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): June 30, 2025

SPECTRAL AI, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-40058	85-3987148
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 $2.75 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 7.01. Regulation FD Disclosure.

On June 30, 2025, the Company issued a press release announcing the submission of its De Novo request to the U.S. Food and Drug Administration of its DeepView System, intended for use in burn care settings including both burn centers and emergency departments, 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 June 30, 2025
104	Cover Page Interactive Data File (formatted as Inline XBRL).

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 officer.

Dated: June 30, 2025

SPECTRAL AI, INC.

By: /s/ Vincent S. Capone

Name: Vincent S. Capone

Title: Chief Financial Officer

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Exhibit 99.1

Spectral AI Announces Submission to FDA of its DeepView® System

DALLAS, TX – June 30, 2025 (GLOBE NEWSWIRE) -- Spectral AI (NASDAQ: MDAI) ("Spectral AI" or the "Company"), developer of the AI-driven DeepView® System, which received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") in 2018 and uses multi-spectral imaging and artificial intelligence ("AI") algorithms to predict burn healing potential, today announced the submission of its De Novo request to the FDA of the DeepView System, intended for use in burn care settings, including both burn centers and emergency departments. The De Novo regulatory pathway is being pursued due to the novel nature of this technology, which does not have a predicate device currently available in the U.S. market.

Spectral AI's DeepView System is a non-invasive, predictive medical device and associated software platform that combines multispectral imaging with a proprietary AI algorithm to assess the healing potential of burn wounds. Trained on more than 340 billion clinically validated data points, the DeepView System provides clinicians with a non-healing prediction—on the same day of injury and up to a week (7 days) post injury, enabling earlier and more informed treatment decisions.

"This FDA submission is a major milestone for Spectral AI and the DeepView System, representing a crucial step toward bringing this innovative diagnostic device to market in the U.S. It provides clinicians with an immediate, data-driven assessment tool designed to assist clinical decision-making and may significantly improve patient outcomes," stated Dr. J. Michael DiMaio, MD, Chairman of the Board at Spectral AI. "I am grateful to our shareholders for their continued support as we reach this important milestone in submitting the De Novo request to the FDA for the DeepView System," DiMaio said. "I am also incredibly proud of our team's dedication and remain confident in our mission to bring this technology to the broader healthcare market worldwide."

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

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 being developed as a predictive device to offer clinicians an objective and immediate assessment of a burn wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal of exceeding the current standard of care in the future, the DeepView System is expected to provide fast and accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. For more information about the DeepView System, 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.

<u>**For Media and Investor Relations, please contact**</u>:

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