Melodiol
GLOBAL HEALTH

ABN: 89 609 406 911

12 October 2023

# Wholly-owned subsidiary Halucenex Life Sciences Inc. achieves remission in 80% of first five patients in Phase II clinical trial

**Highlights:**

- **Encouraging early results from Phase II clinical trial to test the efficacy of psilocybin on treatment-resistant Post Traumatic Stress Disorder (PTSD)**
- **Five patients have undergone testing to date with 80% of participants experiencing total remission from PTSD symptoms following two doses of Halucenex's 100%-owned synthetic psilocybin aqueous solution Lucenex**
- **Additional results from first five patients include:**
  - **50% reduction in anxiety scores from baseline to day 44 of treatment**
  - **57% reduction in depression scores from baseline to day 44 of treatment**
- **Initial results are positive given conventional treatments for anxiety and depression are only around 20-30% effective[i]**
- **Results are a major achievement and have the potential to unlock future commercial opportunities for the Company**
- **Initial data demonstrates that Halucenex's psilocybin product offers a compelling and potentially life altering treatment path for people living with the repercussions of PTSD**
- **Additional two patients have undergone first doses – ME1 to provide ongoing updates are results are received**
- **Results from an additional 13 patients expected to be reported over the coming months, providing additional opportunity for validation of Halucenex's potential**

**Melodiol Global Health Limited (ASX:ME1) ('Melodiol' or 'the Company')** is pleased to advise that wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. ('Halucenex') has achieved encouraging preliminary results record in the first five patients taking part in the Company's phase II clinical trial exploring the use of psilocybin in the treatment of Post Traumatic Stress Disorder ('PTSD'). The Company provides the following information in compliance with section 4.2 of the Code of Best Practice for Reporting by Life Science Companies (Second Edition).

The trial, which commenced in December 2022 (refer ASX release 7 December 2022), is a single-arm, open-lab trial to test the efficacy of psilocybin on treatment resistant PTSD symptoms. The trial utilises Halucenex's 100%-owned and formulated synthetic psilocybin aqueous solution Lucenex, in both 10mg and 25mg formats which is being delivered to 20 respective patients on separate occasions in a micro dose and macro dose format (refer ASX release 6 October 2022).

To date, the Company has administered both micro and macro doses to 5 patients, which has allowed for preliminary results. Initial results from the study highlighted that 80% of participants have achieved remission from treatment resistant PTSD following two doses of psilocybin. This is a major achievement for Halucenex and has the potential to unlock significant commercial opportunities for the Company.

Additionally, the five trial subjects reported on average a 57% reduction in depression scores, as well as a 50% reduction in anxiety scores from baseline by day 44 of treatment. This is very pleasing, given conventional treatments for anxiety and depression are only around 20-30% effective[i].

Further and upon review of the preliminary data, it was noted that three of the five trial participants that scored in a moderate to severe range for depression had reduced to a normal range by day 44 of treatment.

The emerging data from the trial demonstrates that Halucenex's psilocybin product offers a compelling and potentially life altering treatment path for people living with the repercussions of PTSD. The Company will utilise its preliminary results in ongoing discussions with potential partners and collaborators, which is expected to unlock near term revenue generating opportunities for the business division.

Halucenex will continue to advance first dosages with another 15 trial candidates over the coming months. Additional updates will be provided to the market, as further data materialises.

**Management commentary:**

**CEO and Managing Director, Mr William Lay said:** *"Results from the first five patients that have undergone psilocybin dosage, using our unique Lucenex solution are nothing short of exceptional. A remission rate of 80% by day 44 of treatment provides considerable validation of Halucenex's approach and potential as a viable treatment option for patients suffering from treatment-resistant PTSD symptoms.*

*"As trial initiatives continue, another 15 patients will undergo treatment. This has the potential to provide additional data which can be leveraged in discussions with potential partners and for the future commercial application of our products. We look forward to providing additional patient results as they materialise."*

**Paige Stevens, Halucenex's Clinical Trial Technician added:** *"I'm very pleased to be part of this project, encouraged by the early results, and excited to see the project through to completion."*

**Dr Lisa Batten, Halucenex's Clinical Research Director added:** *"Having worked with treatment-resistant mental health disorders my entire career I've seen first-hand the devastating impact of these conditions and the frustrations from lack of effective treatment options. Our psilocybin research shows evidence of an intervention that rapidly treats the underlying pathology rather than offering temporary solutions to get people through their days. It's an exciting prospect to see someone get their life back."*

**-Ends-**

**Authority and Contact Details**

This announcement has been authorised for release by the Disclosure Committee of Melodiol Global Health Limited.

For further information, please contact:

**Investor Enquiries**
Melodiol Global Health Limited
E: info@cresopharma.com
P: +61 (0) 497 571 532

**About Melodiol**

Melodiol Global Health Limited (ASX:ME1) brings the best of cannabis and other plant-based products to better the lives of people and animals. Melodiol strives for the highest quality in its products. It develops cannabis, hemp-derived and other plant based therapeutic, nutraceutical, and lifestyle products with wide consumer reach.

To learn more please visit: https://melodiolglobalhealth.com/

**Melodiol offices:**

**Australia:** Suite 5 CPC, 145 Stirling Hwy, Nedlands, WA, 6009
**Canada:** 59 Payzant Drive, Windsor, Nova Scotia, B0N 2TO and 50 Ivey Ln, Windsor, Nova Scotia, B0N 2TO

**Forward Looking statements**

This announcement contains forward-looking statements with respect to Melodiol 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 Melodiol 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 Melodiol and persons acting on its behalf. Unless otherwise stated, all forward-looking statements speak only as of the date of this announcement and Melodiol has no obligation to up-date such statements, except to the extent required by applicable laws.

[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278188/