



Spectral AI Announces First Site Initiation Visit for DeepView System™ Clinical Study Supporting Label Expansion Strategy to Burns of the Head, Hands, and Feet

Oct 01, 2026

DALLAS, Oct. 01, 2026 (GLOBE NEWSWIRE) -- **Spectral AI, Inc. (Nasdaq: MDAI) ("Spectral AI" or the "Company")**, an artificial intelligence (AI) company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, today announced the completion of the first Site Initiation Visit ("SIV") associated with the commencement of a clinical study designed to support a label expansion of the Company's FDA-cleared DeepView System™ for Burn Indication to include burns involving the head, hands and feet.

The SIV was conducted at Pinderfields Hospital, Wakefield, UK under the leadership of Principal Investigator Dr. Preetha Muthayya, Consultant Burns and Plastic Surgeon and Clinical Lead for Burns. Pinderfields Hospital is part of the Mid Yorkshire Teaching NHS Trust and provides expert care for adult and pediatric patients with serious and life-threatening burn injuries.

Following the completion of all applicable site-readiness requirements, the first SIV represents the operational launch of the clinical study and enables Pinderfields Hospital to begin patient enrollment.

The study is intended to generate additional clinical evidence to support the use of the DeepView System in these anatomically complex burn areas, where timely and accurate assessment of a burn-wound's healing potential can be particularly important to treatment planning.

"Completion of the first site initiation visit is an important step in advancing our strategy to broaden the potential clinical utility of the DeepView System," said Vincent Capone, Chief Executive Officer of Spectral AI. "Burns involving the head, hands and feet present unique clinical considerations, and we believe the ability to provide clinicians with rapid, objective information regarding healing potential in these anatomically complex areas could be especially valuable. This study builds on the clinical and regulatory foundation established by our FDA-cleared DeepView System for Burn Indication and reflects our commitment to expanding the technology's applicability for burn-care providers and their patients."

Mr. Capone concluded, "We are grateful for the commitment of our clinical collaborators and the patients who participate in this important research, and look forward to advancing the study in support of a potential label expansion."

Dr. Muthayya said, "We are delighted to be the first site to complete our site initiation and very much look forward to enrolling patients into this label expansion study."

About the Clinical Study

"Clinical Study of the DeepView AI-System for Assessment of Thermal Burn Healing Potential in Hands, Feet and Head/Face Training and Validation Label Expansion Study."

The prospective training and validation study is expected to enroll adult and pediatric patients with qualifying thermal burns involving the hands, feet or head/face. Participants will be imaged with the DeepView System within 72 hours of injury, with healing outcomes assessed through 21 days. The resulting image dataset will support both algorithm training and independent validation of system performance, with the DeepView System used in a blinded, observational capacity and not to direct patient care. The study will be conducted at multiple sites in the UK and is expected to be completed in 2027.

About the DeepView System™

Spectral AI's DeepView System is a non-invasive, predictive medical device that combines multispectral imaging with a proprietary AI algorithm to assess the healing potential of areas within burn wounds. It was granted De Novo Classification by the U.S. Food and Drug Administration ("FDA") in May 2026 and received its initial UKCA (UK Conformity Assessed) authorization in the United Kingdom in February 2024. The DeepView System provides physicians with an immediate, data-driven assessment of whether areas within burn wounds are unlikely to heal within 21 days and may require significant medical intervention, enabling earlier and more informed treatment decisions. The image acquisition takes 0.2 seconds, and all image processing and AI model classification takes approximately 20 to 25 seconds. The DeepView System is trained and tested against a proprietary and clinically validated database of over 340 billion pixels of burn wound image data.

About Spectral AI

Spectral AI, Inc. is a Dallas-based predictive AI company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, with initial applications involving patients with burns. The Company is working to revolutionize the management of wound care by "Seeing the Unknown®" with its DeepView System. The DeepView System is a predictive diagnostic device that offers physicians an objective and immediate assessment of a wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal to exceed the current standard of care, the DeepView System provides fast and accurate treatment insights to improve patient outcomes and reduce healthcare costs. For more information about the DeepView System, visit www.spectral-ai.com.

The Company's contract with the Biomedical Advanced Research and Development Authority ("BARDA") is held and performed through its wholly owned subsidiary, Spectral MD. References to the contract, associated awards, related revenue, business opportunities, obligations, and other relevant factors should be understood to refer to Spectral MD as the contracting party unless otherwise indicated.

Forward-Looking Statements

Certain statements made in this release are "forward looking statements" within the meaning of the "safe harbor" provisions of the United States Private Securities Litigation Reform Act of 1995, including statements regarding the Company's strategy, plans, objectives, initiatives and financial outlook. When used in this press release, the words "estimates," "projected," "expects," "anticipates," "forecasts," "plans," "intends," "believes," "seeks," "may," "will," "should," "future," "propose" and variations of these words or similar expressions (or the negative versions of such words or expressions) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance, conditions or results,

and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside Company's control, that could cause actual results or outcomes to differ materially from those discussed in the forward-looking statements. As such, readers are cautioned not to place undue reliance on any forward-looking statements.

Investors should carefully consider the foregoing factors, and the other risks and uncertainties described in the "Risk Factors" sections of the Company's filings with the US Securities and Exchange Commission, including the Company's Registration Statement and the other documents filed by the Company. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

Investors:

The Equity Group

Devin Sullivan

Managing Director

Devin.Sullivan@theequitygroup.com

Conor Rodriguez

Associate

Conor.Rodriguez@theequitygroup.com