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Spectral AI, Inc. (MDAI - NASDAQ)

MDAI: Second Quarter Results

Our valuation uses a discounted cash flow model and a 15% discount rate to generate the Spectral AI target price. We forecast revenues from the United States and the United Kingdom in the burn indication to produce our cash flow estimates.

Current Price (8/13/2025)	$2.12
Valuation	**$5.00**

OUTLOOK

Spectral AI is developing an AI-guided predictive medical device that employs multispectral imaging (MSI) to estimate a wound's capacity to heal. The company is pursuing indications in burn and diabetic foot ulcers (DFUs) with the former receiving support from BARDA & other government agencies. Spectral is distinguished by its combination of MSI and AI to improve diagnoses.

Spectral is conducting multiple clinical trials around the world to obtain approval for its device with the FDA & other regulatory agencies. In 2Q:25, a pivotal burn study was submitted to the FDA in a De Novo submission. The device has received the UKCA mark for burn in the UK & has deployed devices in Australia. The company is also pursuing the CE mark in Europe. Spectral will consider new diagnostic areas for DeepView such as amputation & critical limb ischemia.

We forecast DeepView product revenues from burn centers & emergency departments using a licensing fee model that provides access to service, training & algorithm updates. Device sales & per transaction fees may also be part of the reimbursement model. Geographical opportunities include US, the UK and EU with potential for broader distribution.

SUMMARY DATA

52-Week High	**3.25**
52-Week Low	**0.82**
One-Year Return (%)	**41.0**
Beta	**0.9**
Average Daily Volume (sh)	**533,217**
Shares Outstanding (mil)	**26.7**
Market Capitalization ($mil)	**56.6**
Short Interest Ratio (days)	**1.0**
Institutional Ownership (%)	**14.2**
Insider Ownership (%)	**30.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Tech Devices**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	$6.3 A	$7.5 A	$8.2 A	$7.6 A	$29.6 A
2025	$6.7 A	$5.1 A	$4.9 E	$4.8 E	$21.4 E
2026					$43.4 E
2027					$57.7 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2024	-$0.19 A	-$0.16 A	-$0.08 A	-$0.41 A	-$0.85 A
2025	$0.15 A	-$0.31 A	-$0.08 E	-$0.08 E	-$0.38 E
2026					-$0.20 E
2027					-$0.09 E

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WHAT'S NEW

Spectral AI, Inc. (NASDAQ: MDAI) reports second quarter earnings just weeks after announcing the De Novo submission of its DeepView burn diagnostic to the FDA. Research and development revenues were down both sequentially and year over year as activity related to the DeepView decreased in parallel with the end of the pivotal trial and submission of the application.

On the last day in June, Spectral announced the submission of its De Novo 510(k) marketing clearance application. The submission includes data generated by the multi-center burn study that diagnosed wounds in diverse clinical settings. If the application is accepted, Spectral will be eligible to draw another tranche of debt, adding to its capital and supporting the cost of preparing for commercialization. After acceptance, the FDA targets a 150-day review process. If the FDA is able to keep to its published timelines, clearance for the DeepView burn diagnostic could arrive by year end.

Upon receiving a De Novo request, the FDA conducts an acceptance review within 15 calendar days to determine if the submission is administratively complete. If accepted, the application proceeds to substantive review. During the substantive review, the agency evaluates whether the device's safety and effectiveness can be assured through general and special controls. After resolving all deficiencies and completing the review, the FDA will either grant or decline De Novo classification. If granted, a new device classification is established, and the device can serve as a predicate for future 510(k) submissions.[1]

2Q:25 Financial and Operational Results

Spectral reported second quarter 2025 results in a press release on August 12th followed by a conference call to discuss results with investors. A Form 10-Q was subsequently filed with the SEC. For the quarter ending June 30th, 2025, research and development revenues of $5.1 million were recognized. Net loss from operations was ($2.1) million vs. ($2.4) million. For 2Q:25 versus the same prior year period:

- Revenues of $5.1 million fell 32% from $7.5 million due to a decrease in activity related to the Biomedical Advanced Research and Development Authority (BARDA) contract. BARDA revenues totaled $4.6 million while other government contracts composed primarily of Medical Technology Enterprise Consortium (MTEC) funds were $0.4 million;
- Cost of revenue, which can be thought of as research and development expense, totaled $2.8 million, down 33% from $4.2 million due to lower activity levels related to the BARDA contract. Gross margin improved to 45.2% from 44.3%;
- General & Administrative expenses were $4.4 million, down 23% from $5.8 million reflecting lower salaries and consulting fees;
- Net interest expense was $277,000 compared to $6,000 as interest was accrued for the debt taken on from Avenue Capital financing;
- Other expense of $5.8 million was dominated by a change in fair value of warrants reflecting an increase in the company's share price;
- Income tax was $19,000 vs. ($69,000);
- Net loss was ($8.0) million vs. ($2.8) million or ($0.31) and ($0.16) per share, respectively. After removing changes in fair value of financial instruments, net loss was ($2.1) million vs. ($2.5) million or ($0.08) and ($0.14) per share respectively.

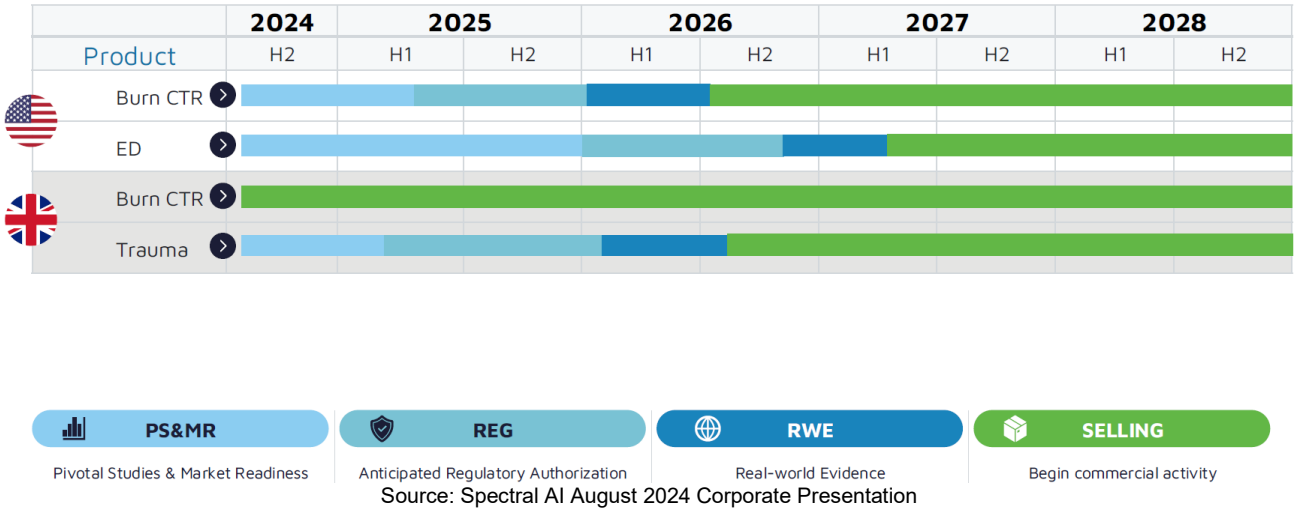
As of June 30th, 2025, cash totaled $10.5 million. This amount compares to the $5.2 million cash balance held at the end of 2024. Several financing transactions took place during the first quarter with the raise of about $11.2 million gross in a debt-and-equity financing. This was attributable to proceeds from the Avenue Financing of $8.5 million and the equity raise of $2.7 million partially offset by the loan repayments on the Yorkville debt facility. Spectral has access to an additional $6.5 million of debt financing upon reaching FDA clearance of DeepView and expects to pursue an additional $7.0 million equity capital raise in combination with the debt financing.

[1] U.S. Food & Drug Administration webpage: De Novo Classification Request. Accessed July 2025.

DeepView Development Progress

Spectral has been consistently advancing its DeepView program, collecting, analyzing and aggregating new data into the algorithm. Last December, Spectral disclosed that it had completed the truthing[2] of burn center images. The dataset used to complete the process consisted of over 3,000 biopsied images. This was followed by the company's update to its software to reflect user feedback that is expected to enhance DeepView's diagnostic precision in UK-deployed systems. Data was generated from real-world physician experience and frontline input from clinicians. The updates improve diagnostic accuracy, workflow integration and patient care. This update is also expected to help support unit deployment in Australia. In May, data from the UK multi-center study were published in the Journal Burns followed by several presentations at the British Burn Association conference in June. Topics as diverse as the ability of AI to capture more data than the human eye, to the patient experience using DeepView were presented at the event in Brighton. These activities were upstaged by the announcement of FDA submission of the De Novo 510(k) marketing clearance application for the DeepView System on June 30th.

Exhibit I – DeepView Product Deployment Timeline



Source: Spectral AI August 2024 Corporate Presentation

UK Multi-Center Burn Study

The submission follows results from DeepView's clinical trial which were published in the Journal Burns. The Journal of the International Society for Burn Injuries is a peer-reviewed medical journal centered on research and advancements in the field of burn care, wound healing and thermal injury treatment. It is a platform for clinicians, surgeons and researchers to share new findings, techniques and best practices in burn management. Results shared in the article highlighted the greater than 95% accuracy of DeepView to predict burn healing. The paper also assessed the sensitivity, specificity, accuracy and predictive value of the DeepView burn diagnostics along with other metrics. Several features of the device represent valuable additions to a burn ward. These include portability, ease of use, easily understandable output and ability to indicate areas of healing and non-healing. The paper concluded that the DeepView device represents a potential solution to burn diagnosis that delivers consistent, reliable and objective results. The device empowers clinicians to diagnose with increased accuracy and to use improved treatment strategies for burn victims.

A link to the Journal article is available here: Artificial Intelligence-Enhanced Multispectral Imaging for Burn Wound Assessment: Insights from a Multi-Centre UK evaluation. We summarize the primary quantitative findings from the paper in the exhibit below.

[2] Truthing is the process of gathering basic data that verifies whether portions of a wound did or did not heal and then using this data to train the AI-powered algorithm. For each patient, images are collected during the early stages of treatment and correlated with biopsies, 21-day wound assessments and expert evaluations. This combination of data creates what is termed the "ground truth" dataset, enabling DeepView to distinguish between wounds likely to heal and those requiring intervention.

Exhibit II – Summary of DeepView Statistics from a Multi-Center Evaluation

Data Type	Value	95% Confidence Interval
Patients (N)	40	
Images	70	
Overall Accuracy	95.3%	93.2%–97.6%
Sensitivity	80.7%	51.8%–100%
Specificity	95.5%	93.3%–97.8%

Source: Analyst compilation of data from Burns Journal Article

Details from the study were further presented by Leslie Poh Hong Tan of the Royal Victoria Infirmary at the British Burn Association conference under the title Artificial Intelligence-Enhanced Multispectral Imaging for Burn Wound Assessment: Insights from a Multi-Centre UK Trial.

Dr. DiMaio Interview Series

Chairman of the board and co-founder Dr. J. Michael DiMaio participated in a series of discussions ranging from the founding of Spectral AI, to the regulatory process and timeline and the company's strategy for obtaining clearance for DeepView.

Exhibit III – Dr. J. Michael DiMaio, Chairman of the Board, Spectral AI



Source: Screenshot from Spectral AI Video Series

Selections from the podcast series with Dr. J. Michael DiMaio:

- Spectral AI Fireside Chat
- Spectral AI: Finance, Focus & Finish
- Spectral AI's DeepView Submission Process
- Spectral AI Origin Story
- DeepView Future Potential
- What Happens After DeepView's FDA Clearance?
- DeepView Article Conclusions
- Spectral AI De Novo Application

Milestones

- Emergency Department enrollment completed in US Burn Pivotal Study – January 2025
- Data analysis completed for US Burn Pivotal Study – February 2025
- Spectral partner RCSI wins Best Research Project at the 2025 Education Awards – May 2025
- Stanley Micek appointed as Chief Operating Officer – May 2025
- Annual meeting of stockholders – May 2025
- British Burn Association (BBA) conference participation – June 2025
- Deployment of DeepView System in UK – 2025
- Participation in the American Burn Association annual meeting & DeepView presentations – April 2025
- Emergency Department Enrollment Completion – April 2025
- De Novo classification request for burn diagnostic – June 2025
- Spin out and IPO of Spectral IP - 2025
- Launch of DeepView in US Burn Centers – 2026
- Launch of DeepView in US Emergency Departments (Burn) – 2026/2027
- DeepView SnapShot M Launch for Military Use - 2027

Summary

Spectral reported second quarter results, which comes several weeks after the submission of its De Novo application of DeepView to the FDA. Corporate efforts are now centered on preparing for commercialization of the diagnostic. Other efforts include presentations at scientific conferences, publications and receipt of awards for the DeepView burn diagnostic since the previous financial update in mid-May. We look forward to acknowledgement of receipt and acceptance of the application in the near term and clearance in the months after. We maintain our price target of $5.00 per share.

PROJECTED FINANCIALS

Spectral AI, Inc. - Income Statement

Spectral AI, Inc.	2024 A	Q1 A	Q2 A	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($US '000)	**$29,581**	**$6,707**	**$5,065**	**$4,875**	**$4,759**	**$21,406**	**$43,351**	**$57,668**
YOY Growth	64%	6%	-32%	-40%	-37%	-28%	103%	
Cost of Goods Sold	$16,307	$3,539	$2,775	$2,608	$2,546	$11,468	$23,063	$31,717
Product Gross Margin	44.9%	47.2%	45.2%	46.5%	46.5%	46.4%	46.8%	45.0%
General & administrative	$19,856	$4,064	$4,413	$4,150	$4,200	$16,827	$25,350	$28,100
Research & development	$0	$0	$0	$0	$0	$0	$0	$0
Income from operations	($6,582)	($896)	($2,123)	($1,883)	($1,987)	($6,889)	($5,062)	($2,150)
Operating Margin								
Interest (expense) income, net	$14	($20)	($277)	($30)	($30)	($357)	($110)	($110)
Other income, net	($8,476)	$3,884	($5,587)	$0	$0	($1,703)	$0	$0
Pre-Tax Income	($15,044)	$2,968	($7,987)	($1,913)	($2,017)	($8,949)	($5,172)	($2,260)
Provision for Income Tax	($271)	($71)	$19	($70)	($70)	($192)	($250)	($250)
Net Income	**($15,315)**	**$2,897**	**($7,968)**	**($1,983)**	**($2,087)**	**($9,141)**	**($5,422)**	**($2,510)**
Net Margin								
Reported EPS	**($0.85)**	**$0.15**	**($0.31)**	**($0.08)**	**($0.08)**	**($0.38)**	**($0.20)**	**($0.09)**
YOY Growth								
Fully Diluted Shares	17,934	19,200	25,422	25,800	25,800	24,055	27,500	29,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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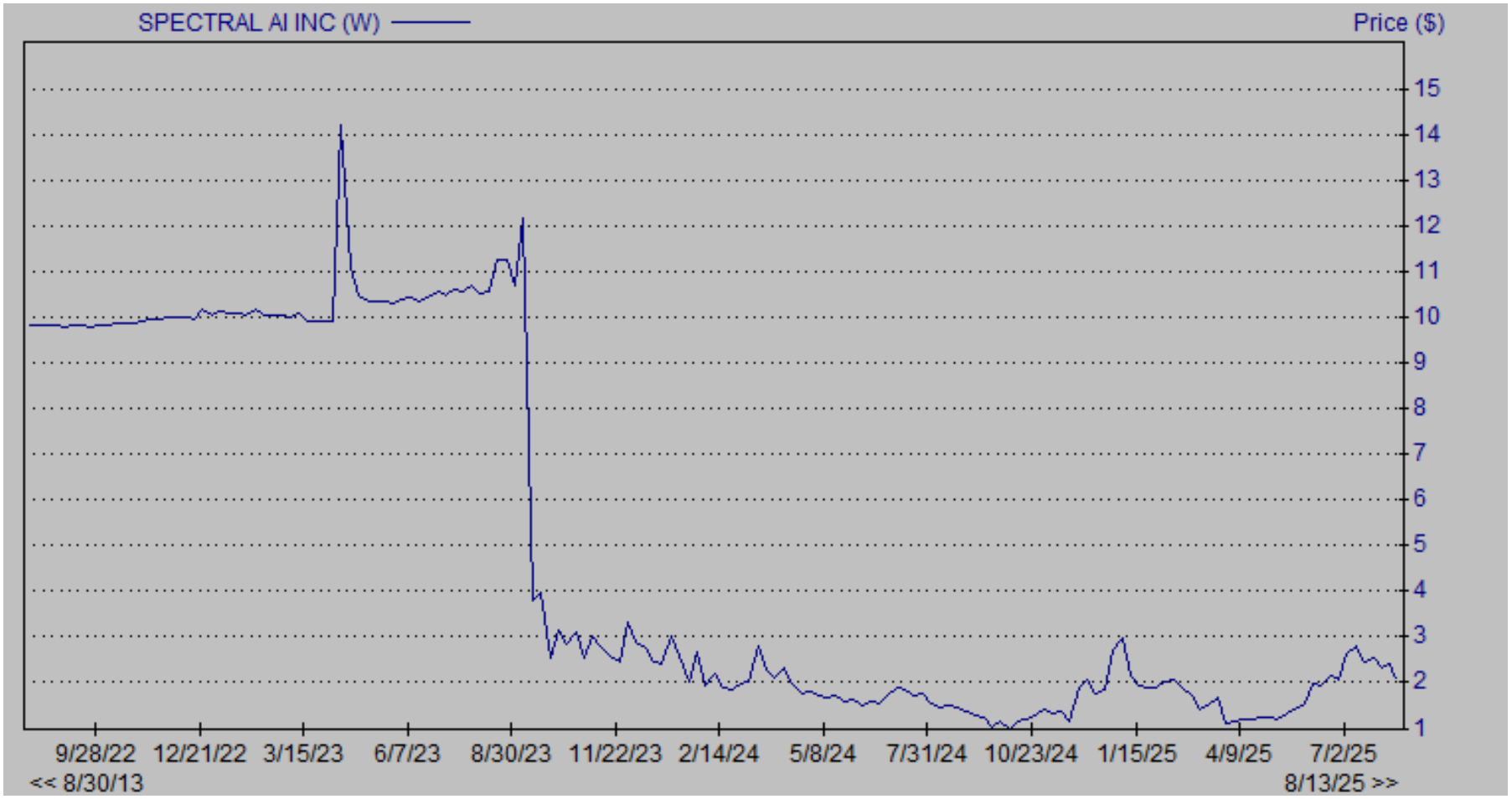
HISTORICAL STOCK PRICE

Spectral AI, Inc. – Share Price Chart[3]



[3] Source: Zacks Research System

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