



Nova Mentis Study Confirms Oral Microdose Psilocybin Treatment of Autism

VANCOUVER, BC, Feb. 16, 2022 /CNW/ - **Nova Mentis Life Science Corp.** (CSE: NOVA) (FSE: HN3Q) (OTCQB: NMLSF) ("**NOVA**" or the "**Company**"), a biotechnology company and global leader in first-in-class psilocybin-based therapeutics and complementary diagnostics for neuroinflammatory disorders is pleased to announce that Nova Mentis successfully completed an oral microdose psilocybin preclinical study, in the laboratory of Dr. Viviana Trezza, Rome Tre University, Rome, Italy. The results exceeded all expectations with the findings that a very low dose of the Company's proprietary psilocybin significantly modulated behavioural and cognitive defects, such as recognition memory, in a genetic model of fragile X syndrome (FXS).

"The science team led by Dr. Hausman, together with Dr. Viviana Trezza from Roma Tre University, continues to deliver promising preclinical results. The recent oral microdose data set not only confirms but exceeds our original injectable formulation results," says Will Rascan, CEO of NOVA. "The clear positive data is critical as we prepare to submit our clinical trial application to Health Canada for a Phase 2A study evaluating psilocybin microdose therapy for fragile X syndrome."

Autism spectrum disorder (ASD) is a complex neurodevelopmental disorder for which no treatments exist. Fragile X syndrome (FXS) is the most common form of inherited intellectual disability and the most frequent monogenic cause of ASD (1). The aim of the present study was to evaluate various oral doses of the company's proprietary psilocybin in a rat model of FXS. A major question to be answered in this preclinical study was whether microdose therapy could be the potential treatment of choice in ASD, as compared to single dose macrodose therapy with associated hallucinogenic and other side effects.

Psilocybin efficacy was tested in FXS, in the Fmr1 knock-out (Fmr1 KO) rat (Fmr1-Δexon 8) – an established genetic model of FXS (1). Wild type control and Fmr1 KO animals were treated with 0.1 mg/kg and 0.3 mg/kg oral psilocybin every other day for 6 treatments, over a 2-week period, and on day 18 underwent object recognition testing. We had great results! Both 0.1 and 0.3 mg/kg were effective in reversing the cognitive impairment displayed by Fmr1 KO animals. Moreover, the 0.1 mg/kg worked best, and did not have any apparent side effects. The 0.1 mg/kg dose in the rat translates into approximately 1.5 mg oral dose in a 70 kg person.

"I am elated to be able to report to the medical community that at long last we may have opened the door to treatment of ASD, an unmet medical need, that has a devastating impact on the patient, family and society," stated Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board. "The rat model that we used mimics key autistic-like features in humans and the study results strongly supports an important role for microdose therapy of

FXS. Moreover, this positive response in the rat of every other day oral 0.1 mg/kg psilocybin, equivalent approximately to a 1.5 mg dose in a 70 kg person, may be the treatment of choice to modulate behavioural changes and cognitive defects, and perhaps have a longer term constructive neuroplastic response in the brain without the need for large doses of psychedelic drugs with associated detrimental hallucinogenic side effects."

Financing

In addition, the Company announces a non-brokered private placement of up to \$1,000,000 (the "Placement").

The Company will issue up to 20,000,000 units at a purchase price of \$0.05 per unit. Each unit will consist of common share of the Company and one transferable share purchase warrant. Each warrant will entitle the holder to acquire one additional common share at an exercise price of \$0.075 for a period of 18 months from the closing date.

The Company will use the proceeds from the Placement towards the launch of its ASD observational study, Health Canada Phase 2A CTA and general working capital clinical trials. Finder's fees may be payable in accordance with the policies of the Canadian Securities Exchange. All securities issued under the Placement will be subject to a statutory hold period of four months and one day from issuance.

References:

- (1) Schiavi S, Carbone E, Mlancia F, Buzzelli V, Manduca A, Campolongo P, Pallottini V, Trezza V. [Perinatal supplementation with omega-3 fatty acids corrects the aberrant social and cognitive traits observed in a genetic model of autism based on FMR1 deletion in rats](https://doi.org/10.1080/1028415X.2020.1819107). *Nutr Neurosci*. 2020 Sep 11:1-14. doi: 10.1080/1028415X.2020.1819107.

About Nova Mentis Life Science Corp.

Nova Mentis Life Science Corp. is a Canadian-based biotechnology company and global leader in developing diagnostics and psilocybin-based therapeutics for neuroinflammatory disorders. Nova is the first biotech company to achieve psilocybin orphan drug designation in both the United States and European Union.

The goal is to diagnose and treat debilitating chronic conditions that have unmet medical needs, such as autism spectrum disorder (ASD) and Fragile X Syndrome (FXS).

For further information on the Company, please visit www.novamentis.ca or email info@novamentis.ca.

On Behalf of the Board

Will Rascan, President & CEO
Nova Mentis Life Science Corp.

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