

January 10, 2023



Irwin Naturals and Braxia Scientific Announce Partnership for In-Human Clinical Studies Supporting Pharmaceutical Companies in the US

LOS ANGELES, Jan. 10, 2023 (GLOBE NEWSWIRE) -- **Irwin Naturals Inc. (CSE: IWIN) (OTC: IWINF) (FRA: 97X) ("Irwin" or the "Company")**, is proud to announce it has signed a Letter of Intent entering into a partnership with Braxia Scientific Corp. ("Braxia Scientific"), (CSE: BRAX) (OTC: BRAXF) (FWB: 4960), a medical research company providing psychiatric, innovative ketamine and psilocybin treatments for mental health disorders, to launch Clinical Research Services across Irwin's growing U.S. based network of clinics, Emergence.

The partnership will bring together Braxia's expertise, track record of leadership in innovative mental health treatments and current comprehensive clinical research capabilities to 12 Emergence clinics in 5 US states. Under the terms of the LOI, Irwin will invest up to \$2 million over the next 12 months to launch initial clinical research services beginning with at least 5 clinics in Florida.

Irwin and Braxia's partnership will create a leading mental health focused clinical research platform designed to streamline and accelerate the process of in-human clinical development of new therapies, including seamless patient recruitment through to FDA application. The partnership will support multiple large and small pharmaceutical sponsors, innovative biotechnology companies, medical device companies, government and non-governmental institutions who seek to carry out the development of new therapies in the area of mental health in the US.

The mental health leadership of Braxia, through its globally recognized management and clinical development teams, will be a major accelerator and differentiator for Irwin's network of clinics across the US. To date, Braxia's CEO, Dr. Roger McIntyre continues to rank as the world's foremost expert in depression research¹. Dr. McIntyre and Dr. Joshua Rosenblat, Braxia Chief Medical and Science Officer have conducted dozens of national and international research studies involving thousands of patients living with depression. This is the type of value added services Emergence is looking to add to its growing network of clinics in the US.

Klee Irwin, CEO, Irwin Naturals commented, "We are extremely pleased to have reached a new milestone in the development of our clinics by establishing a strategic relationship with

Dr. McIntyre and his research team. Having an outstanding reputation for scientific expertise, quality clinical research in depression and other mental health disorders areas that will enable us to further develop our US clinical footprint."

Dr. Roger McIntyre, CEO, Braxia Scientific, commented, "We are conducting a number of ongoing clinical trials and are currently receiving requests from various pharmaceutical sponsors to support international programs to develop novel therapies in mental health. We have been developing a plan to reach a broader market in the US and globally. This exciting partnership allows us to expand our expertise in an effective manner by leveraging the existing Irwin infrastructure deployed over a number of states in the U.S."

The partnership is subject to execution of a final definitive legal agreement covering the above and other material terms of the relationship between Braxia and Irwin.

Share Issuance

Company also announces that it will issue an aggregate 427,377 Subordinate Voting Shares to the owners of Invictus Clinics, LLC, on January 10, 2023, as part of the consideration for the [asset purchase agreement announced August 8, 2022](#)

About Braxia Scientific Corp.

Braxia Scientific is a medical research and telemedicine company with clinics that provide innovative ketamine treatments for persons with depression and related disorders. Braxia also launched its U.S. based end-to-end telemedicine platform KetaMD, that utilizes leading technology to provide access to safe, affordable, and potentially life-changing at-home ketamine treatments for people living with depression and related mental health conditions. Through its medical solutions, Braxia aims to reduce the illness burden of brain-based disorders, such as major depressive disorder among others. Braxia is primarily focused on (i) owning and operating multidisciplinary clinics, providing treatments in-person and virtually for mental health disorders, and (ii) research activities related to discovering and commercializing novel drugs and delivery methods. Braxia seeks to develop ketamine and derivatives and other psychedelic products from its IP development platform. Through its wholly owned subsidiary, Braxia Health (formerly the Canadian Rapid Treatment Center of Excellence Inc.), operates multidisciplinary community-based clinics offering rapid-acting treatments for depression located in Mississauga, Toronto, Kitchener-Waterloo, Ottawa, and Montreal.

About Irwin Naturals

Irwin Naturals has been a household name and best-in-class nutraceutical formulator since 1994. It is now leveraging its household name to enter into the cannabis and psychedelic sectors. Irwin has operated profitably for over 28 years². The Company's growing portfolio of products is available in more than 100,000 retail doors across North America, where over 100 million people know the Irwin Naturals brand.³ In 2018, the Company first leveraged its brand to expand into the cannabis industry by launching hemp-based CBD products into the mass market. The Company is now leveraging its brand trust with an objective to become one of the first household names in THC-based products and the world's largest chain of psychedelic mental health clinics. Irwin Naturals became a publicly traded company on the Canadian Securities Exchange (CSE) in August 2021. The Company's shares began to be

traded on the OTCQB Venture Market in November 2021. More information on the Company's stock can be found [via Bloomberg](#) as well as the [Wall Street Journal](#).

For investor-related information about the Company, please visit ir.irwinnaturals.com/

To contact the Company's Investor Relations department, please call toll-free at (800) 883-4851 or send an email to investors@irwinNaturals.com.

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Regulatory Overview

The following is a brief summary of regulatory matters concerning ketamine in the United States ("US"). Under the Controlled Substances Act (21 U.S.C. § 811) (the "CSA"), ketamine is currently a Schedule III drug as well as being listed under the associated Narcotic Control Regulations and psilocybin is currently a Schedule I drug.

Most US States have enacted Controlled Substances Acts ("State CSAs") which regulate the possession, use, sale, distribution, and manufacture of specified drugs or categories of drugs and establish penalties for State CSA violations and form the basis for many state and local drug laws enforcement activity. State CSAs have either adopted drug schedules identical or similar to the federal CSA schedules or, in some instances, have incorporated the federal scheduling mechanism. Among other requirements, some US States have established a prescription drug monitoring or review programs collect information about prescription and dispensing of controlled substances for the purposes of monitoring, analysis and education.

In the United States, facilities holding or administering controlled substances must be registered with the US Drug Enforcement Agency ("DEA") to perform this activity. As such, medical professionals and/or the clinics in which they operate, as applicable, are also required to have a DEA license to obtain and administer ketamine (a "DEA License"). While ketamine is a controlled substance in the United States, it is approved for general anesthetic induction under the US Food, Drug, and Cosmetic Act. Once a drug is approved for use, physicians may prescribe that drug for uses that are not described in the product's labeling or that differ from those tested by the manufacturer and approved by the Food and Drug Administration (the "FDA"). Licensed medical practitioners may prescribe ketamine legally in Canada or the United States where they believe it will be an effective treatment in their

professional judgment.

Please see Irwin's filing statement on its SEDAR profile for more information on the regulatory environment and regulations surrounding the US ketamine industry.

Forward-Looking Information

This news release contains certain forward-looking statements that reflect the current views and/or expectations of management of the Company with respect to performance, business and future events. Forward-looking statements can often be identified by words such as "may", "will", "would", "could", "should", "believes", "estimates", "projects", "potential", "expects", "plans", "intends", "anticipates", "targeted", "continues", "forecasts", "designed", "goal", "objective," or the negative of those words or other similar or comparable words. Forward-looking statements are based on the then-current expectations, beliefs, assumptions, estimates and forecasts about the business and the industry and markets in which the Company operates. Forward-looking statements in this news release include statements related to information concerning the ability of the Company to perform the terms of the transaction referenced herein; the receipt of all necessary approvals, including regulatory approvals; expectations for other economic, market, business and competitive factors; and the Company actually entering into and doing business in the U.S. cannabis and psychedelics markets. The potential entrance by the Company into these new business segments are in their preliminary stages and may be subject to approval from the board of directors of the Company as well as any regulatory approval, including that of the Canadian Securities Exchange. These statements are based on numerous assumptions that are believed by management to be reasonable in the circumstances, and are subject to a number of risks and uncertainties, including without limitation: board and regulatory approval, including the approval of the Canadian Securities Exchange; Irwin being able to acquire and/or enter into business relationships to enter into these new markets; the Company obtaining the required licenses; and changes to regulations and laws regarding cannabis or psychedelics; finalizing definitive, binding agreements that formalize the terms of the non-binding letter of intent described in this press release. Further information on the regulatory environment and risks will be contained in future disclosures. Forward-looking statements are subject to a number of known and unknown risks, uncertainties, and other factors that may cause actual results, performance, or achievements to be materially different from that which are expressed or implied by such forward-looking statements. Forward-looking statements are not guarantees of future performance and involve risks, uncertainties, and assumptions which are difficult to predict. Accordingly, readers should not place undue reliance on forward-looking statements and information, which are qualified in their entirety by this cautionary statement. The Company does not undertake any obligation to release publicly any revisions for updating any voluntary forward-looking statements, except as required by applicable securities law.

Neither the CSE nor its Market Regulator (as that term is defined in policies of the CSE) accepts responsibility for the adequacy or accuracy of this release.

SOURCE: Irwin Naturals Inc.

¹ <https://expertscape.com/ex/depressive+disorder%2C+treatment-resistant>

² Under several corporate structures, Klee Irwin has operated the Irwin brand profitably since

1994, as measured by EBITDA adjusted for extraordinary costs.

³ Consumer brand recognition information is based on a Company survey with a sample size of 500 randomly selected adults.



Source: Irwin Naturals