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Spectral AI, Inc. (MDAI - NASDAQ)

MDAI: 2024 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 (4/1/2025)	$1.20
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 (%)	**-48.5**
Beta	**0.4**
Average Daily Volume (sh)	**688,746**
Shares Outstanding (mil)	**25.5**
Market Capitalization ($mil)	**30.3**
Short Interest Ratio (days)	**2.9**
Institutional Ownership (%)	**13.4**
Insider Ownership (%)	**32.5**
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	$7.6 A	$29.6 A
2025					$22.0 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	-$0.41 A	-$0.85 A
2025					-$0.45 E
2026					-$0.18 E

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WHAT'S NEW

Spectral AI, Inc. (NASDAQ: MDAI) detailed 2024 financial and operational results in a March 27th press release. Revenues of $29.6 million exceeded guidance of $28 million and our estimates of $29.3 million. Net loss was ($15.3) million or ($0.85) per share. Over the last months, Spectral has been operating at a rapid pace with topline data reported from its burn validation study in a March 17th press release confirming DeepView's superior detection sensitivity relative to burn physicians' assessments. Data regarding DeepView's sensitivity, specificity and Dice Score were provided. We expect an increased allocation of effort towards the submission of the De Novo application to the FDA, which is slated for mid-2025. The company has also raised additional capital, installed three devices in Australia and prepared for the intended spin-off of Spectral IP.



2024 Financial and Operational Results

Spectral reported 2024 results in a press release on March 27th followed by a conference call to discuss results with investors. A Form 10-K was subsequently filed with the SEC. For the year ending December 31st, 2024, research and development revenues of $29.6 million were recognized. Net loss for 2024 totaled ($15.3) million or ($0.85) per share. For 2024 versus the same prior year period in 2023:

- Revenues were $29.6 million up 64% from $18.1 million due to an increase in activity related to BARDA and other US government grant revenues. BARDA revenues totaled $19.7 million while other government contracts composed primarily of MTEC funds were $1.8 million;
- Cost of revenue, which can be thought of as research and development expense, totaled $16.3 million, rising 60% from $10.2 million due to higher activity levels related to the BARDA and MTEC contracts. Gross margin improved to 44.9% from 43.6% due to a higher reimbursement rate in the new BARDA contract;
- General & Administrative expenses were $19.9 million, down 5% from $20.9 million reflecting lower legal and accounting expenses as well as lower overall spending;
- Net interest income was $14,000 compared to $172,000;
- Other expense was ($8.5) million vs. ($8.0) million with borrowing related costs and change in fair value of warrants replacing transaction costs;
- Income tax was ($271,000) vs. ($11,000);
- Net loss was ($15.3) million vs. ($20.9) million or ($0.85) and ($1.48) per share, respectively.

As of December 31st, 2024, cash totaled $5.2 million. This amount compares to the $4.8 million cash balance held at the end of 2023. Several financing transactions took place in 2024 including contributions from issuance of common stock and notes offset by repayment of other notes. The company filed a shelf registration on Form S-3 to raise additional capital in 4Q:24. Days prior to the 2024 report, Spectral announced that it had raised about $11.2 million gross in a debt and equity financing along with access to additional debt of $6.5 million upon reaching FDA clearance of DeepView.

March 2025 Financing

Spectral AI accessed gross proceeds of approximately $11.2 million in a March 2025 financing that was funded with both debt and equity. Avenue Venture Opportunities Fund provided an initial draw down of $8.5 million in a $15 million debt facility. Equity financing was $2.7 million contributed from existing and institutional investors. Total cash following the debt and equity financing is in excess of $14 million. Spectral has access to another $6.5 million in debt following FDA clearance of DeepView. Capital will be used for DeepView commercialization.

The term of the financing is three years with an interest-only payment period of fifteen months. Avenue received warrants with an exercise price of $1.80, equal to 8.5% of the funding commitment. The equity raise sold 2,076,923 shares of the company's common stock at $1.30 per share to raise $2.7 million. Each share has a warrant attached with an exercise price of $1.80. There is a second financing tranche that is contingent on regulatory clearance. This would provide $6.5 million of additional debt financing and require an additional $7 million equity raise by the company.

Registration Statement Filed for Spectral IP IPO

Spectral AI's wholly-owned subsidiary, Spectral IP, Inc., filed a registration statement with the SEC related to the spinoff and an initial public offering of its shares of common stock. The new company will be renamed SIM IP, Inc. The number of shares and pricing have not yet been determined. Dominari Securities is acting as the representative of the underwriters and Revere Securities is acting as the co-underwriter for the proposed offering. Further details of the offering are available in the March 20th press release and in Form S-1.

The company will focus on IP-based financing and monetization strategies including licensing, litigation investment, structured financing, royalty acquisition and opportunistic transactions. It will offer an industry agnostic investment mandate but will focus on healthcare, semiconductors, AI and internet of things (IOT) industries where intellectual property is a critical component of product success. IP related to Spectral AI and its imaging systems will remain with Spectral AI. Ownership in the entity, assuming the company is publicly offered, will be distributed to Spectral AI shareholders. The transaction is expected to be complete in the next three months.

Burn Validation Study Results

On February 7th, Spectral announced that it had completed the data analysis of the burn validation study presaging the release of topline data on March 17th. Results comparing the sensitivity, Dice score and specificity were provided along with anticipated timing for clearance and commercialization.

Burn Trial Background
On January 11th, 2024, Spectral announced that it began enrollment of its pivotal study to validate DeepView for burn injuries. The study enrolled and analyzed data from 164 patients, consisting of 115 adults and 49 children in burn centers and emergency departments throughout the US. The study was filed on clinicaltrials.gov under the designator NCT06131203 and is titled Burn Pivotal Study. Its purpose is to validate the burn healing assessment algorithm for the DeepView device. 16 sites enrolled patients.

Analysis of study data generated results related to the sensitivity, specificity and Dice score of the DeepView system at both a pixel level and full image level compared with the clinical judgment of burn physicians. Findings of the various endpoints were:

- **Sensitivity** - The DeepView System demonstrated a statistically significant improvement in identifying non-healing tissue compared to burn physicians, as judged on sensitivity. At the image-wise level, the DeepView System scored 86.6% while clinical judgment annotation (CJA) of burn physicians scored 40.8%. At the pixel-wise level, the DeepView System scored 81.9% and CJA of burn physicians scored 38.8%;
- **Dice Score**[1] - The DeepView System 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%;
- **Specificity** - The DeepView System produced a specificity of 61.2% (versus an anticipated result of 36.0%) and CJA of 79.1%.

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]

[1] The Dice Score, also known as the Dice Similarity Coefficient (DSC), is a metric used to measure the similarity between two sets, commonly used in image segmentation tasks to compare the predicted segmentation with the ground truth. It is commonly used in medical image segmentation, computer vision and natural language processing. The DSC contrasts with simple accuracy metrics like sensitivity and specificity in that it considers both size and spatial alignment of segmented regions, reflecting perceptual quality more effectively.
[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 de-

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 assisting providers to determine the best course forward. This technology is embedded into the DeepView system and can aid clinicians in their efforts to improve patient treatment decisions. We believe that this functionality will be part of the FDA submission and formalized in the instructions for use.

Australia Device Installations

In July 2024, Spectral announced a collaboration with PolyNovo Limited to conduct a limited deployment for burn evaluation in Australia. PolyNovo develops and sells skin substitutes and distributes them globally. The goal of the deployment is to facilitate access to Australia's Special Access Scheme, which allows certain health practitioners to use medical devices that are not included in the Australian Register of Therapeutic Goods. Spectral is now in the process of fulfilling the requirements before the devices can be deployed down under.

The company updated the progress with this initiative in a March 6th, 2025 press release confirming that three DeepView system devices were installed in Australia. The installations will support the anticipated future rollout of additional DeepView devices based on clinician evaluations and experiences with the device.

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[4] 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.

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 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

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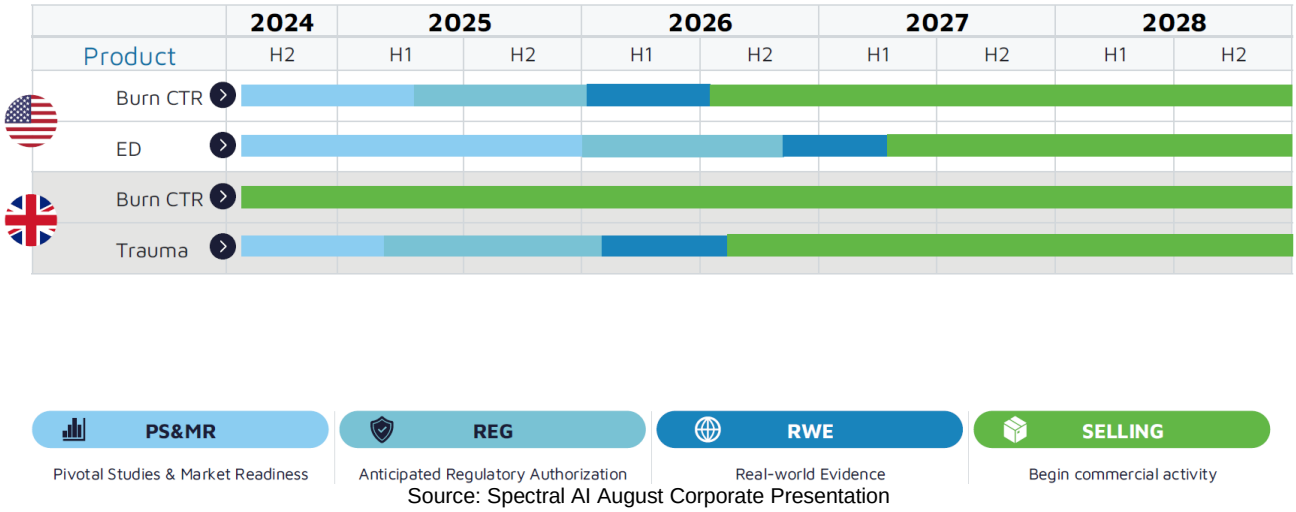
vice's safety and effectiveness. Class II medical devices present moderate risk and can pose a moderate risk to the patient if used incorrectly or malfunction. They require special controls in addition to the general controls required for Class I devices which may include specific labeling requirements, 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.

[4] 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 I – DeepView Product Deployment Timeline



Source: Spectral AI August Corporate Presentation

Summary

Spectral announces 2024 results and updates stakeholders on progress with its burn study and planned regulatory submission. Topline data from the burn center validation study produced impressive sensitivity and Dice score results. Next steps for the program are to compile the De Novo application which should be in front of the FDA by mid-year 2025. DeepView's anticipated submission timeline suggests approval and deployment of the DeepView burn device in 2026. In parallel, Spectral is developing its SnapShot M portable device and reaching into Australia and the UK with new system deployments. 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 A	2024 A	2025 E	2026 E
Total Revenues ($US '000)	**$18,056**	**$6,326**	**$7,478**	**$8,173**	**$7,604**	**$29,581**	**$21,996**	**$43,351**
YOY Growth	-28.8%	25%	76%	138%	44%	64%	-26%	97%
Cost of Goods Sold	$10,176	$3,381	$4,164	$4,506	$4,256	$16,307	$11,768	$23,063
Product Gross Margin	43.6%	46.6%	44.3%	44.9%	46.0%	44.9%	46.5%	46.8%
General & administrative	$20,864	$5,088	$5,756	$4,553	$4,459	$19,856	$20,000	$25,350
Research & development	$0	$0	$0	$0	$0	$0	$0	$0
Income from operations	($12,984)	($2,143)	($2,442)	($886)	($1,111)	($6,582)	($9,772)	($5,062)
Operating Margin								
Interest (expense) income, net	$172	$14	$6	($8)	$2	$14	$50	$50
Other income, net	($8,031)	($1,054)	($359)	($573)	($6,490)	($8,476)	$0	$0
Pre-Tax Income	($20,843)	($3,183)	($2,795)	($1,467)	($7,599)	($15,044)	($9,722)	($5,012)
Provision for Income Tax	($11)	($22)	($69)	($37)	($143)	($271)	$0	$0
Net Income	**($20,854)**	**($3,205)**	**($2,864)**	**($1,504)**	**($7,742)**	**($15,315)**	**($9,722)**	**($5,012)**
Net Margin								
Reported EPS	**($1.48)**	**($0.19)**	**($0.16)**	**($0.08)**	**($0.41)**	**($0.85)**	**($0.45)**	**($0.18)**
YOY Growth								
Fully Diluted Shares	14,088	16,560	17,598	17,862	18,811	17,934	21,675	27,500

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

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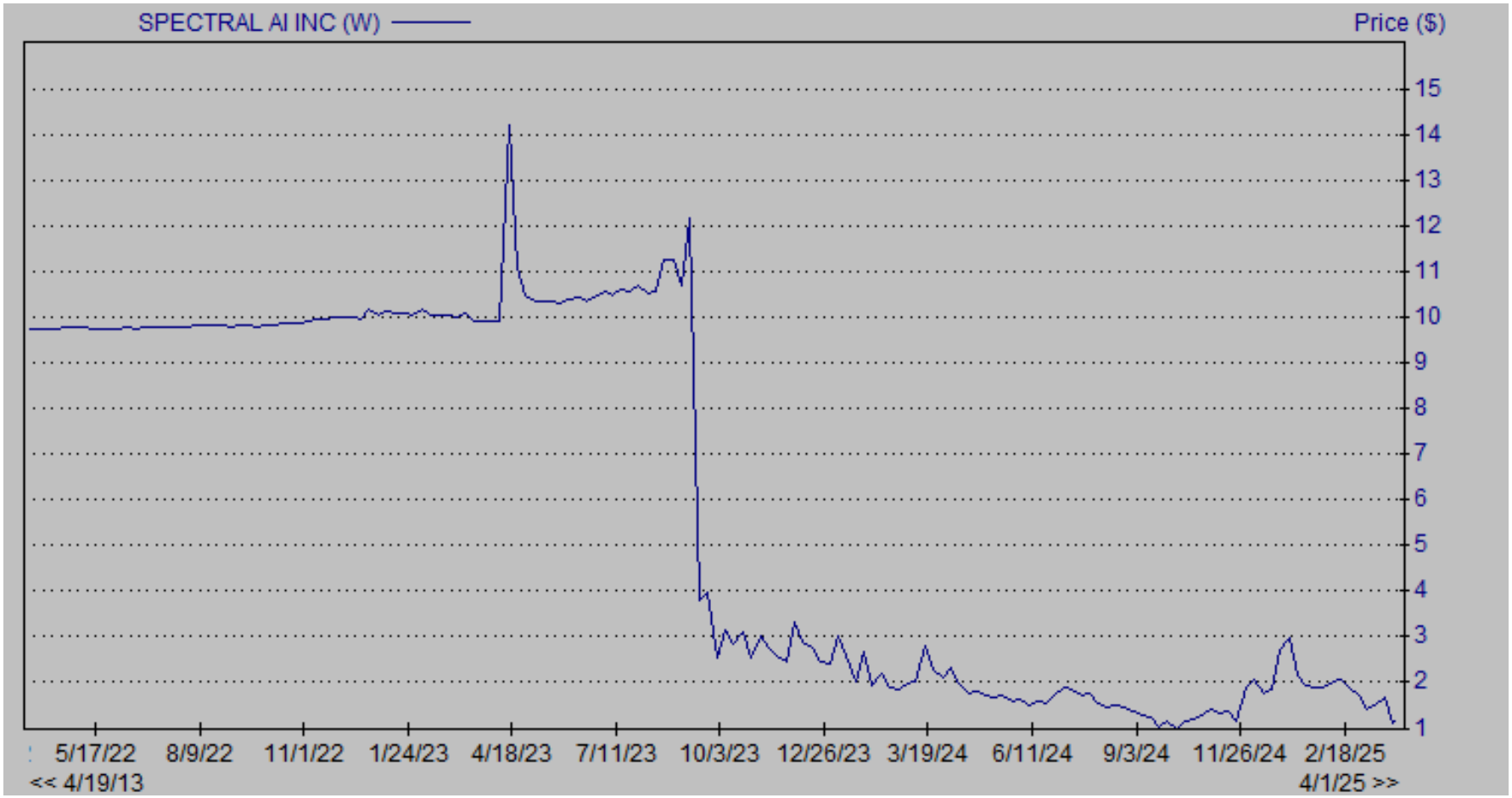
HISTORICAL STOCK PRICE

Spectral AI, Inc. – Share Price Chart[5]



[5] Source: Zacks Research System

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