Spectral AI Announces Publication of Letter to Shareholders

DALLAS, TX - February 5, 2024 - Spectral AI, Inc. (Nasdaq: MDAI) ("Spectral AI" or the "Company"), an artificial intelligence (AI) company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, today announced the publication of a Letter to Shareholders from the Company's CEO and Co-founder, Wensheng Fan, and Chairman of the Board, Richard Cotton.

The Letter to Shareholders addresses the Company's progress along multiple fronts as it continues to evolve from a late-stage development company towards commercialization of its AI-driven DeepView™ System. The Company believes that this proprietary platform technology can revolutionize the standard of care in wound assessment and treatment for burn and Diabetic Foot Ulcer ("DFU") indications.

Highlights of the Letter to Shareholder include:

- The largest contract in the Company's history, a $149 million award from BARDA that provides non-dilutive funding for ongoing product development and procurement.

- An expectation that, pending regulatory authorization in the US and UK, the Company will generate revenue across four separate platforms covering burn and DFU within the next three years, with the potential for initial commercial revenue as soon as the second half of 2024.

- FDA and UKCA marking of the Company's proprietary imaging technology, DeepView Snapshot®, as well as the recent submission of the Company's predictive software, DeepView AI®-Burn, to the UK regulatory body for UKCA marking.

- Promising interim results for the Company's DFU Clinical Study and multiple ongoing clinical trials designed to validate the DeepView™ System for wound healing assessments, including the initiation of a pivotal study in the US for Burn and an anticipated 1H 2025 submission to the FDA for US approval for this indication.

- Appointments that have added strength and depth to the Company's management team and Board of Directors.

The Letter to Shareholders was filed on Form 8-K with the Securities and Exchange Commission and is available free of charge at www.sec.gov. A copy of the letter is also accessible at the Investor Relations section of the Company's website at https://investors.spectral-ai.com/.

About Spectral AI

Spectral AI, Inc. is a Dallas-based predictive AI company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, with initial applications involving patients with burns and diabetic foot ulcers. The Company is working to revolutionize the management of wound care by "Seeing the Unknown®" with its DeepView® System. DeepView® is a predictive diagnostic device that offers clinicians an objective and immediate assessment of a wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal of substantially exceeding the current standard of care in the future, DeepView® is expected to provide faster and more accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. For more information about DeepView®, visit www.spectral-ai.com.

Forward Looking Statements

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February 5, 2024

Dear Shareholders,

Last year was a milestone year for Spectral AI! We are evolving from a late-stage development company embarking on commercialization of our AI-driven technology to revolutionize the standard of care in wound diagnostics. Your Company is proud to share the accomplishments of the Spectral AI team from this past year and provide insight on the initiatives we are pursuing in 2024.

Before addressing our future, let's revisit the compelling reasons you invested in Spectral AI. Leveraging the power and promise of artificial intelligence, your Company is **dedicated to revolutionizing wound care management by enabling clinicians to make faster and more accurate treatment decisions**. We are prioritizing burn and Diabetic Foot Ulcer ("DFU") indications in the United States and United Kingdom markets and continue to deliver against our stated development milestones. Pending regulatory authorization in the US and UK, we anticipate generating revenue across four separate platforms covering burn and DFU within the next three years.

We are at a pivotal juncture where diligent efforts in clinical evaluation and deployment are paving the way for a shift towards the commercialization of our DeepView™ System.

Regulatory

In late 2023, we received both FDA and UKCA marking of our proprietary imaging technology, DeepView Snapshot®. We recently submitted our predictive software, DeepView AI®-Burn, to the UK regulatory body for UKCA marking and anticipate their response in 1H 2024. Completion of this milestone will allow us to sell our DeepView™ System in the UK and we expect to swiftly deploy multiple devices in the UK for customer evaluation and to begin **generating revenue in the second half of this year**.

BARDA Award and Financing

One of last year's highlights was securing **our largest BARDA contract worth $149 million** in September, bringing the total contract awards from BARDA to over $250 million. This contract not only **provides non-dilutive funding for further development, but also secures procurement of medical devices** to expand utilization beyond burn centers to emergency departments, where most patients enter

the healthcare system. Strategically allocated, the award designates $55 million for development activities through the first quarter of 2026 and $95 million for additional development, procurement, and early-adopter deployment of the DeepView™ System. Previously in 2013 and 2019, your Company was awarded BARDA contracts totaling $123 million of which $101 million has been committed to date.

In September, we also made significant strides to enhance your Company's presence in the United States. We **successfully listed on Nasdaq** with the ticker MDAI, leaving the London Stock Exchange. This transition grants us greater access to the United States capital markets; provides you with greater liquidity opportunities in the market; and increases transparency and frequency of our financial activities.

Finally, in December, we completed a Committed Equity Facility with B. Riley Financial Inc., allowing the Company **access up to $10 million** at any time during the next two years. Any such funds would be utilized to support our clinical development activities.

Clinical Trials

Our clinical, regulatory, and engineering teams are leading multiple clinical trials designed to validate the DeepView™ System for wound healing assessments. In the last twelve months alone, we:

- Provided interim results for our DFU Clinical Study. These results will be used in upcoming submissions of DeepView AI®-DFU in the UK (anticipated in 1H 2024) and to the FDA (anticipated in 2H 2024).

- Enhanced both product indications (burn and DFU) to include 3D wound measurements without the use of a reference marker. The benefit to both providers and payers is the creation of standardized digital wound documentation in addition to predictive AI wound healing diagnostic.

- Announced that the wound imaging system, DeepView SnapShot®, received regulatory authorization in the United Kingdom and Class 1 medical device classification with the U.S. Food and Drug Administration (FDA).

- Initiated our pivotal study to validate DeepView AI®. We expect this to be the final clinical trial before seeking FDA marketing authorization for the burn indication in 1H 2025. This study is being conducted in burn centers and emergency departments with an enrollment target of 240 subjects in both adults and pediatric patients.

Product Development

Building on work initially funded by the U.S. Department of Defense, in April 2023, we received a $4 million award from the Medical Technology Enterprise Consortium, providing additional non-dilutive funding to support military battlefield burn evaluation via a handheld, portable, and wireless version of our DeepView technology. We anticipate that our DeepView SnapShot® M will transform wound care in many limited-access areas, including supporting first responder, disaster preparedness and in rural areas. We anticipate originating commercial sales in 2026.

We are proud to have received ISO 13485 certification for the manufacture and distribution of our DeepView™ System in August. ISO 13485 is an internationally recognized standard showing that Spectral MD is committed to the quality of medical device design, development, and production. We believe that this achievement reflects our commitment to fostering a culture of continuous improvement, validates the robust sourcing and operational framework we have created, and provides an important competitive advantage as we continue our regulatory initiatives and advance towards product commercialization.

Management and Board

Since completing the merger that resulted in our Nasdaq listing, our Company has continued to add strength and depth to our management team and the Board of Directors:

- Appointed **Deepak Sadagopan**, MHCDS, to the Board of Directors. Mr. Sadagopan is a high-impact healthcare executive with more than 25 years of senior leadership experience with top Fortune-rated corporations and aggressive startup environments. He also brings to the board expertise in healthcare technology and analytics along with a successful track record in product launches.

- Named Prof. **Paul Chadwick** as Executive Vice President of the Company's United Kingdom subsidiary. Prof. Chadwick is an experienced clinical scientist and wound care key opinion leader (KOL) in the domain of diabetic wound management. Previously, he served as the CEO of the Royal College of Podiatry in the United Kingdom.

- Welcomed back **Erich Spangenberg** to the Board of Directors. Mr. Spangenberg, the Company's initial outside investor in 2011, comes back to the Board of Directors after a short break bringing nearly 40 years of experience as an entrepreneur, investor, investment banker, and attorney.

- Hired **Pete Carlson** as Chief Financial Officer. Mr. Carlson has an exceptional track record as a senior financial executive at several public companies in multiple industries, including two Fortune 50 entities, and most recently at a company focused on chronic and hard-to-heal wounds.

What to expect in 2024

Looking forward, we expect that 2024 will be defined by continuing advancement of clinical trials, health economic and outcome data studies; regulatory submissions; and initial product sales of our DeepView™ System.

As noted earlier, we submitted for regulatory approval in the UK for our DeepView AI®-Burn indication and expect to begin revenue-generating activity in the second half of this year. In addition, we initiated our pivotal study in the US for Burn and anticipate an 1H 2025 submission to the FDA for US approval.

For DFU in the US, our largest market opportunity, we expect to complete our validation study, begin interactions with government payors to establish reimbursement, and in late 2024, to apply with the FDA for approval of the DFU indication.

Outside of the United States, we continue to see strategic opportunities in the EMEA region where diabetes remains a higher medical crisis than in the United States and the UK. A study by the Journal of Diabetes Investigators reported of 3,021 patients from several of the gulf cooperation council "countries", including Saudi Arabia, showed a high prevalence of diabetic peripheral neuropathy, with many also at risk of diabetic ulceration. We expect to continue our work in the EMEA region and hope to transition our clinical studies and work for DFU into commercial activities in early 2025.

In closing, thank you for your continued support of and interest in your Company. We are very excited about our prospects for growth and look forward to apprising you on our progress throughout the year.

We welcome your comments and questions and can be reached at ir@spectral-ai.com.

Sincerely,

Wensheng Fan   Richard Cotton
CEO & Co-Founder   *Chairman*