

## **Predictive**Wound Healing

AI + Multispectral Imaging =

Faster, More Accurate Treatment

Decisions in Healthcare

Nasdaq: MDAI | March 2024



### **ABOUT**





### AI-Driven wound assessment technology

designed to deliver value across

17.5 Million

shares outstanding March 29, 2024

Annual Revenue

2023 **\$18.1M** 

2024E ) **\$28M** 

Supported by \$250M+

non-dilutive government funding

the healthcare continuum



Financial position at 12/31/2023

Cash \$4.8M Long term debt \$0M

Large and growing addressable markets





Intellectual property portfolio

**20** issued

**34** pending

Clear regulatory pathway



Headquarters

Dallas, TX



Limited competition



Founded

2009



Strong competitive barriers to entry



NASDAQ

**MDAI** 





## Recent Accomplishments



Initiated U.S. pivotal
Study to validate the **DeepView System for Burn** 



Strengthened **Board and Management Team** 



Secured **\$10M committed** equity facility



Received **UKCA**classification
for DeepView Al®-Burn



**Secured \$12.5M**Convertible Instrument



Cumulative **proceeds of \$7.3M** through
March 25. 2024 from
equity facilities



Formed and funded **Spectral IP** 



**Deployed DeepView** for UK customer evaluations



## **Revolutionizing**Wound Care

- Our DeepView™ system enables healthcare providers to make more informed treatment choices.
- In a matter of seconds during the initial patient visit,

  DeepView™ **predicts¹** if the wound will heal or not,

  with remarkable accuracy.

## **Delivering** on Commitments



### 11-year track record

2013-2024

of meeting milestones validated by \$250M non-dilutive government funding

- Proof of concept
- Clinical validation
- Product validation

- Product prototyping
- Pre-sub regulatory alignment



Prioritizing growth opportunities in profitable markets, positioning ourselves for near-term commercial success.



DeepView<sup>™</sup> is a single platform supporting multiple indications.



Extensive portfolio of patents, trade secrets and "truthed" images are a significant barrier to competition.

#### **OUR TECHNOLOGY**



### DeepView Imaging

### Data extraction

### Al model building

### **Healing prediction**

Patented proprietary **multispectral imaging** data acquisition in milliseconds

Capturing injured **tissue spectral signature** 

Covering visible near UV through visible spectrum and into near-IR light

Extraction of **AI model features**, such as tissue characteristics that determine health

Combined with **patient** health matrix data

Al model trained and tested against a proprietary clinical database of **340+bn³** clinically validated data points

Al algorithm integrates image and clinical data for model training

Accurate and immediate binary wound healing prediction in seconds

Predicting tomorrow's outcome today



### Non-healing output

Decision: surgery or advanced wound care products

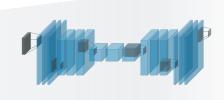


### **Healing output**

Decision: Routine care











## One Imaging Platform, **Multiple Indications**



#### **INDICATIONS**



### **Burn Wound**

TAM \$3.7817 - Anticipate selling







### **Diabetic Foot Ulcer**

TAM \$11B<sup>18</sup> - Anticipate selling







### **Potential Clinical Indications**

Wound Bed Preparedness

**Amputation** 

Digital Guided Therapy

Critical Limb Ischemia

Cosmetics

### DeepView SnapShot® M | Handheld

Military anticipate selling



Miniaturized Mobile

Home Healthcare



### **W** UK Go to Market



**Proof of Concept** 

Earlier entry into UK provides opportunity to demonstrate proof of concept for broader U.S. markets.





Empowering healthcare providers with predictive clinical insights for precise treatment decisions in wounds.



### L DFU Indication





This wound is NOT likely to heal

## PROBLEM

No diagnostic tool for DFUs, which are **complex** with a **non-linear** healing trajectory.

Inconsistent and subjective wound measurement

## **CURRENT SOLUTION**

For DFUs, requires use of standard-of-care (SOC\*) for 4 weeks

Two-thirds (2/3) of DFUs do not heal in 12 weeks.

Current clinical judgement is ~50%.5

## OUR SOLUTION

Our solution is **86% accurate** in predicting if a diabetic foot ulcer will heal.<sup>4\*</sup>

Standardized, threedimensional wound measurement.



### This wound is not likely to heal by 50% within 4 weeks

The DeepView $^{\text{TM}}$  system analyzes multispectral images that combined with clinical data provides a healing prediction on Diabetic Foot Ulcer (DFU).





Width:1.5 cm Length:1.5 cm Depth:0.2 cm Area:1.75 cm2 Volume:0.45 cm3

## DeepView<sup>™</sup> difference

- Objective standardized digital measurements.
- DeepView<sup>™</sup> predictive AI provides the right treatment for the right patient at the right time.
- Leading to anticipated reduction of costs and improved patient outcomes.

SOC\* = off-loading, debridement, and monitoring with multiple patient follow-ups confirming non-healing before approving advanced therapies.





### **Burn** Indication





This wound is NOT likely to heal

## **PROBLEM**

No existing diagnostic tool for burn leading to uninformed decisions. Burn evaluation relies on visual examination and subjective judgement, often leading to inaccuracies.

### **CURRENT SOLUTION**

Standard of care is to wait up to 21 days to determine need for surgery.6

### **OUR SOLUTION**

Burn professional healing accuracy prediction is 50% (generalist) to 75% (specialist).

92% accurate in seconds for DeepView.78



#### This burn will not heal

The DeepView™ system analyzes multispectral images that combined with clinical data provides a healing prediction on burn wounds.



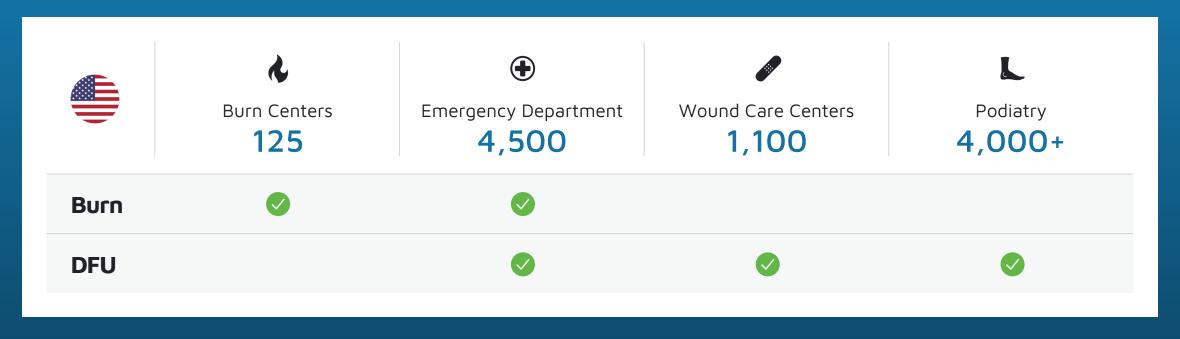


### DeepView™ difference

- Reduces time to surgery<sup>8</sup>
- Avoids unnecessary surgeries9
- Unnecessary burn center transfers.<sup>10</sup>
- Uniformed standardized TBSA measurements



### Targeting Multiple Care Centers



















150



**ICS Foot** 

& Ankle

40



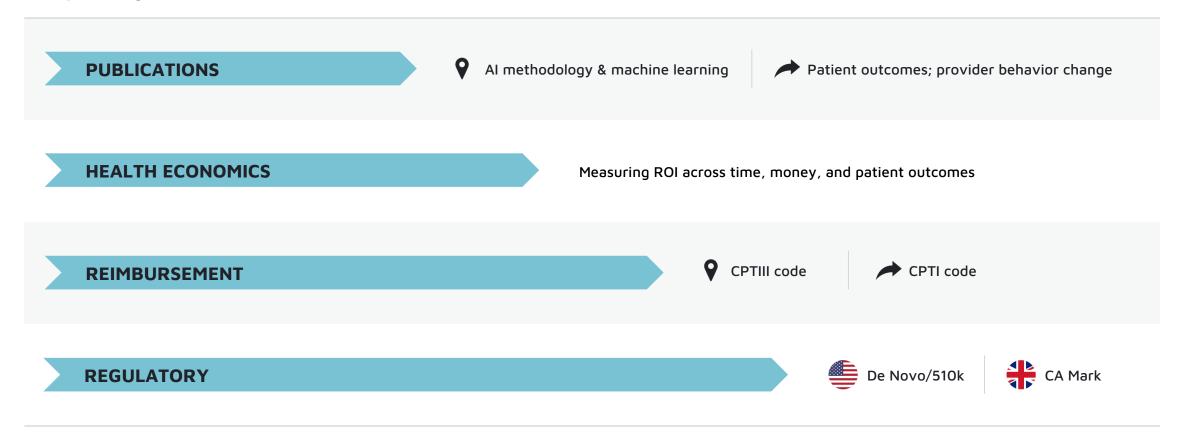
Community Nursing

**500** 



## Commercial strategy includes parallel paths

### Key Steps to Successful Market Access

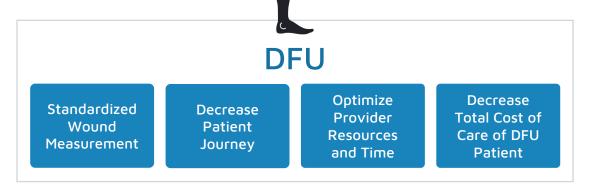




## Prospective clinical evidence with health economics and outcomes will quantify the system benefits

## **Deep**√iew<sup>™</sup>





#### **Anticipated Benefits**

- Standardized total body surface area (TBSA) measurement
- 41% reduction in unnecessary transfer<sup>13</sup>
- Unnecessary surgery admission costs reduction per patient of \$58,315<sup>14</sup> 15
- 3+ day reduction time to surgery for burns<sup>14</sup> <sup>16</sup> (>30% reduction in LOS)

### Healing at 4 weeks?<sup>11 12</sup>

60% YES 🗸

• Standardized digital documentation

### 40% NO 🐸

- Savings of office visits & treatment materials
- Savings of HCP time
- Reduction in patient journey

#### **BARDA SUPPORT OVER THE YEARS**

Management's track record through years of BARDA engagement validates and increases probability of success for DeepView<sup> $\mathbb{M}$ </sup> across clinical indications (Burn and DFU) and geography (U.S., UK, EMEA).

**2013** Burn I

\$26M

Proof of Concept

2019

Burn II

\$75M

Research

Testing

2023

Procurement Contract Base

\$55M

Regulatory

Manufacturing

Commercial Readiness 2025+

Procurement Contract Options

\$95M

Commercialization

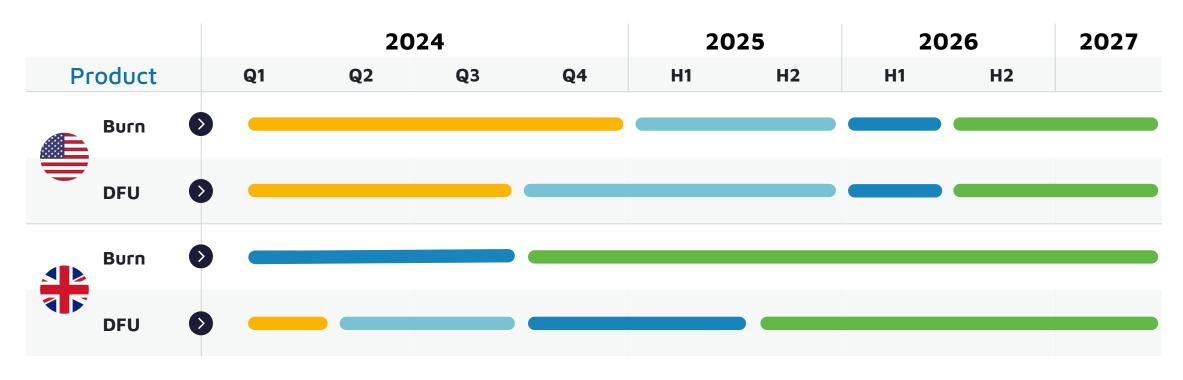
Procurement



**TOTAL** 



## Planned near-term **product deployments**





#### **REVENUE OPPORTUNITY**



# Includes annual license fee and one-time device sale

### **U.S. Device Sales**

- One-time transaction per site/user
- Unit pricing still being determined
- Expect DFU 1H 2026; Burn in 2H 2026
- Potential exists for sale or lease in certain segments

### **UK Device Sales**

- One-time transaction per site/user
- Unit pricing still being determined
- Expect DFU 2H2O25; Burn in 2H2O24
- Potential exists for sale or lease in certain segments

### U.S. R&D

- BARDA PBS Contract includes \$55M R&D revenue spread across 4Q23 - 1Q26
- Modest additional R&D revenue from MTFC in 2024

### U.S. Al License

- Annual license fee for use of Al data
- Separate license for each indication
- Pricing still being determined

### **UK License**

- · Annual license fee for use of Al data
- · Separate license for each indication
- Pricing still being determined





Intellectual Property



20

Allowed U.S. and international patents



34

Pending U.S. and international patent applications



Useful life on key patent protection on core concepts exceeds 14 years



## Improving health and cost outcomes for all



### Clinician

- Informed treatment decisions
- Increased efficiency



### Care Facility

- Uniformed clinical decisions
- Equality of care
- Improved efficiency
- Government digital initiatives



### **Patient**

- Reduced treatment time for patients and caregiver burden
- Reduced infection and treatment complications
- Reduced pain and suffering



### **Payers**

- Eliminated unnecessary payments
- Objective and validated treatment support



IMPROVED PATIENT OUTCOMES



DECREASED COSTS
PER INPATIENT



IMPROVED EXPERIENCE



INNOVATION JUSTIFICATION

**REDUCING LENGTH OF STAY** 



## Investment Summary



Al-Driven Clinical Diagnostics

FDA Breakthrough Designation

> Strong Competitive Barriers



Systemwide Benefits

Identified Regulatory Pathway

Universal Platform for Additional Clinical Indications



Large & Growing Markets

Near-Term Commercial Opportunities

Experienced Management Team



Appendix



**Patents** 





## Summary balance sheets

\$ thousands	2021	2022	2023
Cash	\$ 16,121	\$ 14,174	\$ 4,790
Accounts receivable, net	1,435	2,294	2,346
Other Current Assets	911	1,219	2,766
Total Current Assets	18,467	17,687	9,902
Non-current Assets	72	1,029	790
Total Assets	\$ 18,539	\$18,716	\$ 10,692
Accounts Payable	\$ 1,414	\$ 2,759	\$ 2,683
Accrued Expenses	2,603	2,631	4,300
Other Current Liabilities	769	984	5,418
Total Current Liabilities	4,786	6,374	12,401
Non-current Liabilities	-	346	-
Total Liabilities	4,786	6,720	12,401
Stockholders' Equity	13,753	11,996	(1,709)
Total Liabilities and Stockholders' Equity	\$ 18,539	\$ 18,716	\$ 10,692





## Summary income statements

Net Loss per Share	\$ (0.54)	\$ (0.22)	\$ (1.48)
Net Loss attributable to common stockholders	\$ (5,247)	\$ (2,912)	\$ (20,854)
Dividend on Series A Preferred Stock	(1,259)	-	-
Net Loss	(3,988)	(2,912)	(20,854)
Income Tax (Provision) Benefit	98	(106)	(11)
Loss Before Income Taxes	(4,086)	(2,806)	(20,843)
Other Income (Expense)	93	(159)	483
Transaction Costs	-	-	(8,342)
Operating Income (Loss)	(4,179)	(2,647)	(12,984)
Operating Expenses	11,231	13,484	20,864
Gross Profit	7,052	10,837	7,880
Cost of Revenue	(8,187)	(14,531)	(10,176)
Research and Development Revenue	\$ 15,239	\$ 25,368	\$ 18,056
\$ thousands except per share data	2021	2022	2023





## Summary cash flow statements

\$ thousands	2021	2022	2023
Net Loss	\$ (3,988)	\$ (2,912)	\$ (20,854)
Stock-based Compensation	1,365	1,155	1,243
Depreciation	1,303	1,133	9
	'		
Amortization of Right-of-Use Assets	-	557	713
Issuance of Shares for Transaction Costs	-	-	4,350
Change in Fair Value of Warrant Liabilities	(298)	(57)	(335)
Changes in Assets	919	(751)	(445)
Changes in Liabilities	(917)	835	2,079
Net Cash Used in Operating Activities	(2,918)	(1,162)	(13,240)
Net Cash Used in Investing Activities	(7)	-	-
Proceeds from Issuance of Common Stock	14,618	-	3,351
Cash Received in Business Combination	-	-	660
Payments for Notes Payable	(701)	(785)	(483)
Stock Option Exercises	4	-	316
Net Cash Provided By (Used In) Financing Activities	13,921	(785)	3,844
Effect of Exchange Rate Changes on Cash	-	-	12
Net Increase (Decrease) in Cash	10,996	(1,947)	(9,384)
Beginning Cash Balance	5,125	16,121	14,174





## Non-GAAP reconciliation

Adjusted EBITDA	<b>\$ (2,813)</b>	\$ (1,481)	\$ (11,732)
Transaction Costs	-	-	8,342
Foreign Exchange Transaction (Gain) Loss	188	237	24
Change in Fair Value of Warrant Liability	(298)	(57)	(335)
Stock-based Compensation	1,365	1,155	1,243
EBITDA	(4,068)	(2,816)	(21,006)
Depreciation Expense	1	11	9
EBIT	(4,069)	(2,827)	(21,015)
Net Interest (Income) Expense	17	(21)	(172)
Income Tax Provision (Benefit)	(98)	106	11
Net Loss	\$ (3,988)	\$ (2,912)	\$ (20,854)
\$ thousands	2021	2022	2023

### **EXCEPTIONAL TEAM WITH PROVEN TRACK RECORD**





Peter M. Carlson
Chief Executive Officer
30+ yrs of Finance and
Operations experience in
Fortune 50 and healthcare
corporations, such as MiMedx,
Metlife, and Wachovia.



Vincent Capone
Chief Financial Officer
& General Counsel
25 yrs+ of tech company
Experience KPMG,
Morgan Lewis and Reed
Smith LLP

Mary Regan, PhD

Christine Marks



Chief Commercialization
Officer
20 yrs+ of medical device
marketing experience evidenced
by positions held with Avita
Medical and Allergan.

Jeremiah Sparks



VP of Software & Data Science

10 yrs+ of software and data science leadership experience at St. Jude and Abbot.

**Kevin Plant** 

Louis Percoco



VP of Clinical Affairs
30 yrs+ years of clinical
experience, with board positions
held on the American
Association of Wound Care
Specialists and NWHS.



Chief Scientist

12 yrs+ of clinical R&D of tissue optics. Served as the PI on multiple NSF, NIH, DoD grants and BARDA contracts.

Jeffrey Thatcher, PhD



General Manager – Manufacturing 30 yrs+ of experience in R&D and Production teams in Cardiology, Orthopedic, and Spine disciplines.



**VP of Marketing & Commercialization**20 yrs+ of marketing experience for wound care medical device companies, such as BSN Medical and Lohmann & Raucher.



**EVP of UK and EMEA**Podiatrist with 15 yrs+ of experience in wound care and foot health. Most recently former CEO of Royal College of Podiatry in UK.

Prof. Paul Chadwick



### **Board of Directors**



Financial Advisor to Novumgen Ltd., and held CFO positions at several medical companies.



Deepak Sadagopan

Serves as COO of Population Health at Providence, and CEO of Health Connect Partners, LLC.



Erich Spangenberg

Managing partner at Sauvegarder Investment Management with extensive background in investment banking.



Martin Mellish

Founding director of Aspen Advisory Services Ltd.



Peter M. Carlson

Prior to becoming CEO of Spectral AI, served as CFO since January 2024. Prior to Spectral AI, was CFO of MiMedx Group, Inc.



J. Michael DiMaio, MD

24+ years of experience in cardiothoracic surgery, and Chief of Staff at Baylor Scott & White supervising more than 650 physicians.



Cynthia

Cai

Founder and

### **ADVISORS**



## Strategic Advisory Board



### Toby Cosgrove, MD

- Former president and Chief Executive
   Officer of Cleveland Clinic and currently
   serves as an Executive Advisor for
   Cleveland Clinic
- Former president of the American Association of Thoracic Surgery



### John Botts

- Senior Advisor, Allen and Company, previously 22-year Citi international career, including running its London investment banking division/starting CVC
- Director of Cleveland Clinic London Foundation



## Expert clinical guidance



This technology has promise to be the leap forward we have needed to bring about systematic change in burn care from the frontline all the way to the experts.



DeepView will significantly transform how we treat DFUs through continuous monitoring and measurement ensuring an accelerated healing trajectory and prevent DFU reoccurrence.



JEFF CARTER, MD

**Chief Medical Consultant** 

Dr. Carter has been practicing burn/trauma medicine for over 12 years and currently serves as the Medical Director for the University Medical Center Burn Center in New Orleans, LA, and on faculty at Louisiana State University Health Sciences Center.



**PROF. PAUL CHADWICK** 

EVP of UK and EMEA Former CEO of the Royal College of Podiatry UK

Prof. Chadwick is a world-renowned clinical research scientist, wound care key opinion leader (KOL), and has an extensive publication record on diabetic wound management.



## **Intellectual property** formidable barrier to entry

## Active patent application families protecting our current and anticipated future business

- Burn/Wound classification on MSI and PPG
- Tissue classification on MSI and PPG
- Amputation site analysis on MSI, machine learning and healthcare matrix
- DFU healing potential prediction and wound assessment on MSI, machine learning and healthcare matrix
- High-precision, multi-aperture,
   MSI snapshot imaging

- Wound assessment on MSI, optical, biomarkers, and machine learning
- Burn/Histology assessment on MSI and machine learning
- High-precision single aperture snapshot imaging with multiplexed illumination
- Topological characterization and assessment of tissue including wounds, using MSI and machine learning



20

U.S. & International Patents issued and allowed



34

Pending U.S. & International patent applications

### **ACTIVE MANAGEMENT OF IP PORTFOLIO**

- Useful life on key patent protection on core concepts exceeds 14 years
- Proprietary physician review image library for Burn and DFU
- Engage leading experts to constantly evaluate
   IP strategy and execution

#### REFERENCE LIST

\*

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- 3. Pixel data per Spectral MD clinical studies.
- 4. Data from Spectral MD's IRB approved Proof of Concept Clinical Study
- 5. Clinicians are 50% accurate in assessing healing potential of DFUs <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7950518/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7950518/</a>
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- 10. The Effectiveness of Regionalized Burn Care: An Analysis of 6,873 Burn Admissions in North Carolina from 2000 to 2007. Regional Air Transport of Burn Patients: A Case for Telemedicine?

- 11. Warriner R, Snyder RJ, Cardinal MH et al (2011) Differentiating diabetic foot ulcers that are unlikely to heal by 12 weeks following achieving 50% percent area reduction at 4 weeks. Int Wound J 8(6):632–7. <a href="https://doi.org/10.1111/j.1742-481x.2011.00860.x">https://doi.org/10.1111/j.1742-481x.2011.00860.x</a>
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- 13. Carter NH, Leonard C, Rae L. Assessment of Outreach by a Regional Burn Center: Could Referral Criteria Revision Help with Utilization of Resources? JBCRi2018;39(2):245-51
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- 15. American Medical Association Common Procedural Terminology CPT®
- 16. Huson HB, Phelan HA, G'Sell DJ, Smith S, Carter JE. If Seeing Was Believing A Retrospective Analysis of Potential Reduced Treatment Delays with a Novel Burn Wound Assessment Device. JBCR 2021;(42)S117-18.
- 17. TAM and CAGR Global Burn Care Market Size & Share Report, 2021-2028
- 18. TAM and CAGR Fortune Business Insights: Diabetic Foot Ulcer Treatment Market Worth \$11.16 Billion at 6.8% CAGR; Rise in Clinical Trials to Augment Market

#### FORWARD LOOKING STATEMENTS



Except for the historical information contained herein, this document contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding (i) our strategy, plans, objectives and initiatives, including but not limited to our plans and projected timelines to begin commercialization and product sales, launch new products, complete clinical trials, add additional clinical indications, (ii) the ability to be listed on the Nasdaq Global Market, (iii) Spectral Al's managements' expectations, (iv) potential government contracts, (v) expected beneficial outcomes and synergies, (vi) potential financing opportunities, (vii) Spectral Al's regulatory pathway for and timing of FDA, CE and UKCA regulatory submissions and approvals, (viii) Spectral Al's U.S. government contracts and future awards, (ix) the total anticipated target markets for burn wound and diabetic foot ulcers, (x) possible competitors, (xi) potential future indications and applications for DeepView and areas of interest supported by BARDA, (xii) Spectral Al's future and pending U.S. patent applications and foreign and international patent applications, and (xiii) pro forma information and other estimated values. The foregoing list of risk factors is not exhaustive. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to our ability to obtain and maintain necessary regulatory approvals, general economic conditions, consumer demand for our products and services, challenges relating to entering into and growing new business lines, the competitive environment, and the risk factors listed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, the Registration Statement on Form S-1, as amended, filed with the SEC on January 5, 2024 and any other SEC filings including the sections entitled "Cautionary Note Regarding Forward-Looking Statements", "Cautionary Note Regarding Forward-Looking Statements and Risk Factor Summary", "Risk Factors", "Management's Discussions and Analysis of Financial Condition and Results of Operations" and "Business" and in the Financial Statements. The Company undertakes no obligation to update forward-looking statements except as required by applicable securities laws. Readers are cautioned that forward-looking statements are not quarantees of future performance and are cautioned not to place undue reliance on any forward-looking statements.

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