



Spectral MD Awarded BARDA Project BioShield Contract Valued at \$149 Million for AI-Driven DeepView® Burn Wound Imaging Technology

DALLAS, Sept. 28, 2023 – Spectral MD, Inc. (“SMD”), a subsidiary of Spectral AI, Inc. (Nasdaq: MDAI; MDAIW) (“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 it has been awarded a new contract valued at up to \$149 million by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services. The contract is for the advanced development of the DeepView® System, the Company’s AI-driven burn wound imaging technology, to be used at emergency departments, trauma centers and burn centers, for both routine burn care and as a medical countermeasure for use in burn mass casualty incidents (BMCI).

This multi-year contract includes an initial award of nearly \$55 million to support the clinical validation and FDA clearance of DeepView® for commercial marketing and distribution purposes, a major milestone that enables the technology to become a key component of the U.S. government’s BMCI preparedness efforts. The initial award places up to 30 DeepView® devices at various burn centers and emergency rooms to support the clinical validation study and will transition to being used in routine care upon FDA clearance. The contract also includes options with an additional total value of approximately \$95 million and can be exercised for additional product development, procurement, and deployment of DeepView® at U.S. emergency departments, trauma centers and burn centers in a phased approach. These deployments will enable SMD to conduct health economic and outcome research to support broader clinical adoption of the DeepView® System.

Previously in 2013 and 2019, SMD was awarded BARDA contracts totaling \$123 million, of which \$101 million has been committed to date. Together with this new contract, it brings the total potential support from BARDA to nearly \$251 million. This new contract represents the largest contract ever awarded to SMD.

“We appreciate that our DeepView® platform has been selected to address a critical need in preparing our country for possible BMCI events,” said Wensheng Fan, the Company’s CEO. “This is a significant contract award that enables us to accelerate the late-stage clinical development and commercialization of our DeepView® System. We are most grateful to BARDA for enabling us to help physicians and their burn patients who will benefit from the use of DeepView®. For the first time, there will be an accurate and objective solution in burn wound healing assessment to guide treatment. Spectral MD is committed to the development of impactful medical technologies, and we will aim to bring DeepView® to market as quickly as possible.”

Jeffrey Carter, M.D., the Company’s Chief Medical Consultant, added, “The current standard of care for burn wound assessment that is crucial in determining next-step treatment relies largely on the clinical judgement of physicians. However, diagnostic accuracy can be as low as 50%. This unmet clinical need is dramatically magnified in the event of a BMCI, where the ability to triage burn patients rapidly and properly would be crucial in allocating valuable resources and managing the surgical burden. The DeepView® technology represents a new paradigm in the assessment of burn wounds and can provide meaningful clinical guidance to physicians in their diagnosis and treatment recommendations.”

This work supports BARDA’s mission to identify medical countermeasures which help counter the effects of a BMCI and address the current limitations within the United States’ burn care infrastructure. According to the American Burn Association, 1.1 million Americans suffer from burn injuries each year, with 500,000 presenting to emergency departments, and 40,000 requiring hospitalization. In contrast to this demand, only two percent of U.S. hospitals have burn centers, and there are only about 250 burn surgeons in the United States.

To bridge this gap in care, the Company's DeepView® System, which received Breakthrough Device Designation from the FDA in 2017 for its burn indication, integrates proprietary imaging technology and AI-enabled algorithms to see deep below the surface of the skin to distinguish between healthy and damaged tissue. By seeing what the human eye cannot, DeepView® delivers a binary wound healing prediction to assist physicians in determining whether a burn will heal on its own or if surgery is required. Studies with DeepView® have demonstrated a burn diagnostic accuracy rate of 92% on Day 1, well above the estimated >50% accuracy of non-specialists and even the estimated 70% accuracy of burn specialist assessments.

This project is being supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; BARDA, under contract number 75A50123C00049. The findings and conclusions have not been formally disseminated by the Department of Health and Human Services and should not be construed to represent any agency determination or policy.

About Spectral MD

Spectral MD, Inc., is a subsidiary of Spectral AI, Inc., 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 and diabetic foot ulcers. The Company is working to revolutionize the management of wound care by "Seeing the Unknown®" with its DeepView® System. DeepView® is a predictive diagnostic device that offers clinicians 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 of substantially exceeding the current standard of care in the future, DeepView® is expected to provide faster and more accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. For more information about DeepView®, visit www.spectral-ai.com.

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 SEC, including the 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.

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