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): August 13, 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	(3)	(Zip Code)
	(972) 499-4934 (Registrant's telephone number, including area code)	
(For	Not Applicable mer name or former address, if changed since last repo	ort)
Check the appropriate box below if the Form 8-K is intended t	to simultaneously satisfy the filing obligation of the re	egistrant under any of the following provisions:
☐ Written communication pursuant to Rule 425 under the Sec.	ecurities Act (17 CFR 230.425)	
☐ Soliciting material pursuant to Rule 14a-12 under the Exc	hange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to Rule 14d	d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)))
☐ Pre-commencements communications pursuant to Rule 13	3e-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 the Securities Exchange Act of 1934 (§240.12b-2 of this chapt		ities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of
Emerging growth company ⊠		
If an emerging growth company, indicate by check mark if th accounting standards provided pursuant to Section 13(a) of the		ition period for complying with any new or revised financial

Item 7.01. Regulation FD Disclosure.

On August 13, 2024, the Company posted an investor presentation to its website at www.spectral-ai.com (the "Investor Presentation"). A copy of the Investor Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company expects to use the Investor Presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others.

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	Spectral AI Investor Presentation, dated August 13, 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: August 13, 2024

SPECTRAL AI, INC.

By: /s/ Peter M. Carlson
Name: Peter M. Carlson

Title: Chief Executive Officer



Ş Spectral **AI**®



AI-Driven wound assessment technology

designed to deliver value across the healthcare continuum

17.6 Million

shares outstanding August 9, 2024

2023E \$18M



Supported by \$250M+ non-dilutive government

funding



Financial position at 6/30/2024

Cash **\$6.9M**

Large and growing Large and growing addressable markets

Burn

DFU



Intellectual property portfolio **26** issued | **38** pending

Clear regulatory pathway



Headquarters





Limited competition



Founded 2009



Strong competitive barriers to entry



NASDAQ **MDAI**



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Recent Accomplishments



Received Burn-Al for **UKCA** classification



Secured **\$10.0 Million** Committed
Equity Facility



Strengthened Board and Management Team



Joined Russell Microcap Index



Completed 100% Pediatric Burn
Center Enrollment



PolyNovo MOU to support Australian Special Access Scheme (SAS)



Additional Patent Grants for Total
Number of 26



\$13.8 Million in Revenue for H1 2024

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Revolutionizing

Wound Care

- Our DeepView[™] system enables healthcare providers to make more informed treatment choices.
- In a matter of seconds during the initial patient visit, DeepView[™] **predicts**¹ **if the wound will heal or not**, with remarkable accuracy.

Delivering on Commitments



11-year track record 2013-2024

of meeting milestones validated by \$250M non-dilutive government funding

- Proof of concept
- Product prototyping
- Clinical validation Product validation
- Pre-sub regulatory alignment



Prioritizing growth opportunities in profitable markets, positioning ourselves for nearterm commercial success.



DeepView™ is a single platform supporting multiple indications.



Extensive portfolio of patents, trade secrets and "truthed" images are a significant barrier to competition.

DeepView Imaging

Patented proprietary multispectral imaging data acquisition in milliseconds

Capturing injured **tissue** spectral signature

Covering visible near UV through visible spectrum and into near-IR light

Data extraction

Extraction of AI model features, such as tissue characteristics that determine health

Combined with patient health matrix data

Al model building

Al model trained and tested against a proprietary clinical database of 340+bn³ clinically validated data points

Al algorithm integrates image and clinical data for model training

Healing prediction

Accurate and immediate binary wound healing prediction in seconds

Predicting tomorrow's outcome today



Non-healing output

Decision: surgery or advanced wound care products



Healing output Decision: Routine care

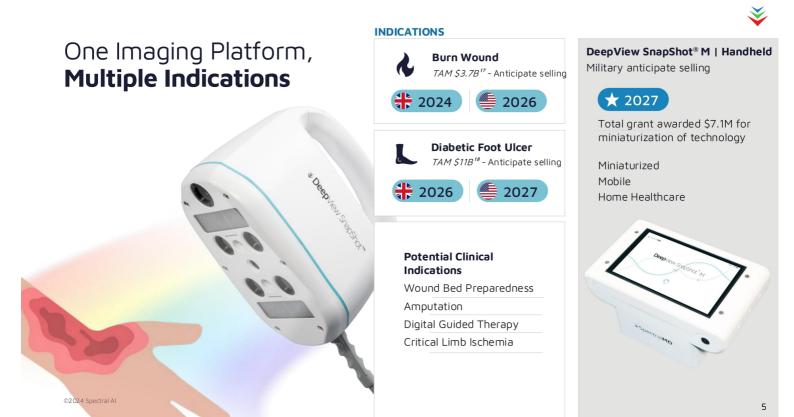






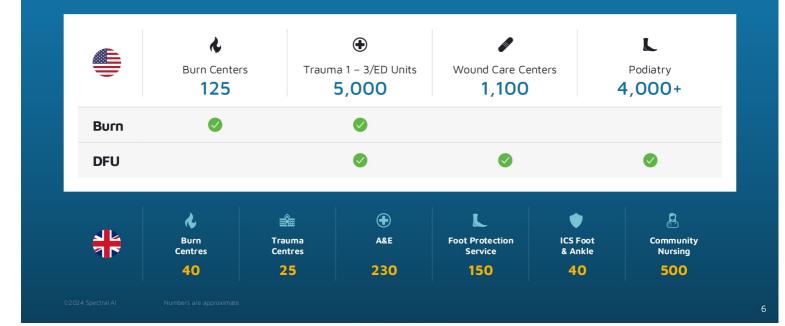








Targeting Multiple Care Centers



Intellectual property formidable barrier to entry

Active patent application families protecting our current and anticipated future business

- Burn/Wound classification on MSI and PPG
- Tissue classification on MSI and PPG
- Amputation site analysis on MSI, machine learning and healthcare matrix
- DFU healing potential prediction and wound assessment on MSI, machine learning and healthcare matrix
- High-precision, multi-aperture, MSI snapshot imaging

- Wound assessment on MSI, optical, biomarkers, and machine learning
- Burn/Histology assessment on MSI and machine learning
- High-precision single aperture snapshot imaging with multiplexed illumination
- Topological characterization and assessment of tissue including wounds, using MSI and machine learning

√

26

U.S. & International Patents issued and allowed X

38

Pending U.S. & International patent applications

ACTIVE MANAGEMENT OF IP PORTFOLIO

- Useful life on key patent protection on core concepts exceeds 14 years
- Proprietary physician review image library for Burn and DFU
- Engage leading experts to constantly evaluate IP strategy and execution

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▼ DeepView **

A PROBLEM

No existing diagnostic tool for burn leading to uninformed decisions. Burn evaluation relies on visual examination and subjective judgement, often leading to inaccuracies.

CURRENT SOLUTION

Wait and See as Tissue Changes to Know Severity

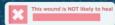
Standard of care is to wait up to 7 days to determine need for surgery.⁶

OUR SOLUTION

Burn professional healing accuracy prediction is 75% (specialist).







ANTICIPATED BENEFITS

- Reduces time to surgery⁸
- Avoids unnecessary surgeries
- Reduced transfers that can be treated locally
- Uniformed standardized TBSA measurements



US Commercialization Sequence





Key Steps to Successful Global Market Access



Publications

Al methodology & machine learning

Impacting patient outcomes

Provider behavior change



Health Economics

Measuring ROI across:

Time

Money

Patient outcomes



Reimbursement

CPTIII code Anticipated 2026

CPTI code Build on market penetration to deliver required evidence package



Regulatory







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Clinical evidence quantifies health system benefits



- Standardized total body surface area (TBSA) measurement
- 41% reduction in unnecessary transfer¹³
- Unnecessary surgery admission costs reduction per patient of \$58,315¹⁴ 15
- 3+ day reduction time to surgery for burns¹⁴ ¹⁶ (>30% reduction in LOS)

Initial penetration in United Kingdom market generates early proof of clinical benefits

BARDA SUPPORT OVER THE YEARS

Management's track record through years of BARDA engagement validates and increases probability of success for DeepView[™] across clinical indications (Burn and DFU/Other) and geography (U.S., UK, EMEA).







Clinical Trial Update



Total Enrollment Goal: 160

85%+ Completed

Anticipated Enrollment Completion: September 2024

Emergency Departments

Total Enrollment Goal: 160

15%+ Completed

Anticipated Enrollment Completion: April 2025

Why are they unique?

125 burn centers with 250 burn surgeons nationwide

High complexity and high volume of cases

Frequent exposure to all burn wound types

Why are they unique?

5,000 Emergency Departments with no burn specialized training

Infrequent exposure to burn severity

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Planned near-term **product deployments**





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While Spectral Al believes it will obtain regulatory clearance on its MSI and Al Software for its DeepView Gen 3 device,

REVENUE OPPORTUNITY

Includes AI annuity and one-time device sales

Research and Development

- BARDA PBS Contract includes \$55M R&D revenue spread across 4Q23 1Q26
- Modest additional R&D revenue from MTEC in 2024
- BARDA PBS Contract anticipates \$95M revenue beginning no later than 2Q26

UK DeepView Commercialization

- Anticipated initial sales are a three-year bundled total, including a leased monthly payment
- Multiple care settings, such as Trauma and A&E, being targeted

U.S. DeepView Commercialization

- Initial sales will also be focused on developing real-world evidence (RWE)
- Ongoing pricing per click and device sales being evaluated
- o Annuity payment with and without device one time sale
- o Reimbursement being developed

Additional Revenue Sources

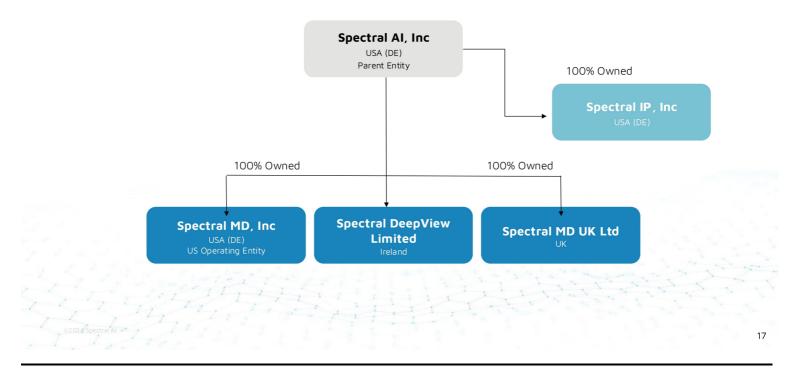
- Global expansion following US De Novo Clearance
- Annuity payment from Al licensing fees

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Spectral IP Subsidiary





Improving health and cost outcomes for all





Investment Summary



Al-Driven Clinical Diagnostics

FDA Breakthrough Designation

> Strong Competitive Barriers



Systemwide Benefits

Identified Regulatory Pathway

Universal Platform for Additional Clinical Indications



Large & Growing Markets

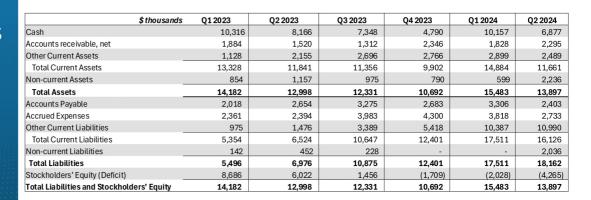
Near-Term Commercial Opportunities

> Experienced Management Team





Summary balance sheets

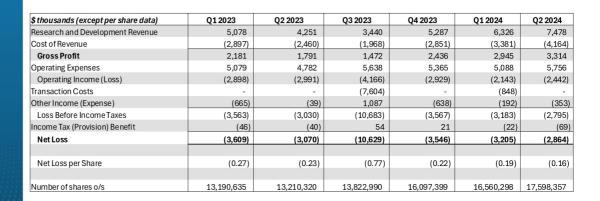


Fiscal year end is December 31st. 21





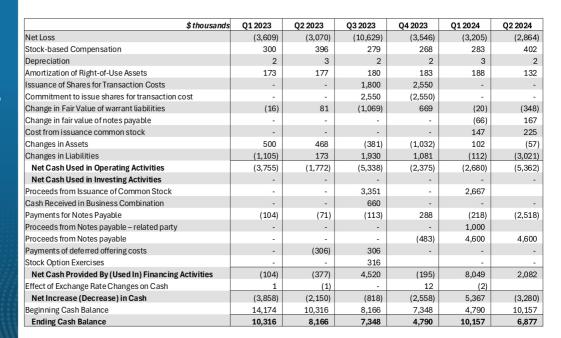
Summary income statements



Fiscal year end is December 31th.



Summary cash flow statements



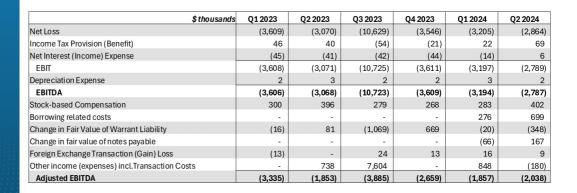
Fiscal year end is December 31th. 23







Non-GAAP reconciliation



Fiscal year end is December 31st. 24





Peter M. Carlson Chief Executive Officer

30 yrs+ of Finance and Operations experience in Fortune 50 and healthcare corporations, such as MiMedx, Metlife, and Wachovia.



Vincent Capone Chief Financial Officer & General Counsel 25 yrs- of tech company experience KPMG, Morgan Lewis and Reed Smith LLP.



Jeremiah Sparks Chief Commercialization Officer 20 yrs+ of medical device marketing

experience evidenced by positions held with Avita Medical and Allergan.



Stan Micek Interim Chief Operations Officer

20 yrs+ of product development and strategic alliances, such as MiMedx and Aster Insights.



Kevin Plant

VP of Research & Development

10 yrs+ of software and data science leadership experience at St. Jude and Abbott.



Louis Percoco General Manager – Manufacturing 30 yrs+ of experience in

R&D and Production teams in Cardiology, Orthopedic, and Spine disciplines.



Mary Regan, PhD VP of Clinical Affairs

30 yrs+ years of clinical experience, with board

positions held on the American Association of Wound Care Specialists and NWHS.



Christine Marks
VP of Marketing & Commercialization

20 yrs+ of marketing experience for wound care medical device companies, such as BSN Medical and Lohmann & Raucher.



Prof. Paul Chadwick EVP of UK and EMEA

Podiatrist with 15 yrs+ of experience in wound care and foot health. Most recently former CEO of Royal College of Podiatry in UK.

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Board of Directors

Marion

Snyder

Sr. Director Corporate Accounts at Shock wave Medical, and founder of Lakeview Healthcare Consulting



Richard Cotton

Financial Advisor to Novumgen Ltd., and held CFO positions at several medical companies.



Deepak Sadagopan

Serves as COO of Population Health at Providence, and CEO of Health Connect Partners, LLC.



Erich Spangenberg

Managing partner at Sauvegarder Investment Management with extensive background in investment banking.



Martin Mellish

Founding director of Aspen Advisory Services Ltd.



Peter M. Carlson

Prior to becoming CEO of Spectral AI, served as CFO since January 2024. Prior to Spectral AI, was CFO of MiMedx Group, Inc.



Dr. J. Michael DiMaio

24+ years of experience in cardiothoracic surgery, and Chief of Staff at Baylor Scott & White supervising more than 650 physicians.





Expert clinical guidance

The technology provides us with high quality photos and gives us a binary output in terms of whether we need to surgically remove an area of burned skin or whether it will heal.

C C DeepView will significantly transform how we treat DFUs through continuous monitoring and measurement ensuring an accelerated healing trajectory and prevent DFU reoccurrence.



CHRIS LEWIS Consultant Burn Surgeon

Mr. Christopher Lewis is a Consultant Burn, Laser and Reconstructive Surgeon at the Northern Regional Burn Centre based at Newcastle's Royal Victoria Infirmary, with a special interest in emergency burn care, reconstruction and laser treatment.



PROF. PAUL CHADWICK EVP of UK and EMEA Former CEO of the Royal College of Podiatry UK

wound care key opinion leader (KOL), and has an extensive publication record on diabetic wound management.

REFERENCE LIST

- 1. Data from Spectral MD's IRB approved Proof of Concept Clinical Study
- 2. https://www.cnn.com/2023/08/09/weather/maui-county-wildfireshurricane-dora/index.html
- 3. Pixel data per Spectral MD clinical studies.
- 4. Data from Spectral MD's IRB approved Proof of Concept Clinical Study
- Clinicians are 50% accurate in assessing healing potential of DFUs https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7950518/
- Anyanwu JA, Cindass R. Burn Debridement, Grafting, and Reconstruction. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK551717/
- Assessment of burn depth and burn wound healing potential. Burns. Volume 34-6. September 2008, pages 761-769
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 with a Novel Burn Wound Assessment Device. JBCR 2021;(42)S117-18
- Definitive Healthcare 2019 Private Pay and CMS pay of inpatient versus outpatient DRG codes
- 10. The Effectiveness of Regionalized Burn Care: An Analysis of 6,873 Burn Admissions in North Carolina from 2000 to 2007.Regional Air Transport of Burn Patients: A Case for Telemedicine?

- Warriner R, Snyder RJ, Cardinal MH et al (2011) Differentiating diabetic foot ulcers that are unlikely to heal by 12 weeks following achieving 50% percent area reduction at 4 weeks. Int Wound J 8(6):632-7. https://doi.org/10.1111/j.1742-481x.2011.00860.x
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- Carter NH, Leonard C, Rae L. Assessment of Outreach by a Regional Burn Center: Could Referral Criteria Revision Help with Utilization of Resources? JBCRi2018;39(2):245-51
- 14. Definitive Healthcare 2019 Cost and Claims Data from Medicare and Private Payer Estimates
- 15. American Medical Association Common Procedural Terminology CPT®
- Huson HB, Phelan HA, G'Sell DJ, Smith S, Carter JE. If Seeing Was Believing A Retrospective Analysis of Potential Reduced Treatment Delays with a Novel Burn Wound Assessment Device. JBCR 2021;(42)S117-18.
- 17. TAM and CAGR Global Burn Care Market Size & Share Report, 2021-2028
- TAM and CAGR Fortune Business Insights: Diabetic Foot Ulcer Treatment Market Worth \$11.16 Billion at 6.8% CAGR; Rise in Clinical Trials to Augment Market

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FORWARD LOOKING STATEMENTS



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Except for the historical information contained herein, this document contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding (i) our strategy, plans, objectives and initiatives, including but not limited to our plans and projected timelines to begin commercialization and product sales, launch new products, complete clinical trials, add additional clinical indications, (ii) the ability to be listed on the Nasdaq Global Market, (iii) Spectral Al's managements' expectations, (iv) potential government contracts, (v) expected beneficial outcomes and synergies, (vi) potential financing opportunities, (vii) Spectral Al's regulatory pathway for and timing of FDA, CE and UKCA regulatory submissions and approvals, (viii) Spectral Al's U.S. government contracts and future awards, (ix) the total anticipated target markets for burn wound and diabetic foot ulcers, (x) possible competitors, (xi) potential future indications and applications for DeepView and areas of interest supported by BARDA, (xii) Spectral Al's future and pending U.S. patent applications and foreign and international patent applications, and (xiii) pro forma information and other estimated values. The foregoing list of risk factors is not exhaustive. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to our ability to obtain and maintain necessary regulatory approvals, general economic conditions, consumer demand for our products and services, challenges relating to entering into and growing new business lines, the competitive environment, and the risk factors listed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, the Registration Statement on Form S-1, as amended, filed with the SEC on April 10, 2024 and any other SEC filings including the sections entitled "Cautionary Note Regarding Forward-Looking Statements", "Cautionary Note Regarding Forward-Looking Statements and Risk Factor Summary", "Risk Factors", "Management's Discussions and Analysis of Financial Condition and Results of Operations" and "Business" and in the Financial Statements. The Company undertakes no obligation to update forward-looking statements except as required by applicable securities laws. Readers are cautioned that forward-looking statements are not guarantees of future performance and are cautioned not to place undue reliance on any forward-looking statements.

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