Spectral AI®
*Seeing the Unknown*

# **Predictive** Wound Healing

**AI + Multispectral Imaging =**

Faster, More Accurate Treatment Decisions in Healthcare

**Nasdaq: MDAI**

September 2026

# Revolutionizing Wound Care

- DeepView System enables healthcare providers to make more informed treatment choices.
- In a matter of seconds during the initial patient visit, DeepView **predicts if the wound will heal or not**, with remarkable accuracy.

# Delivering on Commitments

## 13-year track record

**2013-2026**

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

- Proof of concept
- Clinical validation
- Product validation
- UKCA Approval
- FDA De Novo

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

DeepView is a single platform supporting multiple indications.

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

## Where We Stand Today

# Cleared, Funded, and Entering Commercial Launch

### May 21, 2026

**FDA De Novo classification granted**

Authorized to commence commercial sales in the United States.

### $250M+

**Developed on non-dilutive capital**

Government funding since 2013 carried the platform to FDA clearance

### 30 systems

**First deployments are subsidized**

BARDA funding supports procurement for 30 US burn and trauma centers

### $150M

**Contracted revenue base**

Project BioShield contract with BARDA; $86.6M committed to date.[1]

### 3-year term

**Recurring revenue on every placement**

Device sale plus a multi-year SaaS contract

### Expansion Beyond US

**UK, Australia and Gulf Cooperation Countries**

Evaluation in 5 UK sites and 3 Australian sites

1. Contract values per the Company's Form 10-Q for the quarter ended June 30, 2026. Obligation of contract value not yet committed is at BARDA's election and is not assured.

## Our Diagnostic Advantage

# We See What Clinicians Cannot


> DeepView provides a high-quality image that supports conventional assessment rather than replacing it. Acquisition is fast, non-contact, and practical in the real-world burns setting and usability for surgeons, nurses, and patients appears to be a major strength.

**Dr. Christopher J. Lewis FRCS (Plast),**

**Royal Victoria Infirmary, Newcastle upon Tyne UK**

### The Problem

Burn wound depth and healing potential **are difficult to assess visually,** leading to delayed treatment, unnecessary excisions, and variable outcomes.

Current workflow relies on **subjective clinician judgment** and invasive diagnostics.

### The Solution: DeepView® System

Non-invasive, cart-based imaging platform combines **multispectral imaging + proprietary AI + ground truth data** to predict burn wound healing potential.

### The Result

Provides **same-day, objective assessment** of wound areas that are unlikely to heal within 21 days, supporting clinical judgment and driving **earlier and more accurate** treatment decisions.

## Our Technology

# At Initial Presentation - Image to Wound Prediction in Seconds

**DeepView Imaging** → **Data extraction** → **AI model building** → **Healing prediction**

Patented proprietary **multi-spectral imaging** data acquisition in milliseconds

Capturing injured **tissue spectral signature**

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

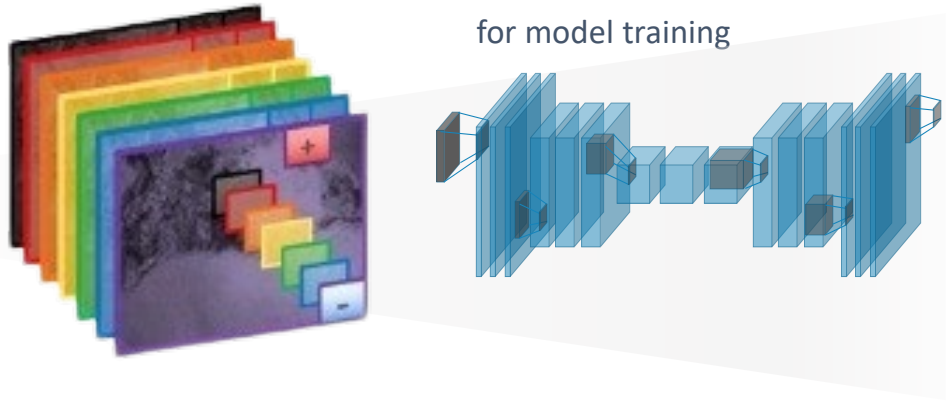
Combined with **patient health matrix data**

AI model trained and tested against a proprietary clinical database of more than **340+bn** clinically validated data points

AI algorithm integrates image and clinical data for model training

Accurate and immediate binary wound healing prediction in seconds

**Predicting wound healing in 21 days at initial presentation**

**Non-healing output**

Decision: surgery or advanced wound care products

**Healing output**

Decision: Routine care

## Competitive Advantage

# Measured Against Clinical Judgment

### Sensitivity

Detecting non-healing tissue

| | |
|---|---|
| **DeepView** | **88%** |
| **Burn physicians** | **42%** |

### Dice score

Accuracy of wound segmentation

| | |
|---|---|
| **DeepView** | **0.69** |
| **Burn physicians** | **0.39** |

**DeepView detected 88% of non-healing burns, while unaided clinical assessment missed 58% at initial presentation. DeepView more than doubles non-healing detection rates. Reproducibility of assessment of wound segmentation from Dice Score shows a consistency not found in clinician evaluation.**

### A category with no predicate

FDA granted De Novo classification because no legally marketed device was substantially equivalent. DeepView® is now itself the predicate.

### Confirmed in a multi-reader study

Clinicians reading the same cases were more accurate overall, and detected more non-healing tissue, when using DeepView than when reading unaided — with no loss of specificity.

Performance as authorized in the DeepView® System labeling. Sensitivity is a detection metric; Dice is a segmentation measure. Physician figures reflect clinical judgment annotation. Specificity data is available on request.

## Competitive Moat

# Data, Algorithm and Patents

**The paired image and outcome data, the AI algorithm and the patent portfolio — backed by thirteen years and over $250.0 million of non-dilutive government funding — provide a strong competitive moat.**

### Truthed burn image bank

Every image paired with a confirmed outcome — histopathological biopsy or 21-day healing, adjudicated by an expert panel of burn surgeons.

**340+bn**
pixels of burn wound image data

### Patents and trade secrets across 9 patent classes

Protection spanning multispectral acquisition, feature extraction and the AI architecture, built over more than a decade of development.

**13 years**
of protected development

### A broad patent and trademark portfolio

13 issued and allowed U.S. patents with 5 applications pending; 21 issued and allowed international patents with 23 foreign and international applications pending.

**34 / 47**
patents and trademarks issued

Pixel count per the Company's De Novo announcement. Ground truth established by histopathological biopsy or 21-day healing assessment. Patent and trademark counts per the Company's Form 10-K filed March 21, 2025; totals comprise 34 patents and 28 patent applications, 47 trademarks and 11 trademark applications.

# Diagnostic Accuracy Gets Made Where the Expertise Is Missing

**~5,000**
U.S. emergency departments with no burn-specialized training

**132**
U.S. burn centers, staffed by roughly 250 burn surgeons[1]

**21 days**
Time required to confirm by observation which burns heal

## *Both directions of error are costly*

### Under-triage

A burn that will not heal on its own is managed conservatively. Surgery is delayed, length of stay extends, patient outcome is worse, hospital costs expanded.

### Over-triage

A burn that would have healed is sent to surgery. The patient undergoes an avoidable operation, length of stay extends, patient outcome is worse, hospital costs expanded.

1. Burn center count per the American Burn Association registry.

## Systemwide Benefits

# 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**

## Regulatory Update

# De Novo Classification Granted: May 21, 2026

**FDA granted De Novo classification as novel, new technology with no substantial equivalent**

### Eligibility

Reserved for devices that are first of their kind, with no suitable predicate on the market.

### Regulatory classification

Reclassifies the device from Class III to a lower class, with special controls.

### Initial Procurement

An initial 30 DeepView systems are subsidized under the BARDA award.

### Commercial Expansion

Initial U.S. Market and expansion to U.K., Australia and Gulf Coast Cooperative countries.

## What the authorization establishes

**First** De Novo authorization for burn wound healing prediction

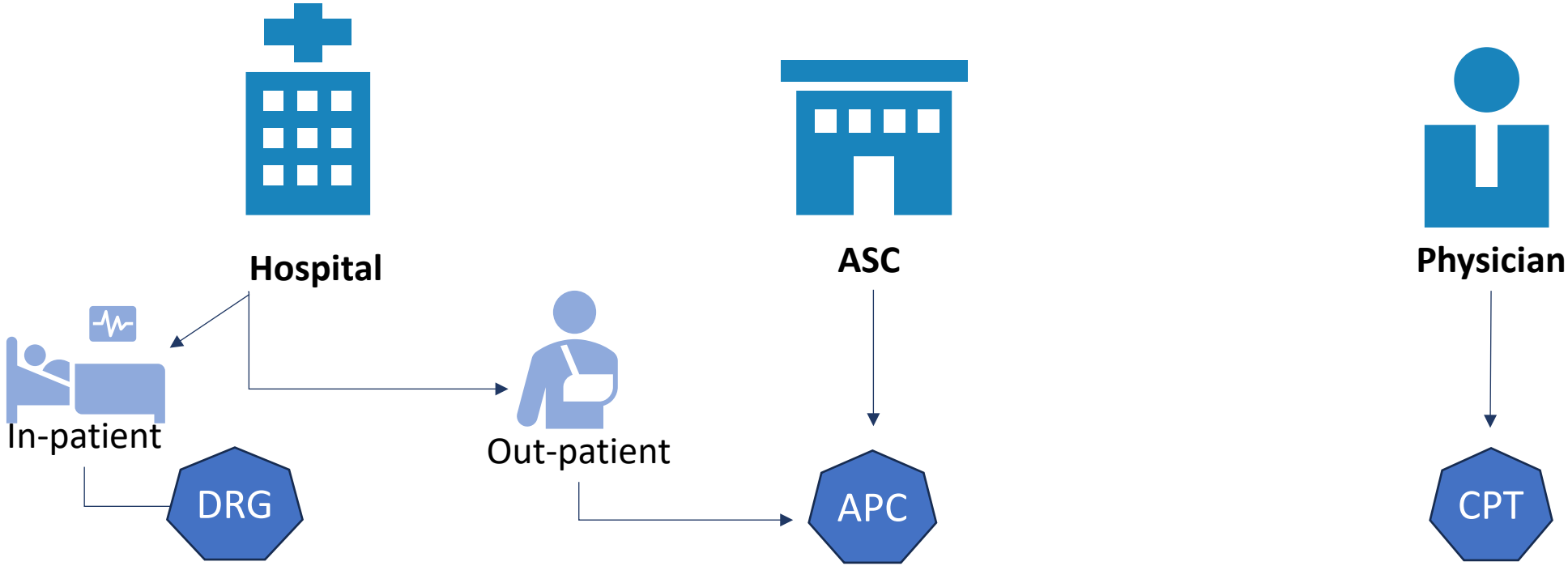
**Only** AI system cleared to predict burn healing on day one

**Basis** A classification other devices must now file against

De Novo classification granted May 21, 2026. BARDA system count per the Company's contract; pipeline targets are estimates and do not represent contracted placements.

## Reimbursement Strategy

# Optimizing Coding, Coverage & Payment




### Site of Service: Inpatient

- ✓**Healthy DRG payments exist for severe burn patients (up to ~$205k)**
- ✓Evaluating opportunities to further increase hospital payment to reflect value of DeepView®

### Site of Service: Outpatient/ASCs

- ✓CMS has proposed assigning software as a medical service (SaMS) to New Tech APCs
- ✓DeepView® may be considered SaMS allowing for separate additional payment
- ✓**Spectral has submitted request to CMS to recognize DeepView® as a SaMS and to assign it to NT-APC 1523 which has a payment rate of $2,750.**

### CPT Code: Physician Services

- ✓**Category III Code Already Attained**
- ✓**CMS proposed rule would enable local MACs the ability to price CPT 0972T**

## Commercial Model

# Two Revenue Lines and a Staged Adoption Path

**Device placement**

### Revenue on delivery

Capital purchase, lease, or outcomes-linked.

**Software and services**

### Recurring annual revenue

Three-year minimum. Compounds with every placement.

## Service and support[1]

**Annual service and support**

Preventive maintenance, helpdesk and warranty, on-site visits, a dedicated account manager and staff training.

### What drives revenue timing

| | | | |
|---|---|---|---|
| **Existing clinical site** | Fastest | **New install, no committee** | Capital review, then procurement |
| **Committee plus AI/IT review** | Slowest — 6 to 12 months | **Clinical exception** | Fast |

1. Service scope shown is illustrative. Contract structure, term and pricing are subject to negotiation and no pricing has been finalized.

## Path to Profitability

# How the Addressable Base Expands

### The addressable base widens on one platform

**Available now**

**~130**

**ABA-verified burn centers**

BARDA subsidizes the first 30 device placements

**Same indication, wider footprint**

**236**

**U.S. facilities treating burns**

Trauma centers and non-verified centers that still see burn volume

**Where patients actually present**

**~5,000**

**U.S. emergency departments**

No burn-specialized training; requires site-of-service expansion

### And margin improves as it grows

**Mix**

Product revenue replaces cost-reimbursed development revenue as the contract scope narrows.

**Recurrence**

Annual contracts persist for as long as a unit is installed and accumulate with every placement.

**Leverage**

The commercial and support organization scales far more slowly than the installed base it serves.

Burn center count per the American Burn Association; facilities treating burns and emergency department counts are estimates derived from registry and claims data. Indications listed are under evaluation and have not been selected; expansion beyond the cleared burn indication requires additional clinical, regulatory and commercial work and is not assured. Illustrative of the operating model; contains no projection of future revenue, expenses, results of operations or the timing of profitability.

## Our Platform

# One Imaging Platform, **Multiple Indications**


### INDICATIONS

**Burn Wound**

*Global market $3.7B*[11]

Anticipate selling

2026 | 2026

**Potential Indications**

Amputation

Critical Limb Ischemia

Diabetic Foot Ulcers

Plastic Surgery

**DeepView SnapShot® M | Handheld**

Military and Commercial

Total grant awarded $7.1M for miniaturization of technology

Miniaturized

Mobile

Home Healthcare

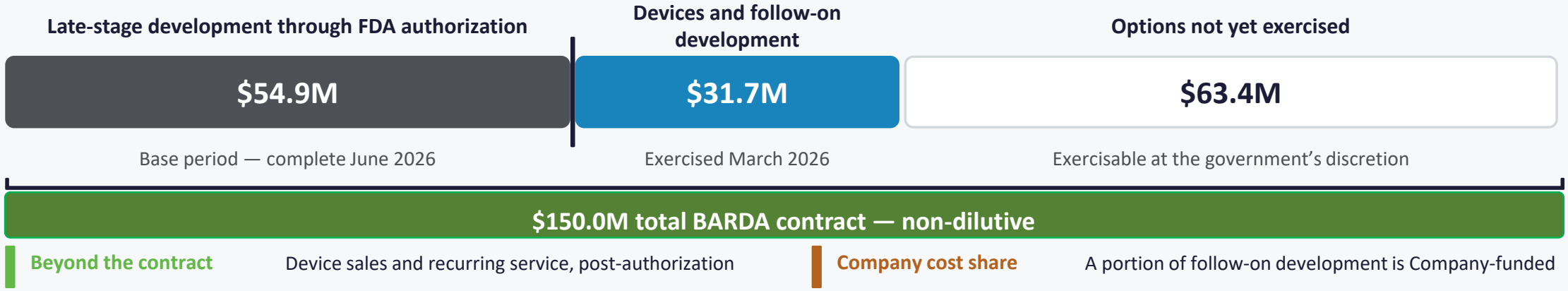
## Financial Position

# Balance Sheet and Results of Operations

| Balance sheet | June 30, 2026 |
|---|---|
| **Cash** | **$14.0M** |
| Total assets | $19.4M |
| Notes payable | $14.9M |
| Total liabilities | $31.5M |
| Stockholders' deficit | $(12.1)M |

| Results of operations | FY2024 | FY2025 | H1 2026 |
|---|---|---|---|
| Revenue | $29.6M | $19.7M | $7.5M |
| Gross profit | $13.3M | $8.9M | $3.1M |
| Operating expenses | $19.9M | $17.5M | $9.4M |
| **Operating loss** | **$(6.6)M** | **$(8.6)M** | **$(6.3)M** |

**Revenue tracked the development program that delivered FDA authorization — which is complete**




Balance sheet at June 30, 2026; results of operations for the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, per the Company's Forms 10-K and 10-Q. Phase bar drawn to scale against the $150.0M PBS BARDA contract. Options are exercisable at the government's discretion and are not assured.

## Capital Deployment

# Funding the Commercial Ramp Beyond BARDA

**Proceeds fund the commercial ramp and the expansion of the cleared indication — the two things that convert FDA authorization into recurring revenue.**

### 1 Commercialization ramp

Building the sales team and device inventory needed to convert FDA clearance into placements.

### 2 International device rollout

Extending placements beyond the United States, supported by the UKCA marking obtained in February 2024.

### 3 Label expansion

Broadening the range of burn diagnostics to hands, head and feet in the US and UK markets.

### 4 Additional indication research

Evaluating and selecting the next clinical indication for the platform, and the work required to support it.

Allocation is indicative and subject to change. Statements regarding the use of proceeds are forward-looking, are not projections of results, and are subject to the risks described in the Company's filings.

## Progress and Catalysts

# What We Have Delivered and What Comes Next

## Delivered

| | |
|---|---|
| **February 2024** | UKCA marking obtained |
| **2025** | Pivotal enrollment complete across 16 sites |
| **March 2026** | BARDA accelerated $31.7M of contract funding |
| **May 2026** | FDA De Novo classification granted |
| **June 2026** | Handheld prototype delivered to MTEC |
| **July 2026** | Chief Commercial Officer appointed |

## Ahead[1]

| | |
|---|---|
| **By year end 2026** | First commercial sales targeted |
| **Late 2026** | MTEC Phase 3 selection expected |
| **November 2026** | CMS final rule on Category III code 0972T |
| **Through June 2027** | Planned deployment of up to 30 systems with BARDA subsidy |
| **June 2027** | Label Expansion for heads, hands & feet, UKCA Expanded approval, Initial Overseas sales |
| **2027-2028** | Expanded US and Overseas sales |

1. Reflects milestones previously disclosed publicly. Forward-looking statements are not guarantees of future performance and timing may change.

## Leadership

# Built for Commercial Execution

### Vincent Capone
**Chief Executive Officer**

Joined March 2022, prior CFO and General Counsel. Former President of a technology/life sciences private equity fund, partner at Reed Smith.

### David McGuire
**Chief Financial Officer**

Joined May 2026. Formerly Chief Accounting Officer of Solo Brands and Deputy CFO of EZCORP. 14 years at EY, CPA.

### Darcy Bajko
**Chief Commercial Officer**

Joined July 2026 from MediView XR, where she launched three FDA-cleared imaging platforms. Previously Smith+Nephew and Integra LifeSciences.

### Stan Micek
**Chief Operating Officer**

SVP for Business Development and Strategy at MiMedx, after leadership roles at Ohio State and Abbott Laboratories.

### Allison Kumar
**Head of Global Regulatory & Clinical Affairs**

A decade at FDA CDRH as lead reviewer and senior program manager for medical countermeasures. Inter-agency work across FDA, CDC, BARDA and DoD.

## Board of Directors

# Clinical, Financial and Commercial Oversight

### Dr. J. Michael DiMaio
**Chairman**

Dr. J. Michael DiMaio, founder and large shareholder with over 30 years of experience in cardiothoracic surgery and specializes in heart valve replacement and lung transplantation.

### Richard Cotton
**Director**

Richard Cotton has a wealth of experience in senior financial roles in life sciences and other sectors, including broadcast and photographic, automotive, filtration and metals.

### Martin Mellish
**Director**

Founding director of Aspen Advisory Services since 1994, a London-based private office investing across North America, Europe and Asia.

### Deepak Sadagopan
**Director**

Deepak Sadagopan serves as Business Lead at Risant Health, where he is accountable for expanding adoption of the value-based platform.

### Marion Snyder
**Director**

Senior Director of Strategic Accounts at Shockwave Medical, leading corporate strategy for corporate and government accounts.

# Appendix

Supporting references, forward-looking statements and additional disclosures

# Appendix

# Reference List


1. Data from Spectral MD's IRB approved Proof of Concept Clinical Study

2. Pixel data per Spectral MD clinical studies.

3. Anyanwu JA, Cindass R. Burn Debridement, Grafting, and Reconstruction. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK551717/

4. 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

5. Definitive Healthcare 2019 Private Pay and CMS pay of inpatient versus outpatient DRG codes

6. Definitive Healthcare 2019 Cost and Claims Data from Medicare and Private Payer Estimates

7. American Burn Association, National Burn Repository and burn incidence statistics.

8. DeepView® System performance data as authorized in FDA labeling, De Novo classification granted May 21, 2026.

9. Centers for Medicare & Medicaid Services, CY2027 Hospital Outpatient Prospective Payment System proposed rule (CMS-1850-P), July 7, 2026.

10. American Medical Association Current Procedural Terminology (CPT®)

11. Grand View Research, Global Burn Care Market Size & Share Report, 2021–2028. Figure reflects the global burn care market, not the Company's addressable market.

# Forward Looking Statements

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