

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): September 27, 2023

SPECTRAL AI, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-40058 (Commission File Number)	85-3987148 (I.R.S. Employer Identification No.)
2515 McKinney Avenue, Suite 1000 Dallas, Texas		75201
(Address of principal executive offices)		(Zip Code)

(972) 499-4934

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencements communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	MDAI	The Nasdaq Stock Market LLC
Redeemable Warrants, each whole warrant exercisable for one share of Common Stock, at an exercise price of \$11.50 per share	MDAIW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On September 27, 2023, Spectral AI, Inc. (the “**Company**”), entered into a contract (the “**BARDA Contract**”) with the Biomedical Advanced Research and Development Authority (“**BARDA**”). BARDA is a division of the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response. Under the BARDA Contract, the Company will receive an award to support 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.

The BARDA Contract could result in payments to the Company of up to approximately \$149 million. The BARDA Contract consists of an initial base period and option periods that BARDA may exercise, subject to the Company achieving specified milestones and deliverables. Together with the Company’s previously awarded BARDA contracts, the BARDA Contract brings the total support from BARDA to nearly \$251 million.

The BARDA Contract contains terms and conditions that are customary for government contracts of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

The foregoing is a brief description of the material terms of the BARDA Contract and does not purport to be a complete description of the rights and obligations of the parties thereunder. The foregoing description is qualified in its entirety by reference to the BARDA Contract, which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the period ending September 30, 2023.

Item 7.01. Regulation FD Disclosure.

On September 28, 2023, the Company issued a press release announcing its entry into the BARDA Contract, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 to this Current Report on Form 8-K, and in Exhibit 99.1 furnished herewith, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Spectral AI, Inc. on September 28, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 28, 2023

SPECTRAL AI, INC.

By: /s/ Wensheng Fan

Name: Wensheng Fan

Title: Chief Executive Officer

**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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