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Former Head Of Psychiatry Products At FDA Joins Psychedelic Drug Developer Cybin

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Magic Mushrooms: Cybin has hired the former director of psychiatric drugs at the FDA to help the ... [+] GETTY

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Psychedelic drug development company Cybin has recruited extra muscle to help navigate the regulatory process as it readies a clinical trial on its sublingual formulation of psilocybin, the psychedelic compound found in "magic mushrooms," for patients with major depressive disorder.

Thomas Laughren, a medical doctor who served as the director of the U.S. Food and Drug Administration's division of psychiatry products for nearly three decades, will join Cybin's clinical advisory board, the company announced Thursday.

At the FDA, Laughren oversaw the research and review of all new psychiatric drug applications and development projects in clinical testing. He also helped with the design and interpretation of clinical trials for psychiatric drugs. Laughren left his post at the FDA in 2012 and has run his own consulting company to help psychiatric pharmaceutical drugmakers gain FDA approval.

Alex Belser, Cybin's chief clinical officer, says that Laughren will help the company plot its regulatory pathway as it studies and develops psychedelic medicines.

"Psychedelic medicines don't fit neatly into the old models for how drugs are studied, reviewed and approved," says Belser. "We brought together experts to help us work within existing clinical and regulatory frameworks while realizing that psychedelics require innovative methods and a new approach."

Cybin will launch a phase 2 clinical trial to study its sublingual formulation of psilocybin for patients with major depressive disorder at the University of the West Indies Hospital in Jamaica later this year. The start of the trial is still subject to final confirmation by Jamaica's Ministry of Health.

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The study will be conducted in two parts. The first part of the clinical trial will consist of a phase 2A study of 40 patients to identify the equivalent dose of Cybin's sublingual psilocybin formulation compared with a 25 mg pill of psilocybin. Cybin's sublingual film is designed for rapid absorption, a faster onset and a shorter duration. The second phase will be a randomized, placebo-controlled Phase 2B study, in 120 patients with major depressive disorder. (Eighty patients will be in the active arm, 40 in the placebo arm.)

Doug Drysdale, the CEO of Cybin, says Laughren's FDA experience will be vital to the company's next chapter.

"Building and maintaining strong relationships and communications channels with regulators will be important for Cybin as their understanding of psychedelic therapeutics evolves over time," says Drysdale.

Psilocybin is a tryptamine that binds to serotonin receptor 5-HT2A in the brain. At certain doses, the psilocybin elicits profound changes in consciousness. Studies in academic institutions including Johns Hopkins and Imperial College London have found that psychedelic drugs have significant potential in treating mental health disorders, including certain types of depression.

Cybin is starting with psilocybin, but the company is also developing novel molecules based on other psychedelic compounds. The company has filed 12 provisional patent applications for novel psychedelic molecules.

The future of psychedelic medicine is in new drugs that are based on classic hallucinogens like LSD and psilocybin, but are modified to shorten the trip,

or remove it altogether. A psychedelic experience can last six to eight hours, which means psychedelic-assisted therapy requires doctors and therapists to work with patients for extended periods.

Doug Drysdale, the company's CEO, told *Forbes* in May that the company is developing "optimized" psychedelic drugs that feature a shorter and less prominent psychedelic experience. "We want to shorten the overall duration of these treatments," Drysdale said. "We have quite a lot of control over it."

Cybin plans to start human trials on a few novel molecules later this year.

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