Spectral AI Announces 2024 Fourth Quarter and Full Year Financial Results

Mar 27, 2025

2024 Research & Development Revenue of $30 Million

Successful Results from the US Burn Validation Study

On Track for Regulatory Submission in US for DeepView™System

DALLAS, March 27, 2025 (GLOBE NEWSWIRE) -- **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 2024") and full year ("FY 2024") ended December 31, 2024, and provided an update on its ongoing business activities.

"Spectral AI achieved much in 2024. Our top-line revenue reflects extensive work on our BARDA PBS contract, and our progress along multiple fronts has continued into 2025," said Dr. J. Michael DiMaio, M.D., the Company's Chairman of the Board. "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 the US government and the American people 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 other indications within the next three years.

"We have a well-defined business focus for 2025 based on the evolution of our DeepView System from clinical stage to commercialization. We will continue to advance our research and development work under our 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 this year. Our recent financing agreements and the multi-year, non-dilutive funding provided by our US government contracts provide us with a sound financial foundation to pursue these objectives."

2024-2025 SELECT BUSINESS HIGHLIGHTS

Government Funding

- The Company continues to build on its BARDA PBS contract awarded in September 2023. This is the largest contract in our history and is 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 to submit a De Novo FDA application for our DeepView System for burns, and for government procurement of the device for distribution to various burn centers and emergency rooms across the United States.

Burn Validation Study

- In March 2025, the Company announced the successful results of its Burn Validation Study. At both a pixel-level and an image-level, the Company's DeepView System performed very well in assessing sensitivity, specificity and Dice score. The Company plans to submit these results to the FDA as part of its regulatory submission by the end of the second quarter of 2025 and hopes to have the FDA grant the De Novo Classification Request of the DeepView System in early 2026. As noted in our March 17, 2025 press release, with respect to scoring, the DeepView System demonstrated a statistically significant improvement for sensitivity in identifying non-healing tissue compared to burn physicians; at the image-wise level, the DeepView System scored 86.6%, while the clinical judgment annotation ("CJA") of burn physicians scored 40.8%. At the pixel-wise level, the DeepView System scored 81.9% and the CJA of burn physicians scored 38.8%. The DeepView System also achieved statistically significant higher Dice Scores when compared to those derived from burn physicians' CJA, representing the improved pixel-wise evaluation between predicated and true segmented wound areas with the DeepView System performing at 68.5% and burn physician's CJA at 39.2%. The DeepView System significantly outperformed the anticipated results for image-wise specificity in segmenting non-healing wound areas with a result of 61.2% (versus management's anticipated result of 36.0%) with the CJA of 79.1% reflecting burn physician's

conservative assessment of burn areas. The clinicians performing CJA tend to be very conservative by being more likely to diagnose wounds as healing, introducing a bias toward higher specificity. Our results exceeded our expectations and met the FDA requirement for non-inferiority of specificity when compared to CJA assessments.

Clinical Trials

- In September 2024, the Company completed its enrollment in the Burn Validation Study, which was one of the largest burn studies conducted in the US. This study was initiated in January 2024 and involved 160 adult and pediatric patients at 14 burn centers across the US.
- In October 2024, we announced the final group of burn center patients for the Burn Validation Study had completed their clinical visits.
- In January 2025, we completed our pediatric enrollment at US emergency departments for the Burn Validation Study.

Product Development

- In March 2024, we received a new contract valued at $500,000 from the Defense Health Agency that provides additional support for the development of the handheld version of our DeepView System called DeepView SnapShot® M.
- In August 2024, we received an additional grant of approximately $900,000 from the Medical Technology Enterprise Consortium ("MTEC") for the development of the DeepView SnapShot ® M bringing the total award to $4.9 million from MTEC. The contract is currently intended to run through December 2025 with funding dependent on various milestones.

Corporate

- In March 2024, we formed Spectral IP Inc. ("Spectral IP"), a dedicated intellectual property subsidiary focused on monetizing third-party IP assets within the healthcare and AI-driven technology sectors. In November 2024, we announced our intention to spin off Spectral IP into an independent, publicly-traded company upon which our shareholders will be receiving shares in the newly publicly-traded company. We anticipate completion of the public merger by the end of the second quarter of 2025.
- In November 2024, the Company repriced its 8,433,333 publicly-traded common share purchase warrants from an exercise price of $11.50 per share to $2.75 per share. The warrants trade on NASDAQ under the symbol MDAIW.
- In December 2024, the Company regained full compliance with the Nasdaq listing rules by meeting the minimum listing requirement regarding its market capitalization.
- In March 2025, the Company was able to increase its cash-flow and operating capital by completing an equity financing and entering into a long-term debt transaction with an initial capital raise of $11.2 million, comprised of $8.5 million of long-term debt and $2.7 million in equity financing from institutional and existing UK investors. The total funding available in this transaction is up to approximately $25.0 million through the completion of the milestones for the second tranche of the debt financing, providing sufficient financing for the Company as it seeks FDA clearance for its DeepView System.

2024 FINANCIAL RESULTS OVERVIEW
All comparisons to Q4 2024 and FY 2024 are to the comparable periods ended December 31, 2023, unless otherwise stated.

Research & Development Revenue

Research & Development Revenue[1] for Q4 2024 was $7.6 million compared to $5.3 million, primarily due to the increased overall percentage of work on the BARDA PBS contract which was awarded in September 2023.

For FY 2024, Research & Development revenue was $29.6 million, a 63.5% increase from $18.1 million in 2023. The year-over-year increase reflects the expanded work on the BARDA PBS contract for the full year 2024.

Gross Margin

Gross margin for Q4 2024 was 44.0% compared to 46.1% in the prior year period, due primarily to a smaller percentage of direct labor as a proportion of total work on the BARDA PBS contract.

For FY 2024, gross margin rose to 44.9% from 43.6%. The improvement in gross margin reflected the expansion of work under the BARDA PBS contract, which carries a higher reimbursement rate than the prior BARDA Burn II contract, which had comprised the majority of revenue in 2023.

General & Administrative Expense

General & administrative expenses in Q4 2024 were $4.5 million compared to $5.4 million. The decrease in Q4 2024 represented reduced spending on legal and accounting consultants.

For FY 2024, general & administrative expenses decreased to $19.9 million from $20.9 million. The decrease for the year was a result of less overall spending in non-revenue generating R&D activities.

Net Loss

Net loss for Q4 2024 was $(7.7) million, or $(0.41) per share, compared to a net loss of $(3.5) million, or $(0.22) per share, for Q4 2023.

For FY 2024, the net loss was $(15.3) million, or $(0.85) per share, compared to a net loss of $(20.9) million, or $(1.48) per share, for FY 2023.

Net loss for FY 2024 included $4.6 million of charges for the change in the fair value of the Company's warrant liabilities and $2.9 million of borrowing related expenses associated with the Company's satisfaction of the Yorkville pre-paid note obligations; there were no such costs incurred in 2023. In FY 2023, the Company incurred $8.3 million in costs associated with its financing operations relating to its business combination.

Cash

As of December 31, 2024, cash was $5.2 million.
During the first quarter of 2025, the Company enhanced its financial position, as follows:

- Received proceeds of $8.5 million via a long-term debt financing as the first tranche in an overall $15.0 million three-year term debt facility.

- Received proceeds of approximately $2.7 million via issuances of the Company's common stock through the Company's Form S-3 Registration Statement to institutional and existing UK investors.

[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.

The Company is forecasting revenue of approximately $21.5 million for FY 2025. Financial guidance for FY 2025 does not reflect contributions from the sale of the DeepView System for burn in the UK or Australia 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:

- 844-481-3008 – U.S.
- 412-317-1892 – 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. 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, 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)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$5,157	$4,790
Accounts receivable, net	2,505	2,346
Inventory	425	230
Unbilled revenue	-	-
Deferred offering costs	-	283
Prepaid expenses	1,289	1,452
Other current assets	746	801
Total current assets	10,122	9,902
Non-current assets:		
Property and equipment, net	2	12
Right-of-use assets	1,971	778
Total Assets	$12,095	$10,692
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$4,035	$2,683
Accrued expenses	3,210	4,300
Deferred revenue	960	2,311
Lease liabilities, short-term	201	853
Notes payable	422	436
Note payable – at fair value	2,365	-
Warrant liabilities	6,451	1,818
Total current liabilities	17,644	12,401
Lease liabilities, long-term	1,702	-
Total Liabilities	19,346	12,401
Stockholders' Equity (Deficit)		
Preferred stock ($0.0001 par value); 1,000,000 shares authorized; no shares issued and outstanding as of December 31, 2024 and December 31, 2023	0	0
Common stock ($0.0001 par value); 80,000,000 shares authorized; 22,594,877 and 16,294,935 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	40,847	31,065
Accumulated other comprehensive income	3	12
Accumulated deficit	(48,103)	(32,788)
Total Stockholders' Equity (Deficit)	(7,251)	(1,709)
Total Liabilities and Stockholders' Equity (Deficit)	$12,095	$10,692

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,	
	2024	**2023**	**2024**	**2023**
Research and development revenue	$7,604	$5,287	$29,581	$18,056
Cost of revenue	(4,256)	(2,851)	(16,307)	(10,176)
Gross profit	3,348	2,436	13,274	7,880
Operating costs and expenses:				
General and administrative	4,459	5,365	19,856	20,864

Total operating costs and expenses	4,459	5,365	19,856	20,864
Operating loss	(1,111)	(2,929)	(6,582)	(12,984)
Other income (expense):				
Net interest income	14	44	14	172
Borrowing related costs	(931)	-	(2,965)	-
Change in fair value of warrant liability	(5,350)	(669)	(4,632)	335
Change in fair value of notes payable	(213)	-	(220)	-
Foreign exchange transaction loss, net	(9)	(13)	(43)	(24)
Transaction costs	1	-	(616)	(8,342)
Total other expense, net	(6,488)	(638)	(8,462)	(7,859)
Loss before income taxes	(7,599)	(3,567)	(15,044)	(20,843)
Income tax provision	(143)	21	(271)	(11)
Net loss	$(7,742)	$(3,546)	$(15,315)	$(20,854)
Net loss per share of common stock				
Basic and Diluted	$(0.41)	$(0.22)	$(0.85)	$(1.48)
Weighted-average common shares outstanding				
Basic and Diluted	18,810,771	16,097,399	17,934,218	14,087,586
Other Comprehensive Income				
Foreign currency translation adjustments	$(22)	$12	$(9)	$12
Total comprehensive loss	$(7,764)	$(3,534)	$(15,324)	$(20,842)

Spectral AI, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$(15,315)	$(20,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	10	9
Stock-based compensation	1,032	1,243
Amortization of right-of-use assets	578	713
Issuance of shares for transaction costs	-	4,350
Change in fair value of warrant liabilities	4,633	(335)
Change in fair value of notes payable	220	-
Costs from issuance of common stock	372	-
Issuance of shares for borrowing related costs	1,143	-
Changes in operating assets and liabilities:		-
Accounts receivable	(159)	(52)
Inventory	(195)	(230)
Unbilled revenue	-	618
Prepaid expenses	163	(377)
Other assets	55	(404)
Accounts payable	1,426	(935)
Accrued expenses	(1,090)	1,359
Deferred revenue	(1,351)	2,311
Lease liabilities	(721)	(656)
Net cash used in operating activities	(9,198)	(13,240)
Cash flows from financing activities:		
Proceeds from issuance of common stock for Equity Raise	4,060	3,351
Cash received in Business Combination	-	660
Payments for notes payable	12,096	-
Proceeds from note payable - related party	1,000	-
Payments for notes payable	(7,758)	(483)
Stock option exercises	177	316
Net cash provided by (used in) financing activities	9,575	3,844
Effect of exchange rate changes on cash	(9)	12
Net decrease in cash	367	(9,384)
Cash, beginning of period	4,790	14,174
Cash, end of period	$5,157	$4,790