

**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): March 27, 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

(Address of principal executive offices)

75201

(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 2.02. Results of Operations and Financial Condition

On March 27, 2024, Spectral AI, Inc. (the “Company”) reported its financial results for the quarter and year ended December 31, 2023. A copy of the press release containing this information is furnished as Exhibit 99.1 hereto and is incorporated by reference in this Item 2.02.

Additionally, the Company hosted a conference call on March 27, 2024 at 5:00 pm Eastern Time with financial analysts to discuss the Company’s financial results and other business matters. The event will be available for replay on the Company’s website: <https://investors.spectral-ai.com/news-events/events>.

As provided in General Instruction B.2 of Form 8-K, the information and exhibits provided pursuant to this Item 2.02 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall they be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Spectral AI, Inc., dated March 27, 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: March 28, 2024

SPECTRAL AI, INC.

By: /s/ Peter Carlson

Name: Peter Carlson

Title: Chief Executive Officer



Spectral AI Announces 2023 Fourth Quarter and Full Year Financial Results

2023 Research & Development Revenue of \$18.1 Million Expected to Increase to \$28.0 Million in 2024

Commercialization Underway with Revenue Expected in 2H 2024 for DeepView AI[®]-Burn Indication in the UK

On Track for Additional Regulatory Submissions in US and UK for DeepView[®] System Burn and Diabetic Foot Ulcer Indications

DALLAS, TX – March 27, 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 financial results for the fourth quarter (“Q4 2023”) and full year (“FY 2023”) ended December 31, 2023 and provided an update on its ongoing business activities.

“Spectral AI achieved much in 2023, and our progress along multiple fronts has continued into 2024,” said Peter M. Carlson, Chief Executive Officer. “The team’s achievements to date, and those on the horizon, are the result of a 10-year record of success in delivering on a promise to develop and commercialize our proprietary AI-Driven DeepView[®] System wound healing assessment platform, a technology that we believe can help change the standard of care while delivering value across the healthcare ecosystem. We expect to realize our first commercial product revenue in the second half of this year. Given the pace of our product development and clinical activities in the US and internationally, we believe that we are on the proper path to generate commercial revenue across four separate DeepView[®] System platforms covering burn and diabetic foot ulcer (DFU) within the next three years.

“We have a well-defined business focus for 2024 based on the evolution of our DeepView[®] System from clinical stage to commercialization. We will continue to advance our research and development work under current US Government contracts for our DeepView[®] System burn indication and plan to submit regulatory filings for the approval of this indication in the US in the first half of 2025. We are pursuing the commercialization of our DeepView[®] System for the assessment of DFU in the US and the UK, and expect to submit regulatory filings for the approval of this indication in the US and UK in 2024. Our recent financing agreements in combination with the multi-year, non-dilutive funding provided by our US Government contracts provides us with a sound financial foundation to pursue these objectives.”

2023-2024 SELECT BUSINESS HIGHLIGHTS

Government Funding

- In September 2023, we were awarded the largest contract in our history from the US Government valued at up to \$150.0 million. This multi-year, non-dilutive contract includes an initial award of approximately \$54.9 million to fund development activities through Q1 2026 for our DeepView^Ô System for burn to submit a De Novo FDA application, and for government procurement of the device for distribution at various burn centers and emergency rooms across the United States.

First Commercial Product Revenue

- In February 2024, we received UKCA Authorization to commence sales of our DeepView^Ô System for burn in the UK. We deployed our first burn device in March 2024 and expect to commence generating commercial revenues in the second half of 2024.

Regulatory

- In October 2023, our DeepView SnapShot[®] wound imaging system received regulatory authorization in the UK and Class 1 medical device classification with the U.S. Food and Drug Administration (FDA).

Clinical Trials

- In January 2023, we provided interim results for our DFU Clinical Study, which will be used in upcoming regulatory submissions in the UK and US.
- In December 2023, we initiated a pivotal study to validate our DeepView^Ô System for burn, which is expected to be the final clinical trial before seeking FDA approval. This study is being conducted in burn centers and emergency departments with an enrollment target of 240 subjects in both adult and pediatric patients.

Product Development

- In March 2024, we received a new contract valued at \$500,000 from the US Government that provides additional support for the development of the handheld version of our DeepView^Ô System called DeepView SnapShot[®] M. This new award brings total support for the DeepView SnapShot[®] M to more than \$6 million.
- In August 2023, we received ISO 13485 certification for the manufacture and distribution of our DeepView^Ô System.

Corporate

- Successfully listed on Nasdaq in September 2023, elevating our profile among US investors and other stakeholders.
- Added significant strength and industry depth to our board of directors with the appointments of Deepak Sadagopan, MHCDS, Erich Spangenberg, Dr. J. Michael DiMaio, and to our management team with the additions of Peter M. Carlson and Prof. Paul Chadwick.
- Enhanced our access to capital by completing an equity financing and entering into a fixed price standby equity purchase agreement with a long-only investor that includes a \$12.5 million prepaid advance.

2023 FINANCIAL RESULTS OVERVIEW

All comparisons to Q4 2023 and FY 2023 are to the comparable periods ended December 31, 2022, unless otherwise stated.

Research & Development Revenue

Research & Development Revenue¹ for Q4 2023 was \$5.3 million compared to \$6.1 million, primarily due to the implementation of the new BARDA PBS contract, executed in September 2023.

For FY 2023, Research & Development revenue was \$18.1 million compared to \$25.4 million, reflecting a decrease in activity due to the completion of work under the BARDA Burn II contract, partially offset by the commencement of work under the new BARDA PBS contract.

Gross Margin

Gross margin for Q4 2023 was 46.1% compared to 41.1%.

For FY 2023, gross margin rose to 43.6% from 42.7%. The improvement in gross margin for both periods reflected the commencement of work under the BARDA PBS contract, which carries a higher reimbursement rate than the prior BARDA Burn II contract.

General & Administrative Expense

General & administrative expenses in Q4 2023 were \$5.4 million compared to \$4.3 million.

For FY 2023, general & administrative expenses rose to \$20.9 million from \$13.5 million. The increase for both periods was the result of increased headcount required to support our organizational growth, and higher costs associated with an increase in non-revenue generating R&D activities.

Net Loss

Net loss for Q4 2023 was \$(3.5) million, or \$(0.22) per share, compared to a net loss of \$(1.7) million, or \$(0.13) per share, for Q4 2022.

For FY 2023, the net loss was \$(20.9) million, or \$(1.48) per share, compared to a net loss of \$(2.9) million, or \$(0.22) per share, for FY 2022.

Net loss for the 2023 period included \$8.3 million of non-recurring transaction costs associated with the consummation of the Company's business combination that resulted in its Nasdaq listing; there were no such costs incurred in 2022.

Cash

As of December 31, 2023, cash was \$4.8 million and the Company had no long-term debt. During the first quarter of 2024, the Company enhanced its financial position, as follows:

- Received proceeds of \$5.0 million via a fixed price prepaid advance and standby equity purchase agreement (SEPA) with a long-only investor with a fixed conversion price of \$3.16 as part of a total advance of \$12.5 million. The SEPA facility provides for financing of up to \$30.0 million in total.
- Received proceeds of approximately \$2.8 million via a committed equity facility that was entered into in December 2023 under which the Company is able to draw an additional \$3.0 million prior to utilizing the SEPA facility.

¹ Research and Development Revenue consisted primarily of funding from 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.

2024 Guidance

The Company is reiterating its revenue guidance of approximately \$28.0 million for FY 2024. Financial guidance for FY 2024 does not reflect expected contributions from the sale of the DeepView[®] System for burn in the UK beginning in the second half of 2024 or any additional material financial contributions that may result from the commercialization of our DeepView[®] System.

CONFERENCE CALL

The Company will host a conference call today at 5:00 pm Eastern Time to discuss these results. Investors interested in participating in the live call can dial:

- 833-630-1956 – U.S.
- 412-317-1837 – International

A simultaneous webcast of the call may be accessed online from the Events & Presentations section of the Investor Relations page of the Company's website at <https://investors.spectral-ai.com/news-events/events>

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 DeepView System. DeepView 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, 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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Spectral AI, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current assets:		
Cash	\$ 4,790	\$ 14,174
Accounts receivable, net	2,346	2,294
Inventory	230	-
Unbilled revenue	-	618
Deferred offering costs	283	-
Prepaid expenses	1,452	331
Other current assets	801	270
Total current assets	<u>9,902</u>	<u>17,687</u>
Non-current assets:		
Property and equipment, net	12	21
Right-of-use assets	778	1,008
Total Assets	<u>\$ 10,692</u>	<u>\$ 18,716</u>
Commitments and contingencies (Note 8)		
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,683	\$ 2,759
Accrued expenses	4,300	2,631
Deferred revenue	2,311	-
Lease liabilities, short-term	853	680
Notes payable	436	175
Warrant liabilities	1,818	129
Total current liabilities	<u>12,401</u>	<u>6,374</u>
Lease liabilities, long-term	-	346
Total Liabilities	<u>12,401</u>	<u>6,720</u>
Stockholders' Equity (Deficit)		
Preferred stock (\$0.0001 par value); 1,000,000 shares authorized; no shares issued and outstanding as of December 31, 2023 and December 31, 2022	-	-
Common stock (\$0.0001 par value); 80,000,000 shares authorized; 16,294,935 and 13,170,148 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	2	1
Additional paid-in capital	31,065	23,929
Accumulated other comprehensive income	12	-
Accumulated deficit	(32,788)	(11,934)
Total Stockholders' Equity (Deficit)	<u>(1,709)</u>	<u>11,996</u>
Total Liabilities and Stockholders' Equity (Deficit)	<u>\$ 10,692</u>	<u>\$ 18,716</u>

Spectral AI, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Research and development revenue	\$ 5,287	\$ 6,096	\$ 18,056	\$ 25,368
Cost of revenue	(2,851)	(3,588)	(10,176)	(14,531)
Gross profit	<u>2,436</u>	<u>2,508</u>	<u>7,880</u>	<u>10,837</u>
Operating costs and expenses:				
General and administrative	5,365	4,277	20,864	13,484
Total operating costs and expenses	<u>5,365</u>	<u>4,277</u>	<u>20,864</u>	<u>13,484</u>
Operating loss	<u>(2,929)</u>	<u>(1,769)</u>	<u>(12,984)</u>	<u>(2,647)</u>
Other income (expense):				
Net interest income	44	20	172	21
Change in fair value of warrant liability	(669)	7	335	57
Foreign exchange transaction loss, net	(13)	18	(24)	(237)
Transaction costs	-	-	(8,342)	-
Total other expense, net	<u>(638)</u>	<u>45</u>	<u>(7,859)</u>	<u>(159)</u>
Loss before income taxes	<u>(3,567)</u>	<u>(1,724)</u>	<u>(20,843)</u>	<u>(2,806)</u>
Income tax provision	<u>21</u>	<u>(15)</u>	<u>(11)</u>	<u>(106)</u>
Net loss	<u>\$ (3,546)</u>	<u>\$ (1,739)</u>	<u>\$ (20,854)</u>	<u>\$ (2,912)</u>
Net loss per share of common stock				
Basic and Diluted	<u>\$ (0.22)</u>	<u>\$ (0.13)</u>	<u>\$ (1.48)</u>	<u>\$ (0.22)</u>
Weighted-average common shares outstanding				
Basic and Diluted	<u>16,097,399</u>	<u>13,164,086</u>	<u>14,087,586</u>	<u>13,136,965</u>
Other comprehensive income:				
Foreign currency translation adjustments	\$ 12	\$ -	\$ 12	\$ -
Total comprehensive loss	<u>\$ (3,534)</u>	<u>\$ (1,739)</u>	<u>\$ (20,842)</u>	<u>\$ (2,912)</u>

Spectral AI, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (20,854)	\$ (2,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	9	11
Stock-based compensation	1,243	1,155
Amortization of right-of-use assets	713	557
Issuance of shares for transaction costs	4,350	-
Change in fair value of warrant liabilities	(335)	(57)
Changes in operating assets and liabilities:		
Accounts receivable	(52)	(859)
Inventory	(230)	-
Unbilled revenue	618	(547)
Prepaid expenses	(377)	615
Other assets	(404)	40
Accounts payable	(935)	1,345
Accrued expenses	1,359	51
Deferred revenue	2,311	-
Lease liabilities	(656)	(561)
Net cash used in operating activities	(13,240)	(1,162)
Cash flows from financing activities:		
Proceeds from issuance of common stock for Equity Raise	3,351	-
Cash received in Business Combination	660	-
Payments for notes payable	(483)	(785)
Stock option exercises	316	-
Net cash provided by (used in) financing activities	3,844	(785)
Effect of exchange rate changes on cash	12	-
Net decrease in cash	(9,384)	(1,947)
Cash, beginning of period	14,174	16,121
Cash, end of period	\$ 4,790	\$ 14,174