Zacks Small-Cap Research
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John D. Vandermosten
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
101 N. Wacker Drive, Chicago, IL 60606

Spectral AI, Inc. (MDAI - NASDAQ)

MDAI: In the Blocks, Ready to Go upon Mid-Year Authorization

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

Current Price (1/20/2026)	$1.55
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	**3.21**
52-Week Low	**1.04**
One-Year Return (%)	**-20.9**
Beta	**0.9**
Average Daily Volume (sh)	**396,868**
Shares Outstanding (mil)	**30.7**
Market Capitalization ($mil)	**47.6**
Short Interest Ratio (days)	**4.7**
Institutional Ownership (%)	**9.6**
Insider Ownership (%)	**25.6**
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	$3.0 E	$18.6 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	-$0.45 E
2026					-$0.50 E
2027					-$0.26 E

WHAT'S NEW

It has now been approximately seven months since Spectral AI, Inc. (NASDAQ: MDAI) announced its De Novo marketing application to the FDA for the DeepView device. Based on historical review times and no mention of unexpected delays, we anticipate that an authorization by the FDA for the DeepView device could come mid-year. We had a chance to catch up with management which remains focused on commercialization preparation activities and interacting with the FDA as it progresses through the review process.

While marketing authorization is not a foregone conclusion, we believe it will be granted given the strength of the package submitted to the agency. As a result, our focus has shifted to the next major step for the company: commercialization. This effort is led by Chief Commercial Officer Jeremiah Sparks, who has experience working with government agencies. He has developed successful commercial teams across multiple ventures and managed market access strategies, including payer and pricing strategies over various geographies. Mr. Sparks' resume includes Johnson & Johnson, Healthpoint and Allergan among other leading companies.

As of November's quarterly earnings report, Mr. Sparks was preparing to add four additional commercialization team members to help with sales and professional education. For its initial sales efforts, 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 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 this year. 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.

FDA Timing for Clearance

Below we provide a breakdown of the steps involved with an FDA De Novo submission:

- Administrative Acceptance Review
  - 15-day period for the FDA to ensure the submission is administratively complete
  - FDA requests any missing items
- Substantive Review
  - 150-day clock begins
  - Review team assigned to evaluate device
- Interactive Review with agency information requests
  - Clarifications, additional analyses, risk mitigation and edits to instructions for use
  - Conducted via rapid written responses
  - Clock may stop during response periods

Following these steps a deficiency letter may be sent if there is insufficient clinical evidence, inadequate risk controls or a need for more testing. FDA and sponsor meetings may also take place to address actual or perceived shortcomings. When the FDA is comfortable with the application and all questions have been answered to its satisfaction, it will draft and send a formal De Novo authorization letter. If authorized, the sponsor is allowed to market the device which can serve as a predicate for future 510(k) submissions.

We consulted several resources[1,2,3] to estimate the duration of FDA De Novo application review and grant of marketing authorization. Based on historical data, a De Novo submission has averaged anywhere from 307 to 394 calendar days for a review to be complete and a decision to be made. 2018 legislation mandated a performance goal of reviewing 70% of submissions within 150 calendar days; however, this does not include periods of time when the review is on hold due to sponsor questions or other reasons. Pre-COVID, review times were in the low 300-day range; however, they rose during the pandemic and have recently been in the high 300-day range. We think that a review period of 11-13 months is reasonable.

A distinguishing feature of DeepView is that it uses artificial intelligence (AI) to generate a diagnosis. The FDA pays special attention to several AI-specific issues for devices that rely on the technology. This includes algorithm transparency and validation, performance consistency, the use of locked vs. adaptive algorithms and other lifecycle management, cybersecurity and post-market monitoring considerations outlined in FDA AI/ML guidance.[4]

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 – 2026
- Launch of DeepView in US Burn Centers – 2H:26
- Launch of DeepView in US Emergency Departments (Burn) – 2026/2027
- DeepView SnapShot M Launch for Military Use - 2027

Summary

As we move into the final months of DeepView's FDA review, we catch up with management on latest thoughts and activities related to the regulatory process and commercialization preparations. Based on a review of literature analyzing FDA review times for De Novo submissions, we see a high probability of DeepView device authorized for marketing activities by the FDA mid-year 2026. Since our previous update, Spectral continues to interact with the agency and respond to its questions. Authorization could come by mid-year allowing for a launch of the device in the second half of 2026. 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 further updates from management. We maintain our valuation of $5.00 per share.

[1] Aboy, M., *et al*. Beyond the 510(k): The regulation of novel moderate-risk medical devices, intellectual property considerations, and innovation incentives in the FDA's De Novo pathway.
[2] Packard, Robert. What is the De Novo review timeline? Medical Device Academy. October 2022.
[3] FDA De Novo Pathway Explained: The Complete 2025 Guide. Complizen. September 2025.
[4] US Food and Drug Administration. Artificial Intelligence in Software as a Medical Device. Accessed January 2026.

PROJECTED FINANCIALS

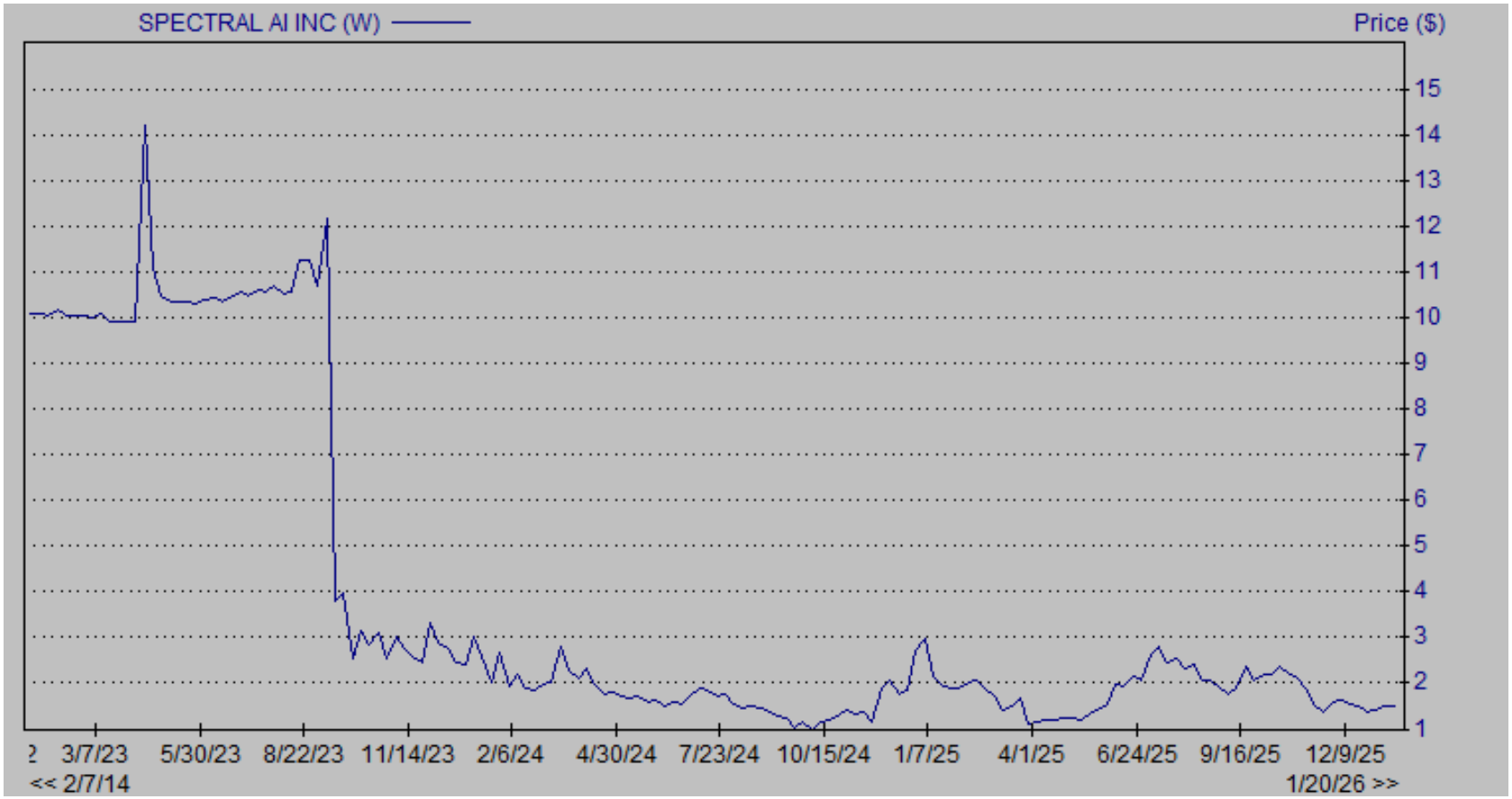
Spectral AI, Inc. - Income Statement

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**	**$2,994**	**$18,558**	**$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	$1,602	$10,087	$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)	($2,808)	($9,168)	($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)	($2,838)	($11,407)	($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)**	**($2,908)**	**($11,531)**	**($16,852)**	**($9,845)**
Net Margin								
Reported EPS	**($0.85)**	**$0.15**	**($0.31)**	**($0.13)**	**($0.10)**	**($0.45)**	**($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

HISTORICAL STOCK PRICE

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



[5] Source: Zacks Research System

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