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Spectral AI, Inc. (MDAI - NASDAQ)

MDAI: December Topline Expected

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 (11/7/2024)	$1.34
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	**3.72**
52-Week Low	**0.82**
One-Year Return (%)	**-52**
Beta	**0.6**
Average Daily Volume (sh)	**251,517**
Shares Outstanding (mil)	**18.6**
Market Capitalization ($mil)	**24.9**
Short Interest Ratio (days)	**3.5**
Institutional Ownership (%)	**19.9**
Insider Ownership (%)	**44.3**
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

Spectral AI, Inc. (NASDAQ: MDAI) reported third quarter results on November 6th, 2024. Revenues totaled $8.2 million and the burn trial has completed enrollment while the emergency department burn enrollment continues. The company also received additional funding from the Medical Technology Enterprise Consortium (MTEC) to further develop the portable SnapShot M device. In October, Spectral enacted structural changes to streamline the organization and replaced the CEO with an executive management team that will now report directly to the board. Further structural changes include a spin-off of the intellectual property subsidiary. During the conference call, Board Chairman Dr. Michael DiMaio highlighted the near- and medium-term orientation of the company towards 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 an anticipated December 2024 topline announcement.

Third Quarter Financial and Operational Results

Spectral reported third quarter 2024 results in a press release and Form 10-Q filing with the SEC on November 6th. A conference call was held to discuss results with investors following the release. For the quarter ending September 30, 2024 research and development revenues of $8.2 million were recognized. Net loss for 3Q:24 totaled ($1.5) million or ($0.08) per share. For the third quarter of 2024 versus the same prior year period:

- Revenues were $8.2 million up 138% from $3.4 million due to an increase in activity related to BARDA and other US government grant revenues. BARDA revenues totaled $7.6 million while other government contracts composed primarily of MTEC funds were $606,000;
- Cost of revenue, which can be thought of as research and development expense, totaled $4.5 million, rising 129% from $2.0 million due to higher activity levels related to the BARDA and MTEC contracts. Gross margin improved to 44.9% from 42.8% due to a higher reimbursement rate in the new BARDA contract;
- General & Administrative expenses were $4.6 million, down 19% from $5.6 million on higher compensation expense;
- Net interest expense was ($8,000) compared to $42,000;
- Other expense was ($573,000) vs. ($6.6) million with borrowing related costs dominating this period vs. transaction costs related to listing on the NASDAQ dominating the year ago period;
- Income tax was ($37,000) vs. $54,000;
- Net loss was ($1.5) million vs. ($10.6) million or ($0.08) and ($0.77) per share, respectively.

As of September 30, 2024, cash totaled $3.7 million. This amount compares to the $4.8 million cash balance held at the end of 2023. Several financing transactions took place year to date including contributions from issuance of common stock and notes offset by repayment of other notes. In the third quarter cash from financing was negative due to the repayment of notes payable. Remaining notes payable are carried on the balance sheet at $6.0 million. After the end of the quarter, the annual interest rate on the notes was reduced to 4% from 8%, the maturity was extended to March 2026 and a conversion feature was added. The company also filed a shelf registration on Form S-3 to raise additional capital.

Management Changes

Spectral AI announced a big change in its leadership ranks on October 14th with founder Dr. J. Michael DiMaio returning as chairman of the Board of Directors. He will guide the newly created Office of the Chairman (OC) to assume day to day operational responsibilities for running the company. The OC will include CFO and General Counsel Vincent Capone, Chief Commercialization Officer Jeremiah Sparks, Interim Chief Operating Officer Stan Micek and General Manager Louis Percoco. The team will report directly to the board.

Dr. DiMaio has set the priorities of becoming more focused on finances, the regulatory pathway forward in burn and interacting with BARDA. On the finances front, while BARDA is supporting the majority of the research and development, Spectral wants to augment this funding with private capital to help with development and support the commercialization into some of the areas that do not receive direct BARDA funding. Spectral is orienting its efforts around the planned FDA submission for the DeepView AI-Burn in 2Q:25. Spectral will pursue a De Novo submission and request classification as a Class II medical device.

We see the change as streamlining the company's efforts towards the advancement of DeepView burn diagnostic towards FDA approval and developing relationships to support financing in pursuit of this objective. The focus on the burn diagnostic includes efforts and sales in the UK which provide real-world experience using the device that can help in the eventual marketing of the product after approval. Additionally, the SnapShot M product, which recently received additional funding from the Medical Technology Enterprise Consortium (MTEC) will help extend this burn diagnosis to mobile settings, first on the battlefield and later in other areas such as ambulances.

Near term will center upon continued enrollment in the emergency department trial and preparation of the De Novo application for DeepView by 2Q:25. Assuming normal review times, the FDA could grant approval by 1H:26.

Spin-Out of Spectral IP

In March 2024, Spectral announced that it had formed an intellectual property (IP) subsidiary to monetize IP in the healthcare space. Shortly after, Spectral IP received a $1 million investment to fund its work which would be led by Erich Spangenberg. The goal of the entity is to raise additional capital and focus on health care IP-related investments and acquisitions. In early November, Spectral announced that it will spin off the IP subsidiary through a transaction with Sauvegarder Investment Management, Inc. None of Spectral AI's patents will transfer to the IP entity. Spectral IP will be distributed to its shareholders as stock where it will become a separate publicly traded company.

Spectral AI Video Series

Select management and front-line research and development team members provided details on Spectral's relationship with BARDA, the difference between hyperspectral imaging and multispectral imaging, and details on the development of the company's device. Links are embedded in the following bullet points.

Exhibit I – Spectral AI Video Series



Source: Screen Capture from Spectral AI Video Series

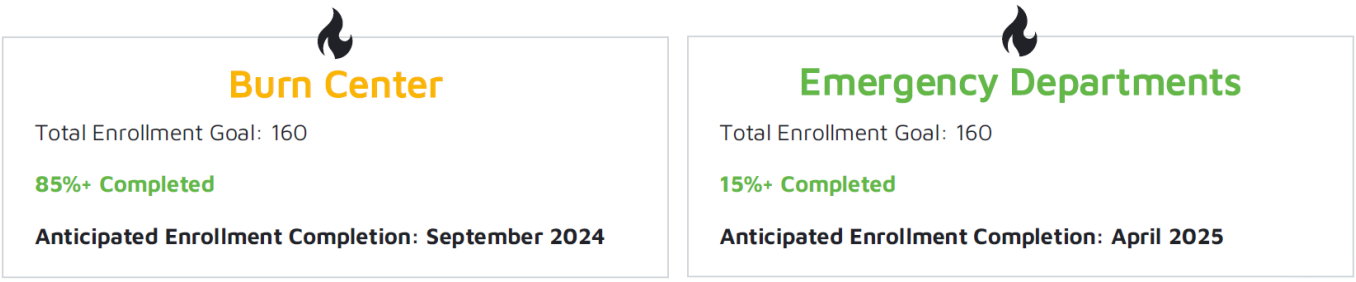
See selected interviews with Spectral AI's team below:

- CFO Vince Capone Elaborates on BARDA Partnership
- Director of Data Science, Jihang Wang Shares DeepView's Features
- Director of Data Science, Jihang Wang Compares Hyperspectral and Multispectral Imaging
- Director of Data Science, Jihang Wang, Explains the DeepView Device

Burn Trial Progress

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 II – 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.

In late 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 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. Topline results from the trial are expected in December 2024.

The anticipated regulatory pathway will include a De Novo FDA submission for DeepView in the second quarter of 2025, which, if successfully approved, will allow for commercialization of the device in early 2026. Spectral will request consideration of DeepView as a Class II device. [1] After receiving the approval for use in burn centers, Spectral will pursue emergency department approval via the 510(k) pathway.[2]

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.

Ex-US Development

Spectral deployed five units to the U.K. after receiving UKCA authorization earlier this year. This has allowed the team to generate real world data which enhances the AI algorithm and allows it to work with stakeholders in order to more effectively commercialize and deploy the device. Additional devices are expected to be sold after feedback is

[1] 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.

[2] 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.

received from the doctors in the field. A foothold in the U.K. could provide a stepping stone to broader exposure to Europe and help the team gain real world experience using the device.

In July, 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 to patients. Spectral is now in the process of fulfilling the requirements before the devices can be deployed down under.

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.

Exhibit III – DeepView SnapShot M



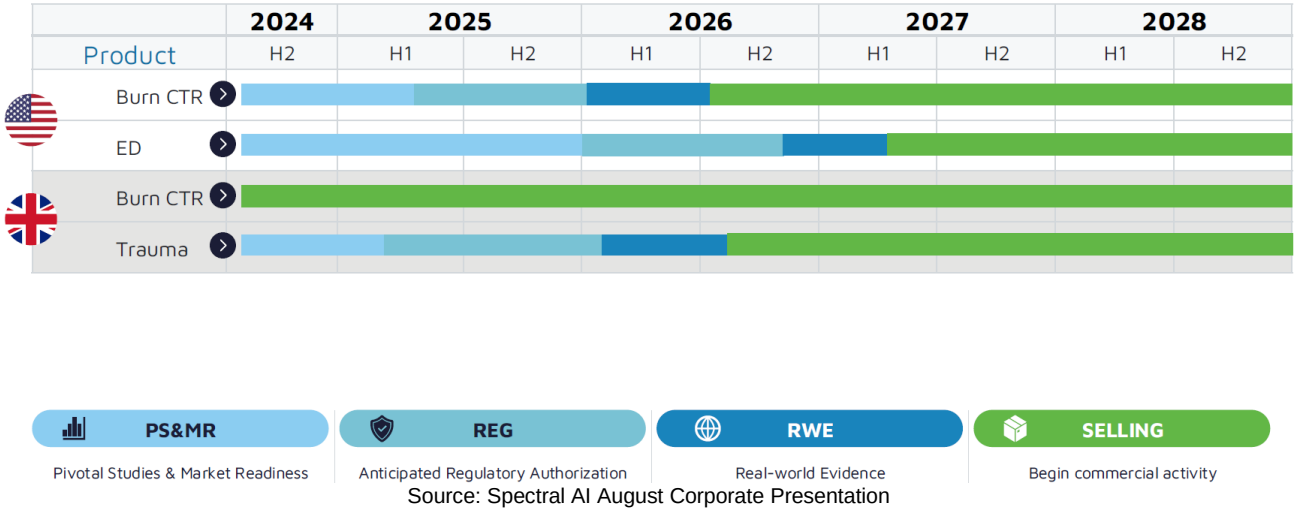
Source: Spectral AI

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 later this year and should recognize first sales shortly after. 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.

Milestones

- Enrollment begins for DeepView burn pivotal validation study – January 2024
- Defense Health Agency contract for development of handheld DeepView system – March 2024
- Note and convertible investment of $12.5 million in Spectral – March 2024
- MDAI to join Russell Microcap Index – July 2024
- Pivotal burn study over half enrolled – June 2024
- Pediatric enrollment target achieved in burn pivotal study and trial site expansion – July 2024
- Collaboration with PolyNovo for DeepView in Australia – July 2024
- Participation in Military Health System Research Symposium – August 2024
- Presentation by Dr. Jeffrey Carter at BBA/ISBI Joint Conference – August 21, 2024
- Completion of burn center enrollment – August 2024
- Burn Center Enrollment Completion – September 2024
- Participation in HC Wainwright & Lake Street conferences – September 2024
- Management restructuring – October 2024
- DeepView Burn Study Topline – December 2024
- Deployment of DeepView System in UK – 2025
- FDA 510(k) submission of DeepView for clearance in burn – 1H:25
- Emergency Department Enrollment Completion – April 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 IV – DeepView Product Deployment Timeline



Source: Spectral AI August Corporate Presentation

Summary

Spectral provided its third quarter financial update sharing its steady progress with the burn trial and anticipated FDA submission next year. It was an eventful period since the second quarter update with completion of enrollment in the Burn Center Pivotal Study, attendance at several scientific and investor conferences, the receipt of additional MTEC funding and a change in the management ranks. Several future milestones were also announced including an anticipated spin of the IP subsidiary, December topline announcement and submission of the new drug application next year. In the meantime, the company is focused on developing and reviewing the data while it undergoes the truthing process for training the algorithm. 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

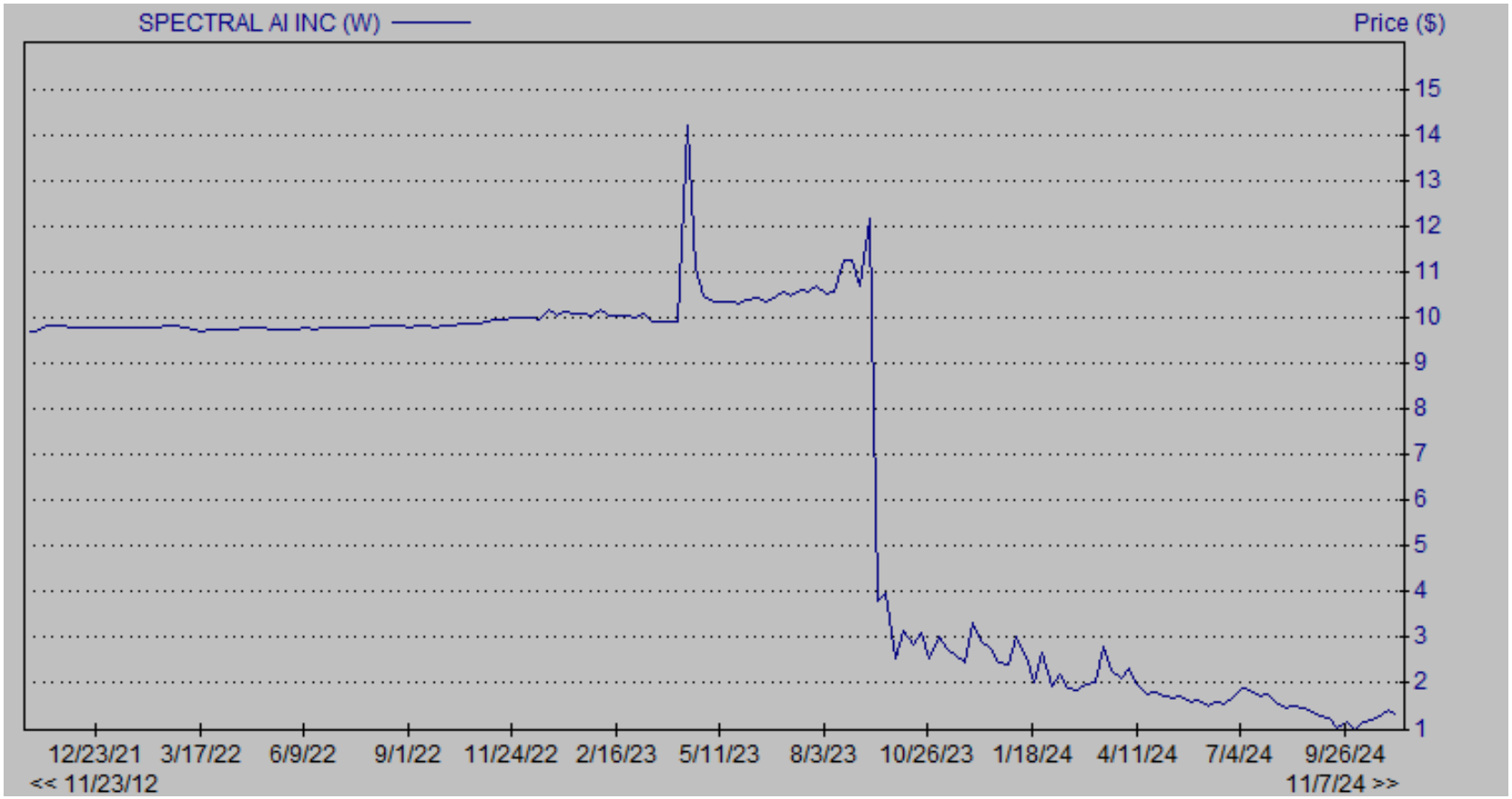
Spectral AI, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US '000)	**$18,056**	**$6,326**	**$7,478**	**$8,173**	**$7,322**	**$29,299**	**$26,606**	**$43,351**
YOY Growth	-28.8%	25%	76%	138%	38%	62%	-9%	63%
Cost of Goods Sold	$10,176	$3,381	$4,164	$4,506	$3,954	$16,005	$14,234	$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[3]



[3] Source: Zacks Research System

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