

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

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Vancouver, British Columbia – September 14, 2021 – Nova Mentis Life Science Corp. (CSE: NOVA) (FSE: HN3Q) (OTCQB: NMLSF) (“NOVA” or the “Company”) 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.

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, fragile X syndrome (FXS) is a 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, CEO. “This application, if approved, will provide NOVA with orphan drug status, which includes benefits such as orphan 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.” ([nova-mentis-files-fragile-x-orphan-drug-designation-with-european-medicines-agency/](#)).

“New clinical treatments for FXS are needed and we believe serotonergic agonists like psilocybin represent a promising option,” stated Dr. Marvin S. Hausman, MD. “We believe that psilocybin-based therapeutics can improve the lives of individuals with FXS by improving brain plasticity, improve cognition, reduce anxiety and behavioural rigidity. NOVA has successfully completed three preclinical studies demonstrating 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 therapeutic and Fragile X Syndrome (FXS).

For further information on the Company, please visit <https://www.novamentis.ca> or email info@novamentis.ca.

On Behalf of the Board

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New treatments for [#FragileX](#) are needed and we believe [#psilocybin](#) is a promising option.

We've filed an application with the US FDA to receive orphan drug designation for our proprietary psilocybin drug to treat patients with fragile X. [\\$NOVA \\$NMLSF bit.ly/3zah3E4](#)



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