

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): February 22, 2024

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 7.01. Regulation FD Disclosure.

On February 22, 2024, the Company issued a press release announcing that its predictive software DeepView AI®-Burn had obtained UK Conformity Assessed (UKCA) authorization for aiding in burn wound diagnosis in the United Kingdom. The Company further announced that it anticipates generating revenue in the second half of 2024. A copy of this release 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, dated February 22, 2024.
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 Current Report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 22, 2024

SPECTRAL AI, INC.

By: /s/ Wensheng Fan

Name: Wensheng Fan

Title: Chief Executive Officer



Spectral Receives UKCA Authorization for Burn Indication Expected Commercialization 2nd Half 2024

DALLAS, February 22, 2024 - 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 that its predictive software DeepView AI®-Burn has obtained the final stage of UK Conformity Assessed (UKCA) authorization, for aiding in burn wound diagnosis in the United Kingdom.

“I am delighted to announce this achievement in our Company’s evolution. The completion of this milestone will allow us to sell our DeepView™ System in the UK and we expect to swiftly deploy six devices in the UK for customer evaluation and to begin generating revenue in the second half of this year.” said Wensheng Fan, the Company’s Chief Executive Officer. “In addition, this regulatory authorization opens up the ability to expand partnerships with regions such as the Middle East that recognize the UKCA authorization.” Revenue from commercialization in the UK in 2024 represents an addition to the \$28 million revenue guidance previously communicated by the Company.

The DeepView® System wound imaging device uses AI-enabled algorithms analyzing real-life patient wounds that assess clinically validated data points to distinguish between healthy and damaged tissue within seconds, unlike the current standard of care, which requires up to three to four weeks of evaluation. The technology establishes a high level of accuracy, 92%, in discerning whether tissue will heal naturally or necessitate surgical intervention, a process that is currently done by clinicians relying on visual observation and resulting in clinical judgement between only 50% to 75% accuracy.

“The current practice of prolonged and expensive observation with open wounds that risk infection before deciding on the best management of care is outdated,” said Prof. Paul Chadwick, Spectral AI’s Executive Vice President of the Company’s United Kingdom subsidiary. “This protracted decision process burdens the patient as well as the healthcare system with unnecessary hospitalization time. The authorization of the DeepView System could effectively obviate the need for these long observation periods, accelerating the way we manage burn wounds in the UK.”

UKCA marking is a certification system established by the UK government to ensure that products meet specified standards for sale in the UK (England, Wales, and Scotland). The DeepView AI®-Burn is currently indicated for individuals aged eighteen and above. The Company aims to extend its technology to benefit pediatric populations and is continuing to initiate case studies and case series with surgeons at leading burn centers.

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 and diabetic foot ulcers. The Company is working to revolutionize the management of wound care by “Seeing the Unknown®” with its DeepView⁰ System. DeepView⁰ is a predictive 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 exceeding the current standard of care in the future, DeepView⁰ 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 DeepView⁰, 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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