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 5, 2024

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 $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 5, 2024, the Company provided a shareholder letter which provides updates on the operations of the Company and expectations for 2024. A copy of the shareholder letter is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The furnishing of the shareholder letter is not an admission as to the materiality of any information therein. The information contained in the shareholder letter is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "**SEC**") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

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	Shareholder Letter, dated February 5, 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 report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 5, 2024

SPECTRAL AI, INC.

By: /s/ Wensheng Fan
Name: Wensheng Fan
Title: Chief Executive Officer

February 5, 2024

Dear Shareholders,

Last year was a milestone year for Spectral AI! We are evolving from a late-stage development company embarking on commercialization of our AI-driven technology to revolutionize the standard of care in wound diagnostics. Your Company is proud to share the accomplishments of the Spectral AI team from this past year and provide insight on the initiatives we are pursuing in 2024.

Before addressing our future, let's revisit the compelling reasons you invested in Spectral AI. Leveraging the power and promise of artificial intelligence, your Company is **dedicated to revolutionizing wound care management by enabling clinicians to make faster and more accurate treatment decisions**. We are prioritizing burn and Diabetic Foot Ulcer ("DFU") indications in the United States and United Kingdom markets and continue to deliver against our stated development milestones. Pending regulatory authorization in the US and UK, we anticipate generating revenue across four separate platforms covering burn and DFU within the next three years.

We are at a pivotal juncture where diligent efforts in clinical evaluation and deployment are paving the way for a shift towards the commercialization of our DeepView™ System.

Regulatory

In late 2023, we received both FDA and UKCA marking of our proprietary imaging technology, DeepView Snapshot®. We recently submitted our predictive software, DeepView AI®-Burn, to the UK regulatory body for UKCA marking and anticipate their response in 1H 2024. Completion of this milestone will allow us to sell our DeepView™ System in the UK and we expect to swiftly deploy multiple devices in the UK for customer evaluation and to begin **generating revenue in the second half of this year**.

BARDA Award and Financing

One of last year's highlights was securing **our largest BARDA contract worth $149 million** in September, bringing the total contract awards from BARDA to over $250 million. This contract not only **provides non-dilutive funding for further development, but also secures procurement of medical devices** to expand utilization beyond burn centers to emergency departments, where most patients enter the healthcare system. Strategically allocated, the award designates $55 million for development activities through the first quarter of 2026 and $95 million for additional development, procurement, and early-adopter deployment of the DeepView™ System. Previously in 2013 and 2019, your Company was awarded BARDA contracts totaling $123 million of which $101 million has been committed to date.

In September, we also made significant strides to enhance your Company's presence in the United States. We **successfully listed on Nasdaq** with the ticker MDAI, leaving the London Stock Exchange. This transition grants us greater access to the United States capital markets; provides you with greater liquidity opportunities in the market; and increases transparency and frequency of our financial activities.

Finally, in December, we completed a Committed Equity Facility with B. Riley Financial Inc., allowing the Company **access up to $10 million** at any time during the next two years. Any such funds would be utilized to support our clinical development activities.

Clinical Trials

Our clinical, regulatory, and engineering teams are leading multiple clinical trials designed to validate the DeepView™ System for wound healing assessments. In the last twelve months alone, we:

- Provided interim results for our DFU Clinical Study. These results will be used in upcoming submissions of DeepView AI®-DFU in the UK (anticipated in 1H 2024) and to the FDA (anticipated in 2H 2024).
- Enhanced both product indications (burn and DFU) to include 3D wound measurements without the use of a reference marker. The benefit to both providers and payers is the creation of standardized digital wound documentation in addition to predictive AI wound healing diagnostic.
- Announced that the wound imaging system, DeepView SnapShot®, received regulatory authorization in the United Kingdom and Class 1 medical device classification with the U.S. Food and Drug Administration (FDA).
- Initiated our pivotal study to validate DeepView AI®. We expect this to be the final clinical trial before seeking FDA marketing authorization for the burn indication in 1H 2025. This study is being conducted in burn centers and emergency departments with an enrollment target of 240 subjects in both adults and pediatric patients.

Product Development

Building on work initially funded by the U.S. Department of Defense, in April 2023, we received a $4 million award from the Medical Technology Enterprise Consortium, providing additional non-dilutive funding to support military battlefield burn evaluation via a handheld, portable, and wireless version of our DeepView technology. We anticipate that our DeepView SnapShot® M will transform wound care in many limited-access areas, including supporting first responder, disaster preparedness and in rural areas. We anticipate originating commercial sales in 2026.

We are proud to have received ISO 13485 certification for the manufacture and distribution of our DeepView™ System in August. ISO 13485 is an internationally recognized standard showing that Spectral MD is committed to the quality of medical device design, development, and production. We believe that this achievement reflects our commitment to fostering a culture of continuous improvement, validates the robust sourcing and operational framework we have created, and provides an important competitive advantage as we continue our regulatory initiatives and advance towards product commercialization.

Management and Board

Since completing the merger that resulted in our Nasdaq listing, our Company has continued to add strength and depth to our management team and the Board of Directors:

- Appointed **Deepak Sadagopan**, MHCDS, to the Board of Directors. Mr. Sadagopan is a high- impact healthcare executive with more than 25 years of senior leadership experience with top Fortune-rated corporations and aggressive startup environments. He also brings to the board expertise in healthcare technology and analytics along with a successful track record in product launches.

- Named Prof. **Paul Chadwick** as Executive Vice President of the Company's United Kingdom subsidiary. Prof. Chadwick is an experienced clinical scientist and wound care key opinion leader (KOL) in the domain of diabetic wound management. Previously, he served as the CEO of the Royal College of Podiatry in the United Kingdom.

- Welcomed back **Erich Spangenberg** to the Board of Directors. Mr. Spangenberg, the Company's initial outside investor in 2011, comes back to the Board of Directors after a short break bringing nearly 40 years of experience as an entrepreneur, investor, investment banker, and attorney.

- Hired **Pete Carlson** as Chief Financial Officer. Mr. Carlson has an exceptional track record as a senior financial executive at several public companies in multiple industries, including two Fortune 50 entities, and most recently at a company focused on chronic and hard-to-heal wounds.

What to expect in 2024

Looking forward, we expect that 2024 will be defined by continuing advancement of clinical trials, health economic and outcome data studies; regulatory submissions; and initial product sales of our DeepView™ System.

As noted earlier, we submitted for regulatory approval in the UK for our DeepView AI®-Burn indication and expect to begin revenue-generating activity in the second half of this year. In addition, we initiated our pivotal study in the US for Burn and anticipate an 1H 2025 submission to the FDA for US approval.

For DFU in the US, our largest market opportunity, we expect to complete our validation study, begin interactions with government payors to establish reimbursement, and in late 2024, to apply with the FDA for approval of the DFU indication.

Outside of the United States, we continue to see strategic opportunities in the EMEA region where diabetes remains a higher medical crisis than in the United States and the UK. A study by the Journal of Diabetes Investigators reported of 3,021 patients from several of the gulf cooperation council "countries", including Saudi Arabia, showed a high prevalence of diabetic peripheral neuropathy, with many also at risk of diabetic ulceration. We expect to continue our work in the EMEA region and hope to transition our clinical studies and work for DFU into commercial activities in early 2025.

In closing, thank you for your continued support of and interest in your Company. We are very excited about our prospects for growth and look forward to apprising you on our progress throughout the year.

We welcome your comments and questions and can be reached at ir@spectral-ai.com.

Sincerely,

Wensheng Fan
CEO & Co-Founder

Richard Cotton
Chairman