

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 14, 2026

SPECTRAL AI, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-40058

(Commission File Number)

85-3987148

(I.R.S. Employer
Identification No.)

2515 McKinney Avenue, Suite 1000
Dallas, Texas

(Address of principal executive offices)

75201

(Zip Code)

(972) 499-4934

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencements communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	MDAI	The Nasdaq Stock Market LLC
Redeemable Warrants, each whole warrant exercisable for one share of Common Stock, at an exercise price of \$2.75 per share	MDAIW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On September 14, 2026, the Company posted an investor presentation to its website at www.spectral-ai.com (the “**Investor Presentation**”). A copy of the Investor Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company will use the Investor Presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others.

The information in this Item 7.01 to this Current Report on Form 8-K, and in Exhibit 99.1 furnished herewith, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Spectral AI Investor Presentation, dated September 14, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Current Report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 15, 2026

SPECTRAL AI, INC.

By: /s/ Vincent S. Capone

Name: Vincent S. Capone

Title: Chief Executive Officer



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.

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.

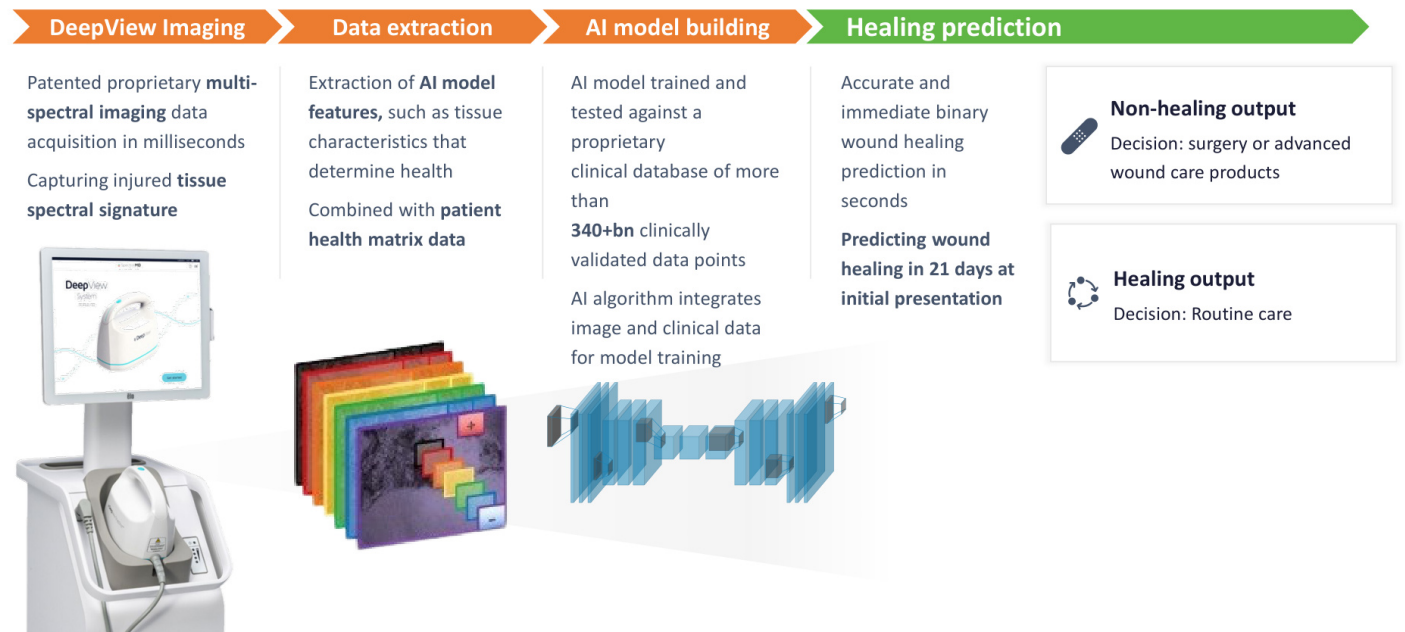
The Solution: DeepView® System

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.

At Initial Presentation - Image to Wound Prediction in Seconds



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
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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.
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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 surgeons¹

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.

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

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.

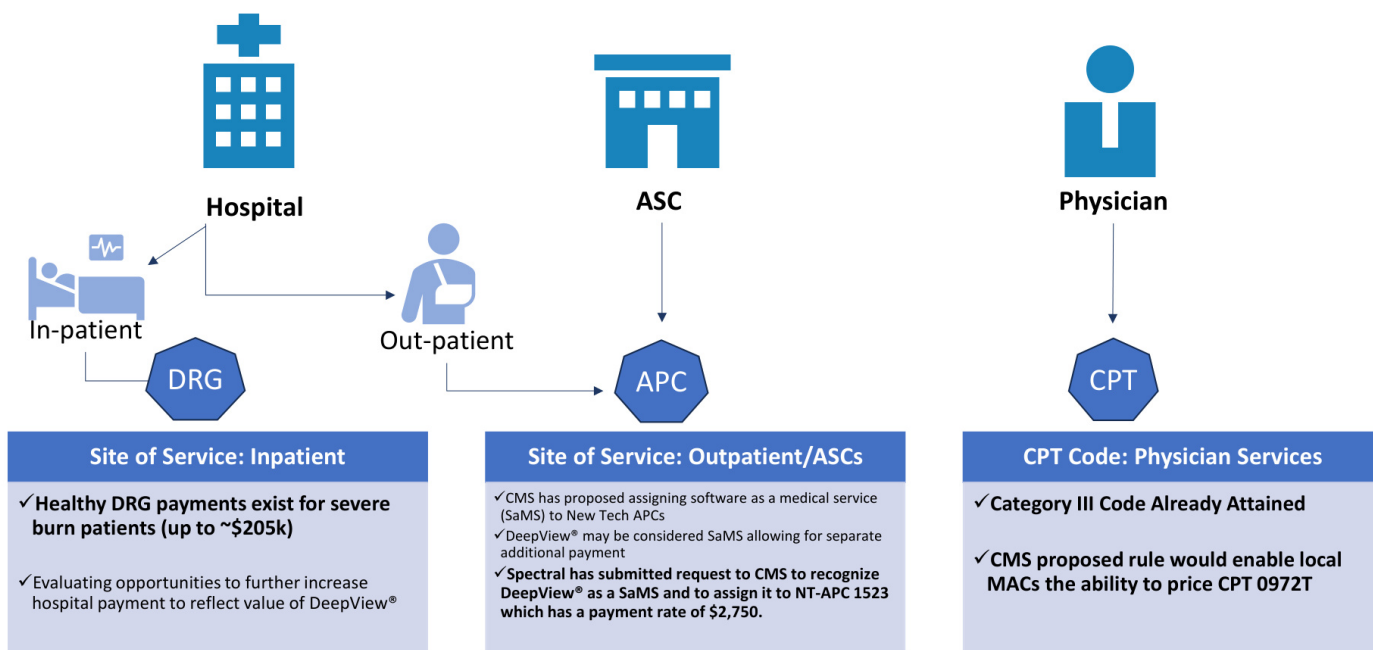
What the authorization establishes

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.



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 support¹

Annual service and support

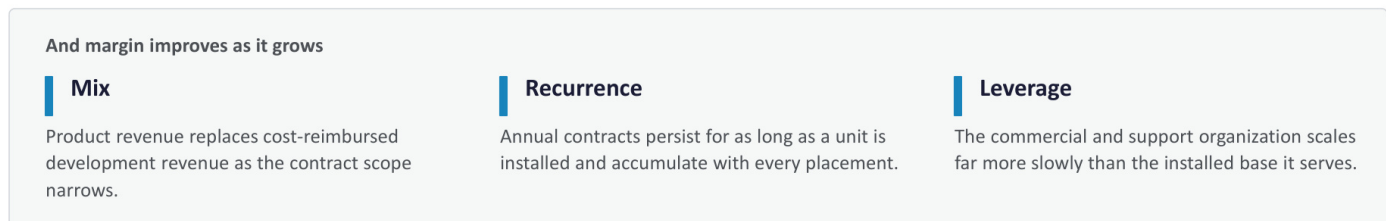
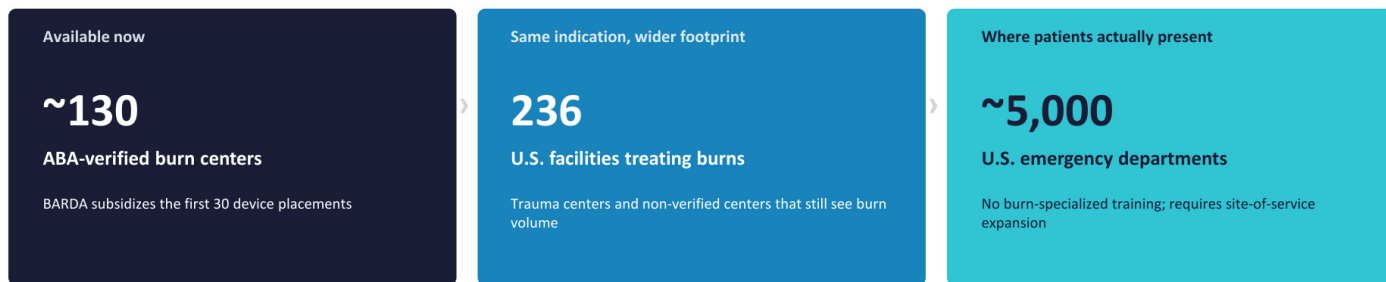
Preventive maintenance, helpdesk and warranty, on-site visits, a dedicated account manager and staff training.

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.

How the Addressable Base Expands

The addressable base widens on one platform



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



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INDICATIONS



Burn Wound

Global market \$3.7B¹¹

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

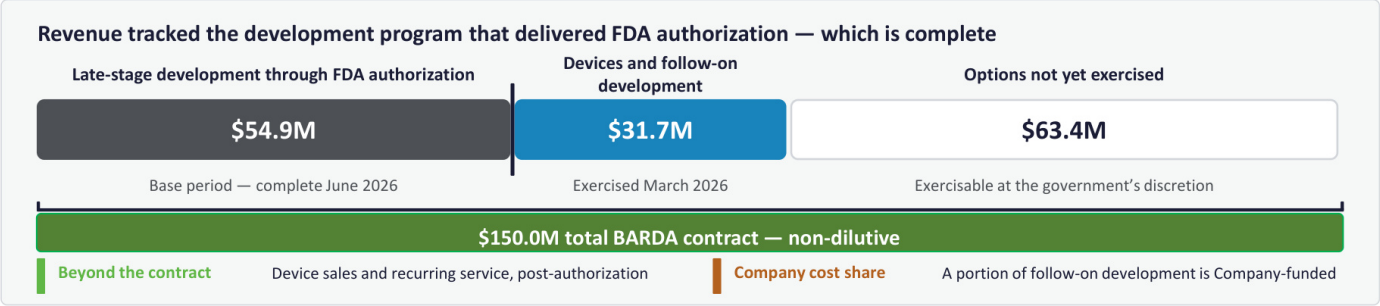
Miniaturized

Mobile

Home Healthcare



Balance sheet	June 30, 2026	Results of operations	FY2024	FY2025	H1 2026
Cash	\$14.0M	Revenue	\$29.6M	\$19.7M	\$7.5M
Total assets	\$19.4M	Gross profit	\$13.3M	\$8.9M	\$3.1M
Notes payable	\$14.9M	Operating expenses	\$19.9M	\$17.5M	\$9.4M
Total liabilities	\$31.5M	Operating loss	\$(6.6)M	\$(8.6)M	\$(6.3)M
Stockholders' deficit	\$(12.1)M				



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.

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.

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

Ahead¹

● 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.

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.

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

Certain statements made in this presentation are “forward looking statements” within the meaning of the “safe harbor” provisions of the United States Private Securities Litigation Reform Act of 1995, including statements regarding the Company’s strategy, plans, objectives, initiatives and financial outlook. When used in this press release, the words “estimates,” “projected,” “expects,” “anticipates,” “forecasts,” “plans,” “intends,” “believes,” “seeks,” “may,” “will,” “should,” “future,” “propose” and variations of these words or similar expressions (or the negative versions of such words or expressions) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance, conditions or results, and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside Company’s control, that could cause actual results or outcomes to differ materially from those discussed in the forward-looking statements. As such, readers are cautioned not to place undue reliance on any forward-looking statements.

Investors should carefully consider the foregoing factors, and the other risks and uncertainties described in the “Risk Factors” sections of the Company’s filings with the US Securities and Exchange Commission, including the Company’s Registration Statement and the other documents filed by the Company. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

Legal

Disclaimers

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