



# Nova Mentis Applies to US FDA for Psilocybin Orphan Drug Designation Fragile X Syndrome Treatment

VANCOUVER, BC, Sept. 14, 2021 /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 it has filed an application with the U.S. Food and Drug Administration (FDA) to receive orphan drug designation for its proprietary psilocybin drug to treat patients with fragile X syndrome (FXS), the most common inherited cause of autism spectrum disorder (ASD).

The U.S. Orphan Drug Act (ODA) grants special status to a drug for the treatment, diagnosis or prevention of a rare disease or condition. In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people. Developmental delays affect ~13% of all American children ages 3-10 and FXS is the most common inherited cause of intellectual disability. The Centers for Disease Control and Prevention estimates FXS prevalence as 1 in 4,000 for males and 1 in 8,000 for females.

"NOVA is committed to accelerating the research and development of psilocybin-based therapeutics to help treat fragile X syndrome," says Will Rascan, NOVA's CEO & President. "With FDA orphan drug designation, our Company would qualify for benefits and incentives such as seven years of market exclusivity after drug approval, tax credits for clinical testing, eligibility for orphan drug grants and the waiver of the FDA New Drug Application filing fee of approximately \$2.4 million," he adds. The Company filed for orphan drug designation with the European Medicines Agency (EMA) on [August 12, 2021](#).

"New clinical treatments for FXS are needed and we believe serotonergic agonists like psilocybin represent a promising option," stated Dr. Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board. "Psilocybin and other tryptamine derivatives are expected to modulate the molecular and behavioural underpinnings of the disorder, improve brain plasticity, improve cognition, reduce anxiety and behavioural rigidity. NOVA has successfully completed three preclinical studies confirming therapeutic efficacy, without apparent side effects, of Nova's proprietary psilocybin drug. Moreover, an important catalyst driving the fragile X clinical program is the ability of our drug to modulate levels of neuroinflammatory molecules (cytokines) measured pre- and post-treatment."

## 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. 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 <https://www.novamentis.ca> or email

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## On Behalf of the Board

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**For further information:** For further information on the Company, please visit <https://www.novamentis.ca> or email [info@novamentis.ca](mailto:info@novamentis.ca); Will Rascan, President & CEO, Nova Mentis Life Science Corp. Phone: 778-819-0244, Toll Free: 1-833-542-5323

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