertise to continue to drive the Company's growth objectives, and leaves the business in a strong position, with the Company's North American operations to remain spearheaded by Jack Yu and its Swiss operations to be driven by existing Commercial Director, Jorge Wernli, who has been responsible for the development and commercialisation of the Company's line of CBD-based nutraceutical products. Her guidance and support has been integral to Creso Pharma's growth trajectory and we wish her well for her future endeavours.

#### Commentary:

**Non-executive Chairman Adam Blumenthal said:** *"The appointment of True North is a pleasing development for Halucenex and we are excited that the company is already making progress with its proposed clinical trial schedule. The appointment of True North will provide the necessary infrastructure needed to undertake a necessary and potentially ground-breaking research initiative."*

*"Board and management continue to undertake due diligence on the acquisition and the exciting opportunities this will unlock for Creso Pharma, as it transitions to a best in class provider of cannabis, cannabinoids and psychedelic alternative medicines to meet the large unmet need for treatments to improve mental health and well being."*



*"I would also like to take this opportunity to thank Miri for her commitment to Creso Pharma. During her time in office, she has been pivotal in Creso Pharma's success and delivered an immense amount of value to the Board and management team, as well as led a number of initiatives, which have unlocked considerable value for our shareholders. On behalf of my fellow Directors and shareholders, I wish her all the best for her future undertakings."*

**Halucenex Founder & CEO Bill Fleming said:** *"Halucenex is proud to be working with True North to progress the development of its future breakthrough therapy for veterans and first responders and help them fight against mental illness. We look forward to a long, productive and successful relationship with True North."*

*"This trial will allow us to bring out clinical trial expertise and psychological expertise together, to maximise the benefit for current and future patients. Veterans and first responders give so much to society on a daily basis and we owe it to them to find the most effective treatments possible."*

*"This trial is a major step in the right direction."*

**True North Founder Dr Mark Johnston added:** *"Despite more than a million veterans around the world being diagnosed with PTSD, effective pharmacological treatments are sorely lacking, which is why True North is excited to work with Halucenex to undertake this ground-breaking research."*

**-Ends-**

### **Authority and Contact Details**

This announcement has been authorised for release by the Creso Board

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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](http://www.cresopharma.com)



### 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](http://www.halucenex.com)

### About True North Clinical Research:

Clinical trials are an essential part of the research and development of all pharmaceutical drugs where the safety and effectiveness of potential treatments are evaluated. At True North Clinical Research, we are committed to industry best practices and ensuring we are consistently providing our clients with the highest quality care. All work done at True North adheres to the principles established by ICH-GCP, TPCS2, and Health Canada Division 5. All clinical trials activity is approved and monitored by an ethics review board and by Health Canada. True North adheres to the Personal Information Protection and Electronics Act (PIPEDA) and the Nova Scotia Health Information Act (PHIA). We have appropriate data collection, storage and processing practices and security measures to protect against unauthorized access, alteration, disclosure or destruction of your personal information and stored data in our database.

[www.truenorthcr.com](http://www.truenorthcr.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.

<sup>i</sup> Credence Research Post-Traumatic Stress Disorder Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026