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Irwin Naturals Emergence to Add Ohio Ketamine Clinic

Company announces agreement that will expand its national chain of health clinics into central Ohio

LOS ANGELES, Sept. 06, 2022 (GLOBE NEWSWIRE) -- **Irwin Naturals Inc. (CSE: IWIN) (OTC: IWINF) (FRA: 97X) (“Irwin” or the “Company”)** announced today that it has **entered into a binding to agreement to** acquire all of the membership interests in Happier You, LLC, which operates a ketamine clinic in central Ohio. This clinic will be added to Irwin Naturals Emergence, a fast-growing national chain of psychedelic mental-health clinics that has previously acquired 10 different clinics across a total of five states.

Klee Irwin, CEO of Irwin Naturals, said, “We are a first mover in this rapidly expanding sector of mental healthcare. By finding independent, financially sound clinics with exceptional customer care, we’re building a national chain that delivers on the quality of care that is embodied by the Irwin Naturals brand.”

Tara J. Dillon, founder of Happier You, said, “We built our practice out of the belief that it was not just possible, but necessary to ease the suffering of those people who had not been helped by traditional mental-health treatments. Becoming part of Irwin Naturals Emergence allows us to be part of a chain capable of making life-changing impact on a national scale.”

Happier You opened in 2020, founded by Tara Dillon, a registered nurse and family nurse practitioner. The clinic provides IV ketamine-infusion therapy, which is used to treat depression, anxiety as well as bipolar disorder, post-traumatic stress disorder (PTSD) and obsessive-compulsive disorder (OCD).

Irwin Naturals was founded in 1994, and has built itself into a brand recognized in 80 percent of American households¹ with its best-in-class nutraceuticals, such as its famous “Power to Sleep PM.” Irwin Naturals products are stocked on the shelves of more than 100,000 storefronts in North America, and now that brand is moving to the forefront of this new frontier of healthcare.

Klee Irwin, CEO of Irwin Naturals, said, “We’ve earned customer trust through nearly 30 years of caring for their health needs. That makes us a familiar friend, providing assurance to consumers in this new area of care. Just being in this space speaks for both the safety and efficacy of this care.”

Irwin Naturals Emergence already includes clinics in Florida, Vermont, New Hampshire, Iowa

and Georgia. By building this national chain of clinics, Irwin Naturals Emergence will drive down operating costs by incorporating its corporate best practices and the savings that come from the ability to buy in larger quantities. These savings can be passed on to consumers, and most importantly, broaden access for those in need through sliding-scale discounts or even pro bono treatment. This will enable the company to serve as a bridge as insurance plans catch up to the importance and power of these treatments.

Currently, ketamine is the only psychedelic available for use in the United States outside of clinical trials. However, MDMA and psilocybin may be authorized for therapeutic use in the future. The effectiveness of these treatments in clinical trials points to the possibility of further revolutionizing the field mental-health treatment. It is estimated that one in four Americans have what would be considered a diagnosable mental-health condition.

Transaction terms

The Agreement is subject to certain customary closing conditions and regulatory approvals. The total consideration is to be paid in a combination of cash and stock, with maximum payable contingent on a number of milestones related to profitability and operation goals. Further detail will be provided upon closing.

About Irwin Naturals

Irwin Naturals has been a household name and best-in-class herbal supplement formulator since 1994. It is now leveraging its brand to enter into both the cannabis and psychedelic industries. On a mission to heal the world with plant medicine, Irwin has operated profitably for over 27 years². Irwin's growing portfolio of products is available in more than 100,000 retail doors across North America, where nearly 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 famous halo of brand trust with an objective to become one of the first household name brands to offer THC-based products and psychedelic mental health treatment. 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 THC 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. 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 Consumer brand recognition information is based on a formal Company survey with a sample size of 500 randomly selected adults.

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 formal Company survey with a sample size of 500 randomly selected adults.



Source: Irwin Naturals