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July 9, 2025
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Spectral AI, Inc.

(MDAI - NASDAQ)

MDAI: DeepView De Novo Submission

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 (7/8/2025)	$2.84
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 (%)	42.7
Beta	0.7
Average Daily Volume (sh)	378,060
Shares Outstanding (mil)	25.7
Market Capitalization ($mil)	73.0
Short Interest Ratio (days)	1.9
Institutional Ownership (%)	14.0
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	$6.3 E	$4.8 E	$4.2 E	$22.0 E
2026					$43.4 E
2027					$43.4 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	-$0.06 E	-$0.09 E	-$0.09 E	-$0.13 E
2026					-$0.20 E
2027					-$0.09 E

WHAT'S NEW

Last week, Spectral AI, Inc. (NASDAQ: MDAI) announced the submission of its De Novo 510(k) marketing clearance application to the FDA for the DeepView system in burn diagnosis. The submission includes data generated by the multi-center burn study that diagnosed wounds in diverse clinical settings. The achievement is a major milestone for the company and positions Spectral for acceptance of the application in the near term. 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]

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 are a few of the benefits that accrue to providers. 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 findings from the paper in the exhibit below.

Exhibit I – 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.

In a separate but related series of interviews, article author Dr. Christopher J. Lewis provides a discussion of DeepView and the results from the UK study. We include links to the excerpts below.

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

Exhibit II – Dr. Chris Lewis, Burn Surgeon, Royal Victoria Infirmary, Newcastle

Source: Screenshot from Spectral AI Video Series

Selections from the podcast series with Dr. Chris Lewis:

- ➢ Spectral AI's DeepView Achieves 95% Accuracy
- ➢ AI Improves Burn Diagnosis
- ➢ Spectral AI's Snapshot M
- ➢ DeepView Results Published in Burns
- ➢ Journal Article Highlights DeepView Diagnostic
- ➢ Dr. Chris Lewis Highlights DeepView's Strengths
- ➢ Dr. Lewis Discusses Unmet Needs in Burn Diagnosis
- ➢ Fireside Chat with Burn Surgeon Dr. Chris Lewis

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.

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[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 III – DeepView Product Deployment Timeline

Source: Spectral AI August 2024 Corporate Presentation
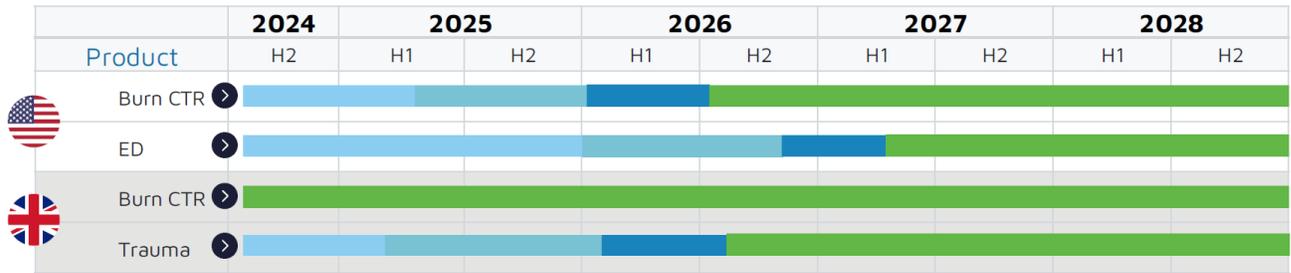
Milestones

- ➢ 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 submitted its De Novo application to the FDA following a series of favorable announcements, presentations, publications and awards for its DeepView burn diagnostic since the mid-May report of 1Q results.. We look forward to acknowledgement of receipt and acceptance of the application in the near term and clearance before year end. We anticipate second quarter earnings to be reported next month where management will provide further detail on progress and expectations related to DeepView's regulatory journey.

PROJECTED FINANCIALS

Spectral AI, Inc. - Income Statement

Spectral AI, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($US '000)	**$29,581**	**$6,707**	**$6,304**	**$4,825**	**$4,159**	**$21,995**	**$43,351**	**$57,668**
YOY Growth	64%	6%	-16%	-41%	-45%	-26%	97%	
Cost of Goods Sold	$16,307	$3,539	$3,373	$2,581	$2,225	$11,718	$23,063	$31,717
Product Gross Margin	44.9%	47.2%	46.5%	46.5%	46.5%	46.7%	46.8%	45.0%
General & administrative	$19,856	$4,064	$4,100	$4,150	$4,200	$16,514	$25,350	$28,100
Research & development	$0	$0	$0	$0	$0	$0	$0	$0
Income from operations	($6,582)	($896)	($1,169)	($1,906)	($2,266)	($6,237)	($5,062)	($2,150)
Operating Margin								
Interest (expense) income, net	$14	($20)	($30)	($30)	($30)	($110)	($110)	($110)
Other income, net	($8,476)	$3,884	$0	$0	$0	$3,884	$0	$0
Pre-Tax Income	($15,044)	$2,968	($1,199)	($1,936)	($2,296)	($2,463)	($5,172)	($2,260)
Provision for Income Tax	($271)	($71)	($70)	($70)	($70)	($281)	($250)	($250)
Net Income	**($15,315)**	**$2,897**	**($1,269)**	**($2,006)**	**($2,366)**	**($2,744)**	**($5,422)**	**($2,510)**
Net Margin								
Reported EPS	**($0.85)**	**$0.15**	**($0.06)**	**($0.09)**	**($0.09)**	**($0.13)**	**($0.20)**	**($0.09)**
YOY Growth								
Fully Diluted Shares	17,934	19,200	20,000	22,500	25,000	21,675	27,500	29,000

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

HISTORICAL STOCK PRICE

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

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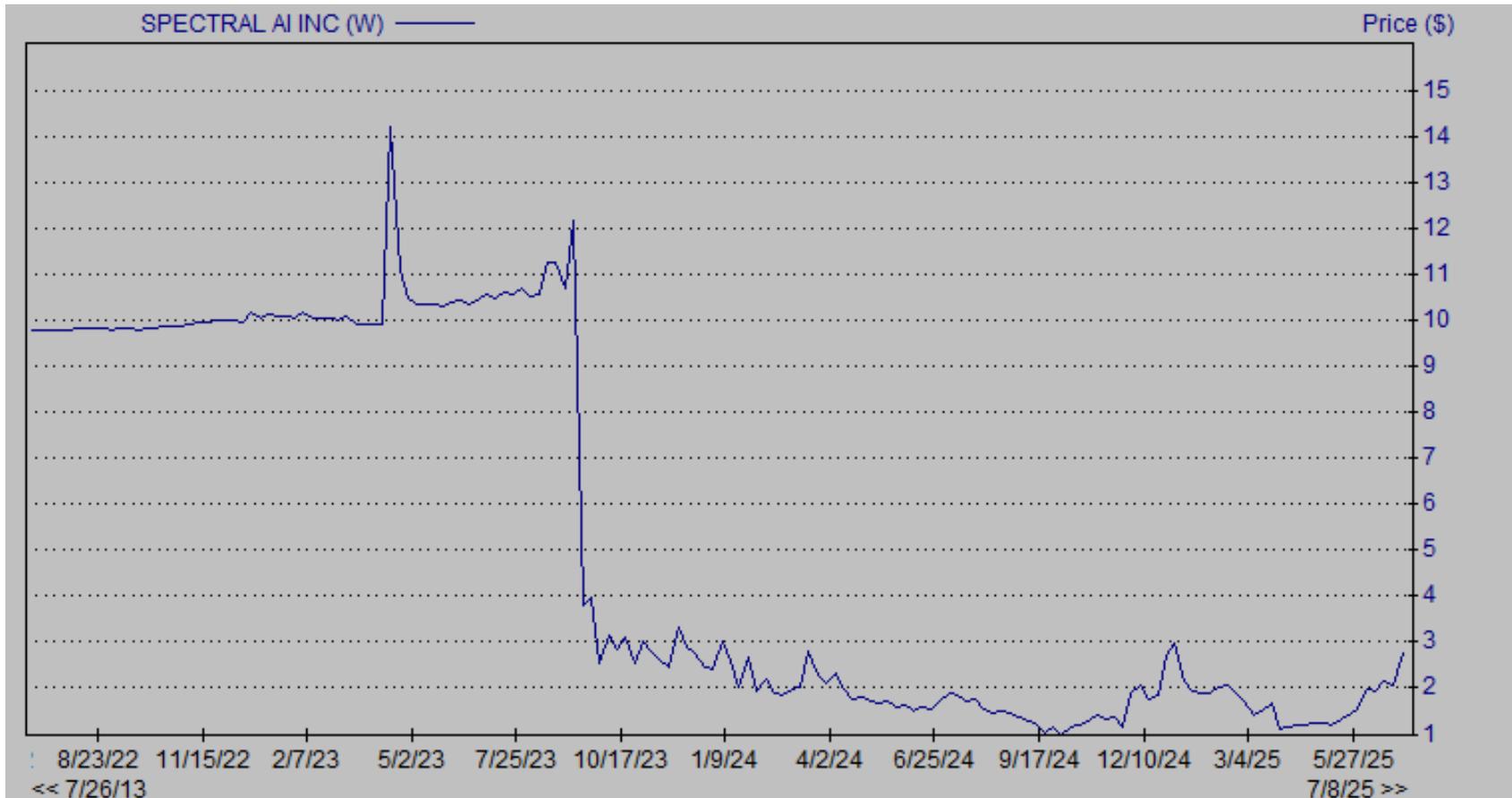
[3] Source: Zacks Research System

DISCLOSURES