

# Nova Mentis and KGK Science Form Tactical Partnership

## The Companies Plan to Jointly Submit a Psilocybin Clinical Trial Application to Health Canada

VANCOUVER, BC, Jan. 27, 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 proud to announce that the Company has formed a tactical partnership with KGK Science Inc. ("KGK"), which is a wholly owned subsidiary of Wellbeing Digital Sciences Inc. (NEO: MEDI), to develop its psychedelic psilocybin drug portfolio in Canada. KGK is a leading North American contract research organization based in London, Ontario that primarily provides high-quality clinical research trials with a focus on the nutraceutical, cannabis and emerging psychedelic industries. Both Companies plan to jointly submit a clinical trial application ("CTA") to Health Canada for a Phase 2A clinical study evaluating psilocybin microdose therapy for fragile X syndrome.

"NOVA and KGK have synergistic capabilities that will facilitate submission of the CTA to Health Canada and achieve, in my opinion, no objection to this unprecedented clinical study," stated Dr. Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board. "In our discussions with KGK, we realized early on that our two teams had the ability to navigate the entire lifecycle journey of our novel psilocybin microdose treatment of fragile X syndrome from a Phase 2A clinical study to drug approval and commercialization."

"I am delighted to work with NOVA's team to advance this novel initiative. NOVA's microdose approach aims to address an unmet need that promises to have a significant impact on the lives of families impacted by fragile X syndrome. KGK is proud to be able to contribute and is confident our expertise will guide NOVA to success through the orphan drug pathway," said Najla Guthrie, President and CEO of KGK.

NOVA's research and clinical team initially identified unique opportunities in psychedelic drug development and chose a classic drug development pathway involving careful planning and execution of chemistry, manufacturing and preclinical proof of efficacy studies. The Company's successes to date include but are not limited to:

- NOVA is the first biotech company to achieve psilocybin orphan drug designation in both the United States and European Union;
- Manufactured a large supply of >98% pure psilocybin for clinical studies and commercialization after drug approval;
- Proof of efficacy and safety in preclinical rat models of autism spectrum disorder (ASD) and fragile X syndrome (FXS); 4 studies completed;
- Established psilocybin microdose levels to treat FXS; and
- Preparing Phase 2 chemistry and manufacturing file for regulatory submission.

KGK's expertise includes:

- Regulatory submission expertise;
- Manage Investigational New Drug ("IND") enabling activities;
- Clinical trial design and trial execution;
- Established clinical sites; and
- In-house virtual behavioural testing models.

## **About KGK Science**

Founded in 1997, KGK is a leading North American contract research organization based in London, Ontario that primarily provides high-quality clinical research trials with a focus on the nutraceutical, cannabis and emerging psychedelic industries. The business has successfully helped hundreds of companies with custom-designed clinical trials and claim substantiation strategies to move products into global markets. KGK's other existing service lines include expert regulatory support and compliance solutions, participant recruitment, research support services and consulting services. On an approximate basis, the business to date has produced 150 publications, executed over 400 clinical trials across more than 40 indications, amassed 25,000 participants in its database and collected 10 million data points.

## **About Wellbeing Digital Sciences**

Wellbeing Digital Sciences Inc. (formerly KetamineOne Capital Limited) is an evidence-based healthcare company focused on innovative clinical solutions, artificial intelligence-powered digital therapeutics and contract research. Its mission is supported by a network of North American clinics that provide ketamine-assisted therapies and other types of treatment to patients as well as through a contract research organization that offer clinical trials services to clients pursuing drug development. In essence, the company exists to make breakthrough treatments more accessible and to offer patients transformational experiences.

## **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](http://www.novamentis.ca) or email [info@novamentis.ca](mailto:info@novamentis.ca).

## **On Behalf of the Board**

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