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Spectral AI, Inc. (MDAI - NASDAQ)

MDAI: Pivotal Data Analysis Complete

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 (2/13/2025)	$2.17
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. A pivotal burn study is underway in order to support a De Novo submission in 2025. It has received the UKCA mark for burn in the UK & expects to commercialize DeepView there in 2H:24. 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 (%)	**4.3**
Beta	**0.6**
Average Daily Volume (sh)	**2,692,968**
Shares Outstanding (mil)	**18.6**
Market Capitalization ($mil)	**40.4**
Short Interest Ratio (days)	**0.8**
Institutional Ownership (%)	**15.9**
Insider Ownership (%)	**38.7**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2023	$5.1 A	$4.3 A	$3.4 A	$5.3 A	$18.1 A
2024	$6.3 A	$7.5 A	$8.2 A	$7.3 E	$29.3 E
2025					$26.6 E
2026					$43.4 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023	-$0.27 A	-$0.25 A	-$0.77 A	-$0.19 A	-$1.48 A
2024	-$0.19 A	-$0.16 A	-$0.08 A	-$0.11 E	-$0.55 E
2025					-$0.57 E
2026					-$0.26 E

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WHAT'S NEW

Since reporting third quarter results in November, Spectral AI, Inc. (NASDAQ: MDAI) has continued to advance its burn program in burn center populations, pediatric burn in emergency departments and with the SnapShot M portable device. Most importantly, Spectral has finished enrollment and evaluation of all patents in the burn center trial and has completed its analysis of the related pivotal data. This achievement places the company in position to make a De Novo submission by June 2025. The pediatric study at emergency departments completed enrollment in January and will follow closely behind the emergency department burn study in terms of regulatory pathway. The portable DeepView SnapShot M is also advancing with feedback from Army stakeholders.

Spectral maintains its emphasis on the three "Fs": Finance, Focus and Finish. In the near term, this will be accomplished by wrapping up the burn trial, conducting analysis and training of the algorithm that will be used to guide DeepView's predictions and submission of the De Novo application.

DeepView Development Progress

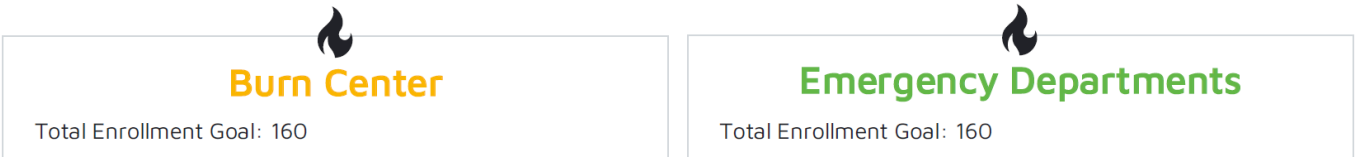
Spectral has been consistently advancing its DeepView program, collecting, analyzing and implementing new data. Last December, Spectral disclosed that it had completed the truthing[1] of burn center images. The dataset used to complete the process consisted of over 3,000 biopsied images. This was followed 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 allow for improved diagnostic accuracy, workflow integration, and patient care. This update is also expected to help support unit deployment in Australia. By February, analysis of the data from the Burn pivotal study was complete. The data will be assembled into an application which is expected to be submitted to the FDA via a De Novo request by June 2025.

In January, pediatric enrollment was completed in Emergency Departments in the US. Results from this trial will also be used to prepare an application to the FDA. Based on the near five-month length of time between the end of enrollment and data analysis for ED burn, we think the pediatric analysis could be complete by mid-year.

Burn Trial Background

On January 11th, 2024, Spectral announced that it began enrollment of its pivotal study to validate DeepView for burn injuries. This study intends to enroll 160 patients in burn centers and 160 patients in emergency departments throughout the US. 25% of the total will be pediatric patients. The study was filed under clinicaltrials.gov under the designator NCT06131203 and is titled Burn Pivotal Study. Its purpose is to validate the algorithm for burn healing assessment for the DeepView device, which will provide burn healing assessment. 16 sites are enrolling patients.

Exhibit I – Clinical Trial Status



Source: Spectral AI August Corporate Presentation

The study is evaluating flame, scald or contact burns that have occurred 72 hours prior to first imaging. The minimum size for consideration is 0.5% of the total surface body area. On the upper end, subjects with burns over 50% of their body area will not be considered. The primary endpoint is to demonstrate that the DeepView AI device's sensitivity is superior to burn center health care provider assessment, while maintaining non-inferior specificity to burn providers. It will also validate the standalone performance of the algorithm on an independent dataset.

Last August, Spectral announced that it had completed enrollment of the Burn Center portion for the US Burn Pivotal Study and on October 30, the burn pivotal study had completed its assessment of its last patient. At the time of the third quarter earnings call, the trial was undergoing the truthing process. Truthing requires a burn biopsy and an

[1] 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.

evaluation of the condition of the burn at 21 days. These data are reconciled with the initial DeepView image in order to train the algorithm. Spectral will work iteratively with the FDA to identify important metrics to review which include the Dice coefficient, sensitivity, specificity and accuracy. Analysis of the pivotal trial data was completed in February 2025.

The anticipated regulatory pathway will include a De Novo FDA submission for DeepView in June 2025, which, if successfully approved, will allow for commercialization of the device in 2026. Spectral will request consideration of DeepView as a Class II device. [2] After receiving the approval for use in burn centers, Spectral will pursue emergency department approval via the 510(k) pathway.[3]

Beyond the binary output provided by the DeepView Burn diagnostic, the device is also able to rapidly and accurately determine burn size. Details of a proof-of-concept module was detailed in an October 3, 2024 press release. In seconds, DeepView Burn can provide the total body surface area (TBSA) of a burn and calculate depth, area and volume helping providers determine the best course forward. This technology is embedded into the DeepView system and can help clinicians improve patient treatment decisions. We believe that this functionality will be part of the FDA submission and be available for clinicians to use to guide their treatment choices.

DeepView SnapShot M

Spectral is developing a portable handheld version of DeepView called SnapShot M. It may incorporate wireless capability. This effort has been supported by funding from multiple government agencies to produce a device that can be used in combat situations for battlefield burn evaluation. The portable device will also be appropriate in other settings including forward deployed military units and mobile emergency units such as ambulances and in home health settings. Other uses for the device may include wound size measurement, with both area and volume parameters generated from a single capture.

The Spectral team has been in close contact with the Brooke Army Medical Center and the US Army Medical Research and Development Command's Institute of Surgical Research. Feedback from these stakeholders under the Medical Technology Enterprise Consortium (MTEC) contract will help guide further design enhancement for the device so it can excel in demanding critical care environments such as combat zones and forward deployed units. Later, the device may be appropriate for mobile applications such as home health and emergency medical services.

Exhibit II – DeepView SnapShot M



Source: Spectral AI

[2] Class II medical devices require greater regulatory controls than Class I devices to ensure safety and effectiveness but are typically less risky than Class III devices. The FDA classifies medical devices based on the level of control necessary to provide a reasonable assurance of the device's safety and effectiveness. Class II medical devices present moderate risk and can pose a moderate risk to the patient if used incorrectly or malfunction. They require special controls in addition to the general controls required for Class I devices which may include specific labeling requirements, mandatory performance standards and post-market surveillance.

[3] The 510(k) pathway is designed for devices that are substantially equivalent to a legally marketed device known as a predicate device. The device must not pose new risks. 510(k) is primarily intended for Class II devices, but some low-risk Class I devices also follow this pathway. The approval process calls for the manufacturer to demonstrate that the device is similar in safety and effectiveness to an already-approved device. Clinical trials are usually not required unless substantial changes are made to the design or use.

The FDA granted DeepView Breakthrough Device Designation (BDD) status in 2018. This classification allows for prioritized reviews and a dedicated line of communication with reviewing members of the FDA. DeepView received the United Kingdom Conformity Assessed (UKCA) mark for use in the UK for burn indications in February 2024. Spectral expects to receive the required UKCA certificates and should recognize first sales shortly after. In parallel, Spectral is making enhancements to its technical file based on input from clinicians. This information will support software upgrades that should improve diagnostic accuracy, workflow integration and patient care in both the UK and in Australia. The company is further pursuing the CE Mark in the EU but it will also require clearance from the EMA before marketing approval. Further support of the device came from additional funding from another Medical Technology Enterprise Consortium (MTEC) award of $850,000 bringing total government funding for the portable device to over $7.0 million.

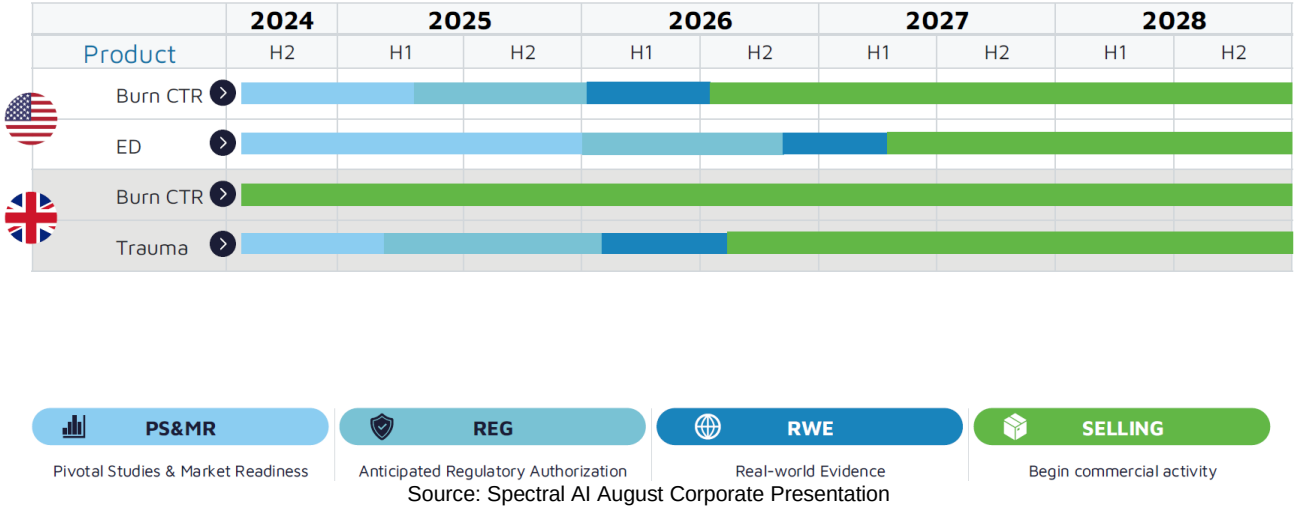
Financing

Spectral AI completed an approximate $5 million capital raise in November which was completed in two tranches. Part of the proceeds from the financing will be used retire obligations with Yorkville Advisors. The financing was executed in an at-the-market transaction and included equity and pre-funded warrants.

Milestones

- Completion of burn center enrollment – August 2024
- Management restructuring – October 2024
- Warrant repricing – November 2024
- Stakeholder involvement in DeepView training & validation – December 2024
- Confirmation of compliance with NASDAQ listing requirements – December 2024
- DeepView Burn Study Topline – December 2024
- Emergency Department enrollment completed in US Burn Pivotal Study – January 2025
- Data analysis complete for US Burn Pivotal Study – February 2025
- Deployment of DeepView System in UK – 2025
- Emergency Department Enrollment Completion – April 2025
- De Novo classification request for burn diagnostic – June 2025
- Spin out of Spectral IP - 2025
- Launch of DeepView in US Burn Centers – 2026
- Launch of DeepView in US Emergency Departments (Burn) – 2026/2027
- Launch of DeepView for Diabetic Foot Ulcer – 2026/2027
- DeepView SnapShot M Launch for Military Use - 2027

Exhibit III – DeepView Product Deployment Timeline



Source: Spectral AI August Corporate Presentation

Summary

Spectral continues to move its DeepView burn program forward in the burn pivotal studies and with design refinements for SnapShot M. De Novo submission for the burn center application is expected in June which will pave the way for approval and later submission for the emergency department burn diagnostic. We continue to see Spectral AI as being on track with its goals to obtain approval for the DeepView device. We maintain our valuation of $5.00 per share.

PROJECTED FINANCIALS

Spectral AI, Inc. - Income Statement

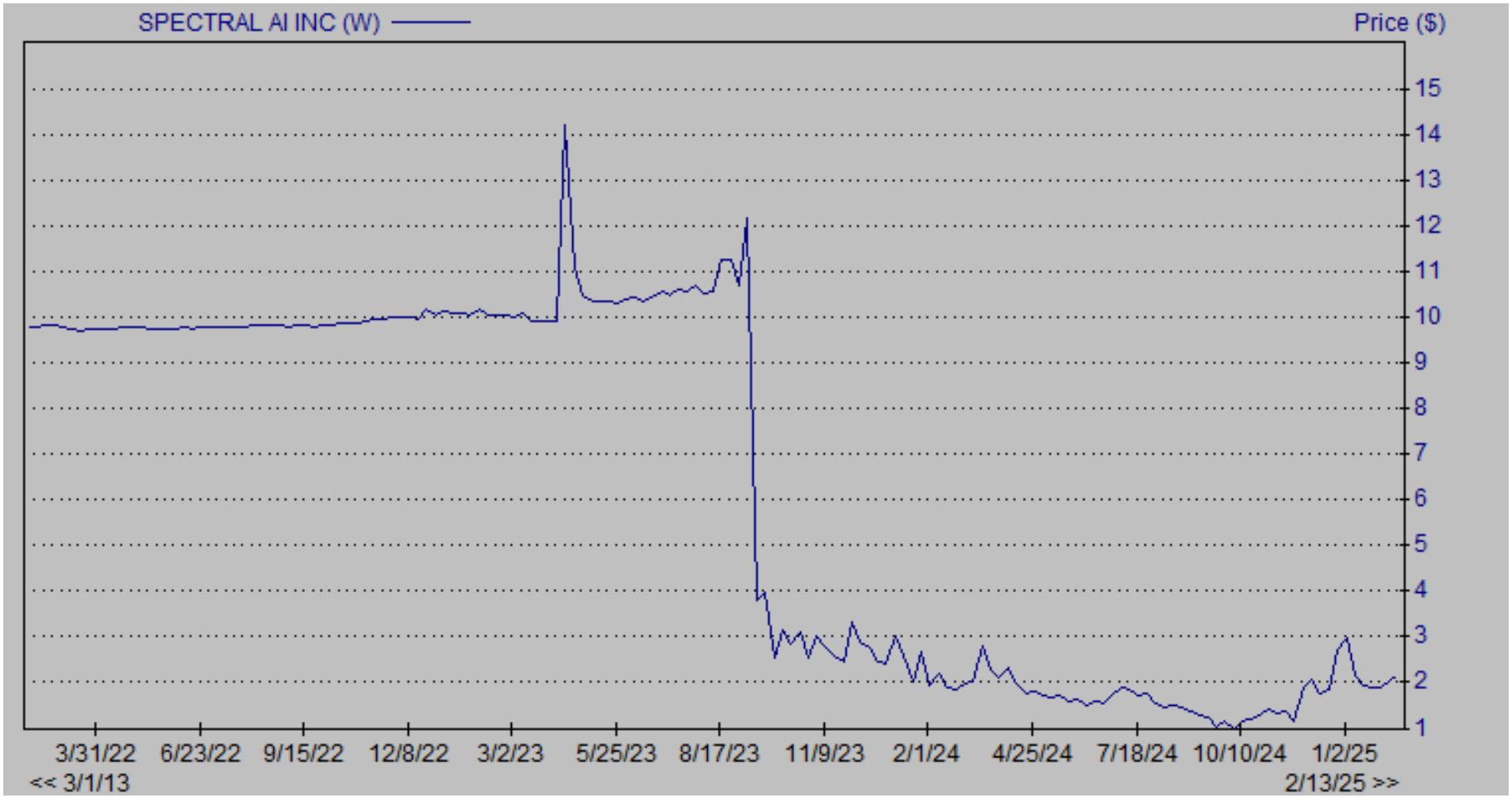
Spectral AI, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US '000)	**$18,056**	**$6,326**	**$7,478**	**$8,173**	**$7,322**	**$29,299**	**$26,606**	**$43,351**
YOY Growth	-28.8%	25%	76%	138%	38%	62%	-9%	63%
Cost of Goods Sold	$10,176	$3,381	$4,164	$4,506	$3,954	$16,005	$14,234	$23,063
Product Gross Margin	43.6%	46.6%	44.3%	44.9%	46.0%	45.4%	46.5%	46.8%
General & administrative	$20,864	$5,088	$5,756	$4,553	$5,511	$20,908	$24,750	$27,500
Research & development	$0	$0	$0	$0	$0	$0	$0	$0
Income from operations	($12,984)	($2,143)	($2,442)	($886)	($2,143)	($7,614)	($12,378)	($7,212)
Operating Margin								
Interest (expense) income, net	$172	$14	$6	($8)	$3	$15	$50	$50
Other income, net	($8,031)	($1,054)	($359)	($573)	$0	($1,986)	$0	$0
Pre-Tax Income	($20,843)	($3,183)	($2,795)	($1,467)	($2,140)	($9,585)	($12,328)	($7,162)
Provision for Income Tax	($11)	($22)	($69)	($37)	$0	($128)	$0	$0
Net Income	**($20,854)**	**($3,205)**	**($2,864)**	**($1,504)**	**($2,140)**	**($9,713)**	**($12,328)**	**($7,162)**
Net Margin								
Reported EPS	**($1.48)**	**($0.19)**	**($0.16)**	**($0.08)**	**($0.11)**	**($0.55)**	**($0.57)**	**($0.26)**
YOY Growth								
Fully Diluted Shares	14,088	16,560	17,598	17,862	18,750	17,693	21,625	27,500

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

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HISTORICAL STOCK PRICE

Spectral AI, Inc. – Share Price Chart[4]



[4] Source: Zacks Research System

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