



Stimulating Patients to
Facilitate Breathing on Their Own

2023 - A Year of Milestones and Advancements

As we look back on the past year, we're excited to share key milestones that have shaped our path and positioned us for a future characterized by innovation and expansion. Our unwavering dedication to excellence is highlighted by significant advancements in our pdSTIM™ System, the initiation of our pivotal IDE clinical study, strategic growth initiatives, and the addition of a renowned principal investigator to our team.

Completed Verification and Validation Testing of our Updated pdSTIM™ System



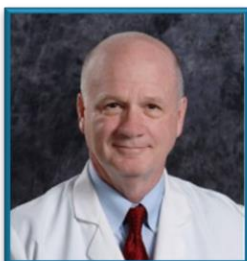
We evaluated and critiqued the performance of the pdSTIM device's features to meet specifications for awakening and reconditioning the diaphragm. With the objective of equipping healthcare providers with a therapeutic solution that accelerates their patients' transition from mechanical ventilation towards autonomous breathing, the System's performance met or exceeded requirements and was robust enough for submissions to regulatory bodies.

Obtained FDA Approval to Initiate our Pivotal Study, ReInvigorate



The ReInvigorate Study is a randomized, controlled trial enrolling approximately 350 patients on mechanical ventilation in the ICU. Patients are randomly assigned to receive phrenic nerve stimulation (PNS) therapy using Stimdia's pdSTIM System or standard of care. The study's primary efficacy endpoint will evaluate the time to liberation from mechanical ventilation.

Dr. Steven Conrad of LSU Health Sciences, Division of Critical Care Medicine, Joined Us as Our National Principal Investigator of The ReInvigorate Study



"The pdSTIM System has the potential to introduce a novel approach to ICU patient management, assisting physicians, respiratory therapists, and nurses in expediting the liberation of patients from mechanical ventilation. I look forward to clinicians engaging in this therapy as part of the study and await the trial's outcomes as it progresses toward completion."

– Dr. Steven Conrad



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Continued Clinical Trial Enrollment



In 2023, we initiated enrollments and engaged with 28 out of the 35 total sites that will participate in The ReInvigorate Pivotal IDE Study. Stimdia is honored to collaborate with these clinical experts and applaud them for their pursuit of innovative technologies and procedures to enhance patient care while striving to reduce healthcare costs.

Submitted Three Articles for Presentation or Publication



These articles detail our groundbreaking research and clinical findings related to our innovative pdSTIM System, highlighting its effectiveness and potential impact on patient care. These publications and presentations signify a significant step in establishing Stimdia Medical as a leader in the field and demonstrating the advancements we're making in critical care medicine.

LSI - Emerging MedTech Summit



Tim Miller, our CEO, presented at LSI USA '23, showcasing the remarkable progress achieved with pdSTIM, significantly advancing critical care practices with neurostimulation technology, a much-needed therapy to help accelerate liberating patients from mechanical ventilators. Discussions underscored compelling value statements affirming the potential for pdSTIM to positively affect outcomes, safety, cost-efficiency, and operational efficacy.

These milestones and achievements serve as a solid foundation to propel us towards even greater success in 2024 and beyond. We extend our heartfelt gratitude to our dedicated team, partners, and supporters for their invaluable contributions to our efforts of empowering physicians and helping patients gain independence from mechanical ventilation. Thanks for being part of our journey!

Best,

Tim Miller
Stimdia Medical CEO

CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use.