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November 13, 2025
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Spectral AI, Inc.

(MDAI - NASDAQ)

MDAI: Looking Ahead to 1H:26 DeepView Clearance

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 (11/12/2025)	$1.60
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 using the De Novo pathway. 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	1.01
One-Year Return (%)	18.5
Beta	0.9
Average Daily Volume (sh)	551,490
Shares Outstanding (mil)	30.7
Market Capitalization ($mil)	49.1
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	$3.8 A	$2.8 E	$18.5 E
2026					$18.9 E
2027					$41.4 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	-$0.31 A	-$0.13 A	-$0.10 E	-$0.46 E
2026					-$0.50 E
2027					-$0.26 E

WHAT'S NEW

Spectral AI, Inc. (NASDAQ: MDAI) reported third quarter earnings results on November 11th. Highlights since our previous update include several presentations at the European Burns Association Congress, recognition as a top HealthTech company from Time Magazine and a raise of $7.6 million of additional capital. Research and development revenues were down both sequentially and year over year as activity related to DeepView decreased in parallel with the end of the pivotal trial and submission of the application. Revenues were also impacted by project timing and the government shutdown, which caused management to reduce revenue guidance to $18.5 million from $21.5 million. Much of this is expected to be recaptured in 2026.

As the FDA is reviewing DeepView, Spectral's attention has turned to pre-commercialization activities and the handheld SnapShot device. The company's Chief Commercialization Officer, Jeremiah Sparks, is preparing for DeepView product revenues and he plans to add four additional persons to support the effort who will help with sales and professional education. Spectral will be relying on the burn units and hospitals that participated in the DeepView studies to be first movers and add the devices to their treatment facilities. It will also receive help from the Biomedical Advanced Research and Development Authority (BARDA) contract which will fund device deployment at sites that need them following the De Novo approval of the burn diagnostic. SnapShot, a handheld version of DeepView, is undergoing additional testing for durability in the battlefield for the Department of Defense and, in parallel, Spectral is in discussions with civilian authorities for its use in public settings such as ambulances. Management expects that regulatory clearance for SnapShot will follow the faster 510(k) pathway, relying on the DeepView device as a predicate.

Despite all of the obstacles related to the federal government and its funding, Spectral reports that interactions with the FDA have been productive and it is on track to support DeepView clearance in 1H:26. One of the more important interactions that the company has held with the agency revolves around the statistical analysis plan (SAP), which vets and validates the artificial intelligence (AI) algorithm. Management expects further touch points with the FDA in the coming weeks which should provide further clarification.

3Q:25 Financial and Operational Results

Spectral reported third quarter 2025 results in a press release on November 11th followed by a conference call to discuss results with investors. A Form 10-Q was subsequently filed with the SEC. For the quarter ending September 30th, 2025, research and development revenues of $3.8 million were recognized. Net loss from operations was ($3.3) million or ($0.13) per share. For 3Q:25 versus the same prior year period:

➤ Revenues of $3.8 million fell 54% from $8.2 million reflecting a reduction in direct labor, clinical trial and other reimbursed study costs related to the BARDA contract. BARDA revenues totaled $3.4 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 $2.2 million, down 52% from $4.5 million due to lower activity levels related to the BARDA contract. Gross margin fell to 42.7% from 44.9% due to a reduction in direct labor costs as a proportion of total costs, which have a higher-than-average margin;

➤ General & Administrative expenses were $5.0 million, up 9% from $4.6 million on account of increased consultant and third-party service provider costs;

➤ Net interest expense was $300,000 compared to $8,000 as interest was accrued for the debt taken on from Avenue Capital financing;

➤ Other income of $91,000 was dominated by a change in fair value of warrants reflecting an increase in the company's share price partially offset by borrowing related costs and foreign exchange transaction loss;

➤ Income tax was ($2,000) vs. ($37,000);

➤ Net loss was ($3.6) million vs. ($1.5) million or ($0.13) and ($0.08) per share, respectively.

As of September 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. During the third quarter there were a number of warrant and option exercises that added approximately $2.5 million in

capital, offsetting cash burn of $2.5 million. Following the end of the third quarter, Spectral raised an additional $7.6 million in equity. The company will have 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 this debt financing.

European Burns Association (EBA) Congress Presentations and Posters

Investigators and other experts involved with DeepView burn trials presented on a variety of topics touching on the device and its capabilities. The presentations took place in Berlin, Germany the first week in September 2025 at the 21st Congress of the European Burns Association. We think that the presentations will expand awareness of the DeepView device further into Europe. Below we summarize each of the presentations or posters with the title, authors and conclusions. Abstracts, summaries and conclusions from the presentations listed below are found here: 21st Congress of the European Burns Association (EBA).

- Multispectral Imaging and Assessment of Burns Healing Potential: A Prospective Real-World Study to assess the DeepView Snapshot Imaging Platform – Sam Snelling, North Bristol NHS Trust, Bristol, United Kingdom
  - The DeepView Snapshot Imaging Platform (DVS) is a rapid, simple, and pain-free method of assessing burns depth. DVS is as accurate in assessing burn healing potential as specialist burns clinician's assessment. DVS has future capabilities in supporting early diagnosis of non-healing burns and subsequent management.
- The First Reader Study of Burn Wounds with Predictive Artificial Intelligence Analysis – Victoria Miles, Louisiana State University Health and Science Center, New Orleans, US
  - The study demonstrated that multi-spectral imaging (MSI) with AI is a valuable tool for burn wound assessment, offering high reliability, improved diagnostic accuracy, and greater objectivity compared to traditional methods. This technological advancement could help standardize burn wound evaluation, reducing unnecessary transfers and hospital stays, while offering more prudent surgical intervention.
- Artificial Intelligence-Enhanced Multispectral Imaging for Burn Wound Assessment: Insights from a Multi-Centre UK Trial – Mr. Leslie Poh Hong Tan, Royal Victoria Infirmary, Newcastle, United Kingdom
  - The study demonstrates that the AI-enhanced multispectral imaging (MSI) system offers high accuracy compared to clinical healing outcomes as the ground truth. Its combined attributes of diagnostic precision, operational efficiency, and portability position this device as a transformative tool for revolutionizing current clinical practices in burn wound assessment.
- Early Experiences of the DeepView System wound imaging technology in a UK regional burn centre – Megan Beese, Queen Elizabeth Hospital, Birmingham, United Kingdom
  - Providers found that DeepView is easy to use and requires minimal training. The high sensitivity supports Spectral AI's findings, suggesting that the unit is a useful safety-net triage tool for less experienced practitioners to confirm superficial burns that may be managed in a nurse-led clinic.
- Patient Experience of Using Artificial Intelligence-Enhanced Multispectral Imaging to Measure Burn Depth: A Regional Burns Centre Review – Miriam Nyeko-Lacek, Manchester University NHS Foundation Trust, United Kingdom
  - Patients were highly receptive to the technology, reporting that it improved their understanding of burn depth. They found the device comfortable and efficient, indicating its potential for use in paediatric settings. The study supports the acceptability of AI-powered multispectral imaging in clinical consultations for burn assessments.
- Preliminary Experience Using Artificial Intelligence and Multispectral Imaging for Burn Depth Assessment – Nicholas Solanki, Burns Unit Royal Adelaide Hospital, Adelaide, Australia
  - AI and MSI technology shows promise in burn depth assessment and healing prediction. Further multi-centre validation with larger patient cohorts is needed to refine accuracy and reliability. The integration of AI-based tools with clinical expertise could enhance burn care decision-making.

Capital Raise

In late October, Spectral AI announced the pricing of a $7.6 million capital raise. It consisted of 4.0 million shares of common stock or pre-funded warrants sold at $1.90 per share. A warrant was attached to each share with an exercise price of $2.51 and a five-year life. Net proceeds were $7.0 million.

UK Multi-Center Burn Study

DeepView clinical trial data was 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.

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 in June 2025 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.

Estimate Update

We update our estimates to reflect company guidance and timing for the planned rollout of DeepView. 2025 revenues move from $21.4 million to $18.5 million due to timing delays and impacts from the government shutdown. We see a 2H:26 launch of 30 units supported by the BARDA contract. This causes a reduction in both 2026 and 2027 revenue due to a later start. We also update our shares outstanding to reflect recent and near-term future capital raises.

Milestones

- Data analysis completed for US Burn Pivotal Study – February 2025
- Stanley Micek appointed as Chief Operating Officer – 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
- DeepView at European Burns Association Congress – September 2025
- Spectral AI named on Time Magazine's Top HealthTech Companies – September 2025
- Spin out and IPO of Spectral IP – 2025/2026
- 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

<u>Summary</u>

Spectral reported third quarter results as the FDA reviews DeepView's De Novo application. Since the previous update, the company has been interacting with the agency and responding to questions. It expects to receive clearance by 1H:26 followed by a launch of the device in the second half. Corporate efforts are now centered on preparing for commercialization of the diagnostic and developing the SnapShot M in parallel. Other work includes presentations at scientific conferences and publications. We look forward to updates on 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 A	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($US '000)	**$29,581**	**$6,707**	**$5,065**	**$3,792**	**$2,944**	**$18,508**	**$18,928**	**$41,368**
YOY Growth	64%	6%	-32%	-54%	-61%	-37%	2%	119%
Cost of Goods Sold	$16,307	$3,539	$2,775	$2,171	$1,575	$10,060	$10,070	$22,752
Product Gross Margin	44.9%	47.2%	45.2%	42.7%	46.5%	45.6%	46.8%	45.0%
General & administrative	$19,856	$4,064	$4,413	$4,962	$4,200	$17,639	$25,350	$28,100
Research & development	$0	$0	$0	$0	$0	$0	$0	$0
Income from operations	($6,582)	($896)	($2,123)	($3,341)	($2,831)	($9,191)	($16,492)	($9,485)
Operating Margin								
Interest (expense) income, net	$14	($20)	($277)	($300)	($30)	($627)	($110)	($110)
Other income, net	($8,476)	$3,884	($5,587)	$91	$0	($1,612)	$0	$0
Pre-Tax Income	($15,044)	$2,968	($7,987)	($3,550)	($2,861)	($11,430)	($16,602)	($9,595)
Provision for Income Tax	($271)	($71)	$19	($2)	($70)	($124)	($250)	($250)
Net Income	**($15,315)**	**$2,897**	**($7,968)**	**($3,552)**	**($2,931)**	**($11,554)**	**($16,852)**	**($9,845)**
Net Margin								
Reported EPS	**($0.85)**	**$0.15**	**($0.31)**	**($0.13)**	**($0.10)**	**($0.46)**	**($0.50)**	**($0.26)**
YOY Growth								
Fully Diluted Shares	17,934	19,200	25,422	26,319	30,500	25,360	34,000	37,500

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

Spectral AI, Inc. – Share Price Chart[1]
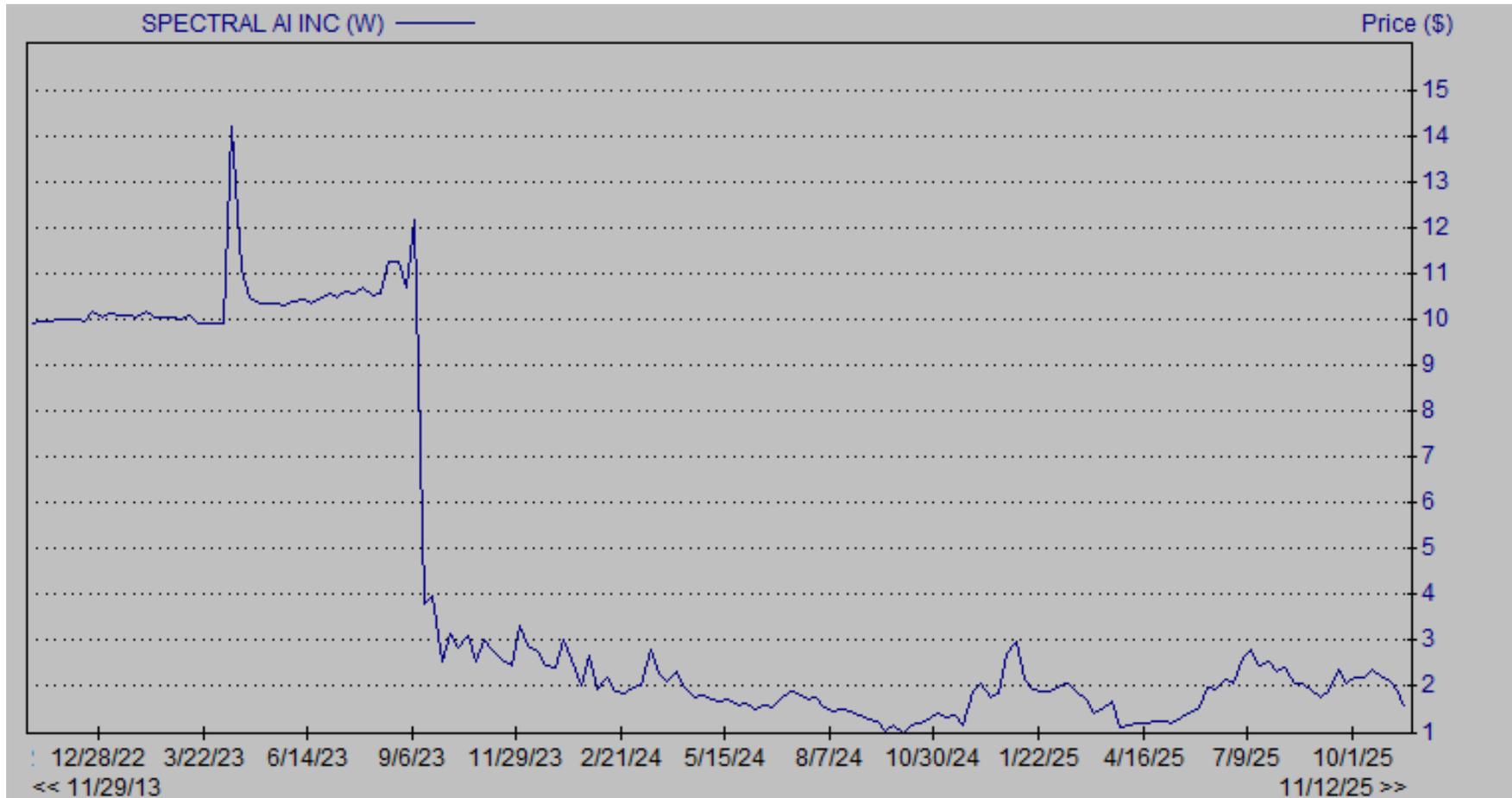
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