



# Mycrodose Therapeutics and Nova Mentis Announce LOI to Co-Develop Advanced Drug Delivery System

*Partnership will Create Patented Products for the Treatment of Neuroinflammatory Disorders*

VANCOUVER, BC, Oct. 19, 2021 /CNW/ - **October 19, 2021 – 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, and **Mycrodose Therapeutics** ("**Mycrodose**"), a US pharmaceutical company focused on developing advanced drug delivery systems for use with psychedelic compounds, announce that they have entered into a letter of intent ("**LOI**") to develop patented products to treat neuroinflammatory disorders, such as fragile X syndrome ("**FXS**") and autism spectrum disorder ("**ASD**").

The Joint Venture ("**NewCo**") will accelerate the research and development of psilocybin-based therapeutics by utilizing Mycrodose Therapeutics' patented advanced drug delivery systems with Nova's proprietary psilocybin drug to treat patients with neuroinflammatory conditions, including FXS, the most common inherited cause of ASD.

"NOVA's lead drug candidate, psilocybin, has revealed significant promising results in preclinical models of fragile X syndrome and autism spectrum disorder. The results are exciting and have shown that psilocybin corrects the cognitive deficits displayed by a rat model of FXS and mitigates the anxiety-like traits observed in an environmental model of autism based on prenatal exposure to valproic acid," stated [Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board](#). "We have established a microdose therapeutic level for psilocybin in our most recent study that can be used in a planned upcoming human clinical study. This collaboration with Mycrodose Therapeutics is a 'hand and glove fit' with our breakthrough psilocybin microdose discovery, as their advanced drug delivery technologies offer many advantages for microdosing drug delivery, including providing a non-invasive, sustained and controlled dose of medicine that can be self-administered."

NOVA has already successfully completed four preclinical studies confirming the therapeutic efficacy of the company's proprietary psilocybin drug. The ability of the drug to modulate levels of neuroinflammatory molecules (cytokines) measured pre- and post-treatment is an important catalyst driving the fragile X clinical program.

"With the high safety profile of Mycrodose's technologies and NOVA's FDA/EU FXS orphan drug indication for its proprietary psilocybin, this partnership opens microdosing psilocybin-based drugs to a broader patient base, including pediatric applications. To our knowledge, the planned therapeutic study for autism and fragile X will be the first to research the potential for psilocybin to help treat pediatric patients," says [Chad Conner, Chief Executive Officer, Mycrodose Therapeutics](#). "The complementary relationship between NOVA and Mycrodose definitely helps everyone get into clinical trials faster with fewer hurdles. The sum of this partnership with NOVA is much greater together than each individual company alone, and allows our combined team to deepen its research on our kids and young people, a segment of the population that truly touches all of our hearts."

NOVA has applied to the US FDA and European Union for psilocybin Orphan Drug designation for fragile X syndrome treatment, which would provide a wide range of financial and regulatory benefits.

The US [Orphan Drug Act](#) grants very attractive financial incentives to companies through a seven-year period of market exclusivity for the drug approved, even if the product is not under a provisional or granted patent. In addition, the US Orphan Drug Act provides tax credits of up to 50% of the qualified clinical testing expenses, provides grants for clinical testing, additional assistance in framing protocols for investigations, and the FDA waives the \$2.4 million New Drug Application filing fee.

Summary Terms of the LOI include:

- The Parties will incorporate a company ("**NewCo**") whereby both Nova Mentis and Mycrodose Therapeutics will subscribe for shares to become equal 50% shareholders of NewCo and nominate an equal number of individuals to the Board of Directors of NewCo.
- NewCo will be the owner of the Product(s), technologies, R&D protocols, and data gathered.
- The Parties will mutually develop a R&D and Clinical Plan.
- Mycrodose Therapeutics will give an exclusive license of its patented technologies to the collaboration for agreed upon indications.
- A Scientific Advisory Board ("**SAB**") will be created by the Parties to decide priorities based on rationales (financial, medical, clinical, scientific, delivery, etc.) that ranks the importance of specific product development and applicable clinical programs. The formalization of a definitive agreement is subject to satisfactory due diligence from both parties as well as other conditions customary for such a transaction.

## About Mycrodose Therapeutics

[Mycrodose Therapeutics](#) is a US-Based pharmaceutical company headquartered in San Diego, California specializing in the development of advanced drug delivery systems utilizing psychedelic compounds to treat mental health and cognitive degenerative diseases. Mycrodose is one of only a few private companies that has been granted a Schedule I License and been approved by the United States Drug Enforcement Agency (DEA), State of California Attorney General's Research Advisory Board, and The US Food & Drug Administration (FDA) to research four (4) psychedelic compounds: psilocybin, LSD, MDMA, and DMT. The company believes that its IP-Protected [Sustained Microdosing Technology™](#) is a smarter and safer approach to delivering pharmaceutical compounds to patients of all ages and allows for an expandable and scalable business model.

## 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).

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