

Spirify Pharma Awarded NIH STTR Grant to Advance Research on Novel Non-Opioid Therapeutics for Chronic Pain in Collaboration with Florida Atlantic University

Naples, FL — September 30, 2025 — Spirify Pharma, Inc., a biotechnology company developing next-generation therapeutics for pain and neurological disorders, today announced it has received a competitive Small Business Technology Transfer (STTR) Phase I grant from the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH). The award, totaling \$616,349, will fund pioneering research on hydroxynorketamine (HNK) analogs as promising non-opioid analgesics for the treatment of chronic pain. The project will be conducted in collaboration with Florida Atlantic University.

Pioneering the Next Generation of Non-Psychedelic Neurotherapeutics

According to CDC, chronic pain affects approximately 50 million US adults and 20% of the population worldwide, with current treatment options often inadequate. Opioids remain the standard of care, but long-term use carries severe risks including addiction, dependence, and diminished effectiveness. Alternative drugs such as antidepressants or gabapentin show limited efficacy.

The drug development landscape is rapidly evolving, driven by the need for treatments that address the underlying pathophysiology of neurological conditions. Psychedelic compounds like ketamine have demonstrated the ability to induce rapid and long-lasting therapeutic effects by promoting neuroplasticity (the growth and reconnection of neurons). However, their clinical use is currently limited by the need for professional supervision due to their dissociative and psychotomimetic effects.

HNK, a non-proprietary metabolite of ketamine, has emerged as a potential breakthrough, providing analgesia without psychotomimetic effects. Spirify's research focuses on novel, next-generation proprietary HNK analogs (HNK-SPs) designed to enhance this therapeutic profile and to decouple the beneficial therapeutic effects of ketamine from the drug's undesirable side effects. This precision pharmacology approach is intended to deliver the long-term, rapid efficacy of the original compound but in a safer, more scalable, and non-hallucinogenic form -addressing the urgent need for non-opioid pain relief. Preclinical work conducted by Spirify and its academic partners has demonstrated that HNK-SPs reduce pain behaviors in animal models without an indication of opioid- or ketamine-like side effects.



A Collaborative Effort

With support from the NIH, Spirify Pharma and Florida Atlantic University will work together as STTR partners to study the potential of the company's HNK analogs to relieve chronic pain. The research will look at how these compounds reduce different types of pain in well-established models, while also evaluating how the drugs are absorbed and processed in the body. The goal is to identify the most promising candidates for further development into safe and effective treatments.

Dr. Irving Wainer, Chief Scientific Officer of Spirify Pharma, commented:

"We believe HNK analogs represent a new class of non-opioid pain therapeutics with the potential to transform how chronic pain is treated. This NIH STTR award validates the promise of our approach and will accelerate our ability to generate critical data to advance our lead candidates toward the clinic."

Dr. Lawrence Toll, Principal Investigator at Florida Atlantic University, added:

"Our joint studies will explore the unique mechanisms of HNK analogs, particularly their ability to modulate AMPA receptor activity and D-serine pathways, which could provide analgesia without the burdens of opioid use. We are excited to partner with Spirify on this important work which aims to rapidly translate foundational science into urgently needed safer clinical treatments."

Looking Ahead

This project marks a significant milestone for Spirify Pharma as it expands its pipeline of innovative non-opioid therapeutics. Results from the collaboration are expected to lay the groundwork for clinical development of novel analgesics addressing the enormous unmet need in chronic pain management.

About Spirify Pharma

Spirify Pharma, Inc. (http://www.spirifypharma.com) is a privately held biopharmaceutical company based in Naples, Florida, focused on the discovery and development of novel therapies for neurological and psychiatric disorders. The company leverages advanced pharmacology and proprietary compound libraries to identify new treatment paradigms with improved safety and efficacy profiles.



About Florida Atlantic University

Florida Atlantic University serves more than 32,000 undergraduate and graduate students across six campuses along Florida's Southeast coast. Recognized as one of only 21 institutions nationwide with dual designations from the Carnegie Classification - "R1: Very High Research Spending and Doctorate Production" and "Opportunity College and University" - FAU stands at the intersection of academic excellence and social mobility. Ranked among the Top 100 Public Universities by U.S. News & World Report, FAU is also nationally recognized as a Top 25 Best-In-Class College and cited by Washington Monthly as "one of the country's most effective engines of upward mobility." As a university of first choice for students across Florida and the nation, FAU welcomed its most academically competitive incoming class in university history in Fall 2025. To learn more, visit www.fau.edu.

Spirify Contact

Sigal Kremer-Tal CEO & Co-founder

Email: stal@spirifypharma.com

Tel: 201-750-2347

Florida Atlantic University contact

Lawrence Toll, Ph.D

Professor, Biomedical Science, FAU, Stiles-Nicholson Brain Institute

Email: Itoll@health.fau.edu

Tel: 561-297-2578