INITIATION OF COVERAGE

Non-Independent Research
MiFID II Exempt
28th March 2024

Spectral AI (MDAI.NQ)*

Predictive AI to improve wound healing

** SP Angel acts as UK Broker to Spectral AI and this research note should be viewed as a Marketing Communication; One of the authoring analysts has an interest in Spectral AI*

Stock Data

Ticker	MDAI.NQ
Share Price:	$2.10
Target Price:	$10.60
Market Cap:	$34.5m

Source: Bloomberg (prior trading day's close)

Company Description

Revenue-generating company developing the DeepView® Wound Imaging Solution (DeepView®), a non-invasive imaging technology which uses AI to provide a quantitative assessment of wound healing

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Key points

- **DeepView AI-Burn pivotal trial underway** with US regulatory approval expected in FY25E and commercial sales set to begin in FY26E. Accuracy is currently at 92%, substantially higher than conventional wound assessments which are highly subjective and reliant on clinician experience (typically between 50% for a generalist and 75% for a burn specialist).
- **UKCA mark approval received for DeepView AI-Burn:** Marks first regulatory approval for DeepView AI-Burn with modest initial revenues expected in the second half of FY24E.
- **$150m BARDA Project BioShield (PBS) contract award:** BARDA continues to fund DeepView Burn development, regulatory and commercial activities. BARDA PBS is the largest award received to date by the Company, bringing the total potential support from BARDA to c.$251m, with $101m of this already deployed under previous BARDA contracts.
- **DeepView AI-DFU pivotal trial nearing readout** with UK and US regulatory submissions planned for later this year and sales expected in FY25E and FY26E, respectively. Current accuracy of DeepView is 86% compared to c.50% for current techniques.
- We initiate coverage with a target price of **$10.60** and a **Buy** recommendation.

Spectral AI (MDAI, the Group, the Company) is developing the DeepView® Wound Imaging Solution (DeepView®), a non-invasive imaging technology which uses AI to provide a quantitative assessment of wound healing. Clinicians can use this data to support earlier treatment decisions, leading to improved patient outcomes and lower overall treatment costs. MDAI is developing DeepView® to provide healing assessments for burn wounds and diabetic foot ulcers (DFU). These indications have large addressable markets which are underserved by current technologies. The Company is currently conducting pivotal clinical trial programmes in each indication to support regulatory clearances in the UK, US, and Europe. The recent approval of DeepView Burn in the UK supports commercial revenue generation this year and bodes well for approval in other regions.

Development has been supported by significant non-dilutive grant contracts from the Biomedical Advanced Research and Development Authority (BARDA), a US federal agency which supports the development of products considered priorities for national health security. We expect the DeepView AI-Burn programme to be fully funded by BARDA. In September 2023, MDAI was awarded a new BARDA contract (PBS BARDA) valued at up to $150m to support further clinical validation work, FDA clearance, and commercial activities. This is the largest contract ever awarded to MDAI and brings the total potential support from BARDA to c.$251m, with $101m of this already deployed under previous BARDA contracts.

We believe the current market valuation of MDAI does not reflect the value of the BARDA PBS contract let alone the commercial potential of DeepView, a significantly de-risked, commercial stage product which has the potential to provide substantial clinical benefits over conventional techniques. We initiate coverage with a target price of $10.60 and a Buy recommendation.

Year-end Dec ($m)	2023A	2024E	2025E	2026E	2027E	2028E
Revenue	18.1	28.4	33.1	47.5	66.6	82.7
EBITDA profit / (loss)	(12.3)	(8.1)	(4.5)	(0.6)	8.2	11.0
Pre-tax profit / (loss)	(20.8)	(8.8)	(5.3)	(1.4)	7.4	10.1
Net Cash/(Debt)	4.9	16.1	12.7	13.1	20.3	29.4
EPS ($)	(1.28)	(0.38)	(0.23)	(0.06)	0.24	0.33
EPS - diluted ($)	(1.28)	(0.31)	(0.18)	(0.05)	0.19	0.27

Source: Spectral AI financial reports and SP Angel estimates

Investment Thesis

DeepView provides quantitative method to aid diagnosis on Day 1

DeepView® can provide an assessment of whether a wound is likely to heal with conventional treatments, the point when a patient first presents in a clinic or hospital. This could improve clinical benefit, such as wound healing rates, by enabling an accurate and timely diagnosis for patient triage and treatment decisions. Wound treatment decisions are typically driven by the subjective assessments of a clinician with a period of watchful waiting usually required prior to the progression to advanced treatments or surgery. This can unnecessarily increase hospital stay for patients with wounds which could heal without further treatment or delay the initiation of advanced treatments in difficult to heal wounds.

Targeting large addressable markets in underserved indications

Spectral AI is initially focused on commercialising DeepView® for the assessment of burn wounds and Diabetic Foot Ulcers (DFU). These are two indications with large addressable markets which are currently underserved by current techniques. There are estimated c.486,000 burn injuries per year which require medical treatments[1]. The cost of diabetes in the US is c.$237b, with c.30% of these costs associated with care for diabetic foot disease[2]. The cost of treating a DFU patients in the US is between $8k to $17k, dependant on the level of infection and severity of the wound.

US Government commitments continue to support development

To date, DeepView® has received significant commitment and technical support from BARDA. This non-dilutive financing has supported the development of DeepView® to assess burn wounds. We believe there is scope for additional grant funding from the Government to support development and rollout of the system. Alongside BARDA, the Company has an agreement with the Defence Health Agency of the United States Department of Defence to develop a fully portable, handheld version of DeepView.

$150m Project BioShield contract awarded

In September 2023, DeepView Burn was selected for Project BioShield, a US federal programme to support national preparedness in the case of a mass casualty event. This is a significant validation of the ability of DeepView® Burn to support patient triage, diagnosis and resource management, in the event of a surge in patients after a disaster. Such a contract is transformative for Spectral AI and could generate over $150m in revenues by FY30E. Given the total amount of funding that BARDA has awarded to date, and the history of the Company of striking federal contracts, we expect that there is scope for the procurement of additional system units or grant funding as part of an additional contracts. However, we have not included these in our current estimates.

[1] https://www.cdc.gov/nchs/ahcd/web_tables.htm#2011
[2] Armstrong DG et al. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. J Foot Ankle Res. 2020;13(1):16.

Significant library of clinical-grade data

Spectral AI has built a large library of wound images and pathology data. This has been used to develop predictive algorithms for DFU and Burn wound assessment. The AI model has been trained and tested against a proprietary database of medical image and tissue data which translates to over 263bn pixels worth of DFU and Burn data. Ongoing clinical studies for both the DFU and Burn applications will further add to this database. Spectral AI owns and controls the entirety of its data pipeline, as well as the imaging technology. Not only does this data support the development of the algorithm, but a competitor would have to build its own database to ensure comparable accuracy.

Recurring revenue model provides incremental revenues whilst providing economic benefit to customers

Spectral AI is looking to offer the DeepView® system to Burn and DFU customers as a capital equipment purchase with an annual base subscription. At the initial commercial rollout, the Company aims to leverage existing reimbursement codes with a view to seek higher reimbursement codes. If Spectral AI can demonstrate significant clinical benefit over conventional techniques, the Group will be well-placed to negotiate an additional or higher reimbursement rate for the use of the AI element of DeepView®, which should further drive adoption. A high reimbursement rate, driven by the improved diagnostic information offered by DeepView®, would present an attractive case to customers to buy and use the system.

News flow

We believe there is considerable news flow over the coming years as the Company seeks regulatory approvals in the US and Europe and begins commercial sales.

Table 1: Anticipated news flow

Year	DFU Events	Burn Events
2024E	DFU – US: Validation study readout DFU – UK: UKCA Mark approval DFU – US: FDA regulatory submission	Burn – US: Validation study readout Burn – UK: First commercial sales in UK Burn – EU: CE mark submission
2025E	DFU – UK Commercial sales DFU – US FDA regulatory approval DFU – EU: CE Mark submission DFU – EU: CE Mark approval	Burn – US FDA regulatory submission Burn – US FDA regulatory approval Burn – EU: CE mark clearance
2026E	DFU – US commercial sales DFU – EU commercial sales	Burn – US: First commercial sales Burn – EU: First commercial sales

Source: Company announcements; SP Angel estimates

Valuation – $10.60

We believe MDAI is grossly undervalued given the low regulatory risk, significant BARDA commitments awarded to date and substantial improvements DeepView can offer compared to conventional techniques.

Our DCF indicates a fair value of $305m implying a $10.60 target price. Our forecasts incorporate the rollout of DeepView for DFU and Burn indications. Terminal value is calculated using a 4% long-term free cash flow growth rate. We applied a conservative 15% discount rate to account for regulatory and commercial risk across our forecast.

To support our valuation, we compiled a peer group of companies developing diagnostics or offering services and/or products with a focus on wound care or digital health. We compared current enterprise value to revenues estimates for FY26E, the first year of US commercial sales. Spectral AI's FY26E EV/Sales (0.5x) remains well below the median (2.7x) and corroborates with the target price derived from our DCF ($10.60).

Table 2: Discounted cash flow ($)

DCF (Dec year end)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Operating CF	**(6.8)**	**(3.3)**	**0.5**	**9.2**	**11.8**	**14.1**	**31.3**	**53.6**	**82.6**	**107.1**
Capex	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Tax (net)	-	-	-	(1.8)	(2.5)	(3.2)	(7.6)	(13.2)	(20.6)	(26.8)
FCF	**(6.9)**	**(3.4)**	**0.4**	**7.2**	**9.1**	**10.7**	**23.6**	**40.2**	**61.8**	**80.0**
Discounted FCF	**(6.9)**	**(3.0)**	**0.3**	**4.7**	**5.2**	**5.3**	**10.2**	**15.1**	**20.2**	**22.7**
NPV	73.9									
TV	215.0									
EV	288.9									
Net Cash/(Debt)	16.1									
Fair Value ($m)	**305.0**									
Fully diluted shares (m)	28.7									
Target Price ($)	**10.6**									
Current share price ($)	2.4									
Discount rate	*15%*									
Terminal growth rate	*4%*									

Source: Spectral AI financial reports and SP Angel estimates

Table 3: Peer Group analysis ($)

					Best Sales						EV / Sales					
Company name	Ticker	MCAP	EV	Price	FY24	FY25	FY26	FY27	FY28	FY29	FY24	FY25	FY26	FY27	FY28	FY29
Average	**Average**	**783.1**	**747.6**	**32.4**	**190.3**	**230.9**	**266.7**	**272.8**	**305.7**	**351.6**	**5.1**	**4.4**	**3.8**	**3.3**	**3.0**	**2.7**
Median	**Median**	**438.7**	**364.1**	**8.1**	**75.2**	**123.7**	**136.9**	**109.5**	**125.6**	**138.5**	**5.1**	**2.8**	**2.7**	**2.5**	**2.2**	**1.9**
Spectral AI Inc	**MDAI US**	**34.5**	**29.6**	**2.2**	**28.4**	**33.1**	**47.5**	**66.6**	**82.7**	**95.9**	**1.0**	**0.9**	**0.6**	**0.4**	**0.4**	**0.3**
Mimedx Group	MDXG US	1,108.1	1,076.6	8.0	357.4	355.8	402.2	451.5	496.0	552.0	3.0	3.0	2.7	2.4	2.2	2.0
Mediwound	MDWD US	147.5	143.7	13.1	24.1	23.8	33.7	53.5	85.7	125.0	6.0	6.0	4.3	2.7	1.7	1.1
Adv. Medical Sol.	AMS LN	519.2	454.0	2.6	184.4	172.6	185.0	200.7	211.5	248.0	2.5	2.6	2.5	2.3	2.1	1.8
Vericel Corp	VCEL US	2,469.6	2,448.1	49.5	239.3	240.8	295.2	385.7	471.3	575.3	10.2	10.2	8.3	6.3	5.2	4.3
Organogenesis	ORGO US	348.4	343.5	3.4	454.7	456.0	488.0	522.0	-	-	0.8	0.8	0.7	0.7	x	x
Polynovo Ltd	PNV AU	964.5	943.8	1.3	67.1	65.3	85.8	107.7	118.4	142.1	14.1	14.5	11.0	8.8	8.0	6.6
Iradimed Corp	IRMD US	544.2	496.5	44.9	72.0	72.0	80.1	-	80.1	80.1	6.9	6.9	6.2	x	6.2	6.2
Butterfly Network	BFLY US	214.4	105.0	1.0	72.9	74.9	82.5	-	82.5	82.5	1.4	1.4	1.3	x	1.3	1.3
EKF Diagnostics	EKF LN	149.5	146.3	0.4	71.1	72.0	78.3	84.9	84.9	84.9	2.1	2.0	1.9	1.7	1.7	1.7
Caredx Inc	CDNA US	498.6	297.4	8.2	266.6	260.7	285.6	-	285.6	285.6	1.1	1.1	1.0	x	1.0	1.0
Irhythm Technologies	IRTC US	3,566.6	3,562.6	112.2	580.9	578.5	680.8	769.2	881.8	1,051.0	6.1	6.2	5.2	4.6	4.0	3.4
Renalytix AI	RENX LN	53.0	55.9	191.6	7.7	781.4	948.2	1,132.7	1,348.9	1,560.7	7.3	0.1	0.1	0.0	0.0	0.0
Neuropace	NPCE US	378.7	384.6	17.5	75.2	74.6	88.7	111.4	132.8	135.0	5.1	5.2	4.3	3.5	2.9	2.8
Better Therapeutics	BTTX US	0.7	8.4	0.2	x	3.8	-	-	-	-	x	2.2	x	x	x	x

Source: Bloomberg, Spectral AI financial reports and SP Angel estimates

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Company overview

Company history

Spectral AI is a specialist developer of diagnostic devices and predictive software for wound care. Founded in 2009, the Company is based in Dallas, Texas. Spectral AI is focused on the development and commercialisation of its DeepView® System. Driven by a lack of standardised tools for wound assessments, DeepView® assists clinicians with treatment decisions by providing a quantitative assessment of wound healing. Since founding, the Group has developed two generations of DeepView® which have achieved FDA clearance and is looking achieve regulatory approvals for a third-generation system.

DeepView® aims to provide immediate healing assessments for burn wounds and Diabetic Foot Ulcers (DFU). These are two indications with large addressable populations which are currently underserved by current techniques. The Company has demonstrated clinical proof of concept in these indications and is undergoing pivotal clinical trials for both indications. Upon successful regulatory clearance, the Group is looking to commercialise the platform in the US, UK and Europe. Spectral AI has recently received UK clearance for DeepView Burn and is building out its network of early-adopters and conducting extensive reimbursement preparations to drive successful launches.

Over $250m committed by US government to support development

Development of DeepView has been supported by contracts from the Biomedical Advanced Research and Development Authority (BARDA). BARDA is a US federal agency which supports the development of products considered priorities for national health security. To date, the company has received c.$101m in funding from BARDA with a new contract award in September 2023 (PBS BARDA) valued at up to $150m, bringing the total support to c.$251m if all future options are executed. The Group has received funding from other federal government agencies, including over $6m to fund the development of a portable version of DeepView which could be used in a military setting.

Listing on AIM and subsequent business combination onto Nasdaq

Spectral AI listed on the AIM market of the London Stock Exchanges in June 2021. Trading as Spectral MD, the Company raised $16m to support late-stage clinical trials and progress regulatory activities in the US, EU & UK. The Company subsequently moved to Nasdaq in September 2023 via a business combination with Rosecliff Acquisition Corp. I (RCLF), a Nasdaq-listed special purpose acquisition company (SPAC). Under the terms of the deal, Spectral MD and RCLF became a combined entity, with Spectral MD's existing shareholders rolling 100% of their equity into the combined company. Alongside the transaction, Spectral MD changed its name to Spectral AI and cancelled its AIM listing with all public trading of securities of the Company now taking place on Nasdaq.

Product Overview

DeepView® Wound Imaging Solution

DeepView® is a non-invasive medical imaging device for wound assessment. The system provides a predictive analysis of whether a wound is likely to heal when a patient first presents at a clinic or hospital. This system aims to improve clinical benefit by enabling a more accurate and timely diagnosis for patient triage and treatment decisions. Funded by BARDA, MDAI is developing DeepView® for the assessment of burn wounds but is also developing the system for the assessment of Diabetic Foot Ulcers (DFU), having identified an unmet need in this large and growing population.

Currently, wound assessments and subsequent treatment decisions are driven by a naked-eye-assessment by a clinician. This technique is highly subjective and reliant on clinician experience. This results in incorrect assessment of burn wound healing in up to 25% of cases. Furthermore, a period of watchful waiting is usually required prior to the progression to advanced treatments or surgery. This can unnecessarily increase hospital stay for patients with wounds which may heal without further treatment. Conversely, it may negatively impact wounds which may benefit from earlier advanced treatments.

Table 4: Comparison of DeepView® vs standard of care for Burn and DFU wound assessment

	Burn	DFU
Current Time to Decision	21 Days	30 Days
DeepView® Time to Decision	Day 1	Day 1
Current Clinical Accuracy	60%	50%
DeepView® Accuracy	92%	86%

Source: Spectral AI

Clinical and regulatory pathway

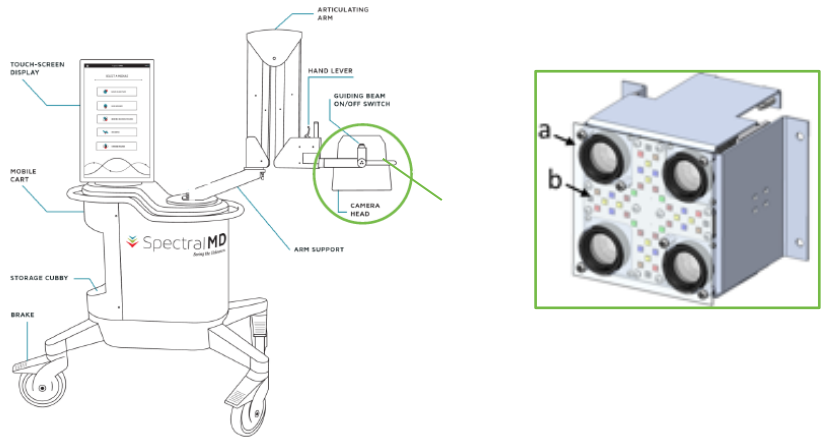
MDAI is looking to commercialise DeepView® Gen 3, which the FDA has assigned as a Class 1 medical device. Whilst DeepView® Gen 3 is yet to receive FDA clearance, we view regulatory clearance as low risk given the non-invasive nature of the device and the clearance of two previous generations. Furthermore, the system has received UKCA marking and clearance for DeepView SnapShot, the imaging platform that houses the predictive AI software as well as DeepView AI®-Burn, the Group's predictive software for burn wound healing. The Group has successfully demonstrated clinical proof-of-concept for DeepView® and is now progressing pivotal clinical trial programmes for both DFU and Burn applications. These studies aim to provide additional data to further improve the accuracy of the DeepView® predictive algorithm and support the US and European regulatory approval processes.

DeepView® product characterisation

Wound healing assessment in under a minute

The DeepView® Snapshot system consists of a camera head, a mobile cart and a display screen. Image capture and analysis using DeepView® is a straightforward process. An image is captured of the wound, with appropriate positioning of the camera module supported by the articulating arm. The system then uses AI-assisted image analysis to evaluate the presence of certain optical biomarkers which correspond to healing or non-healing tissue. The whole process takes place in under a minute.

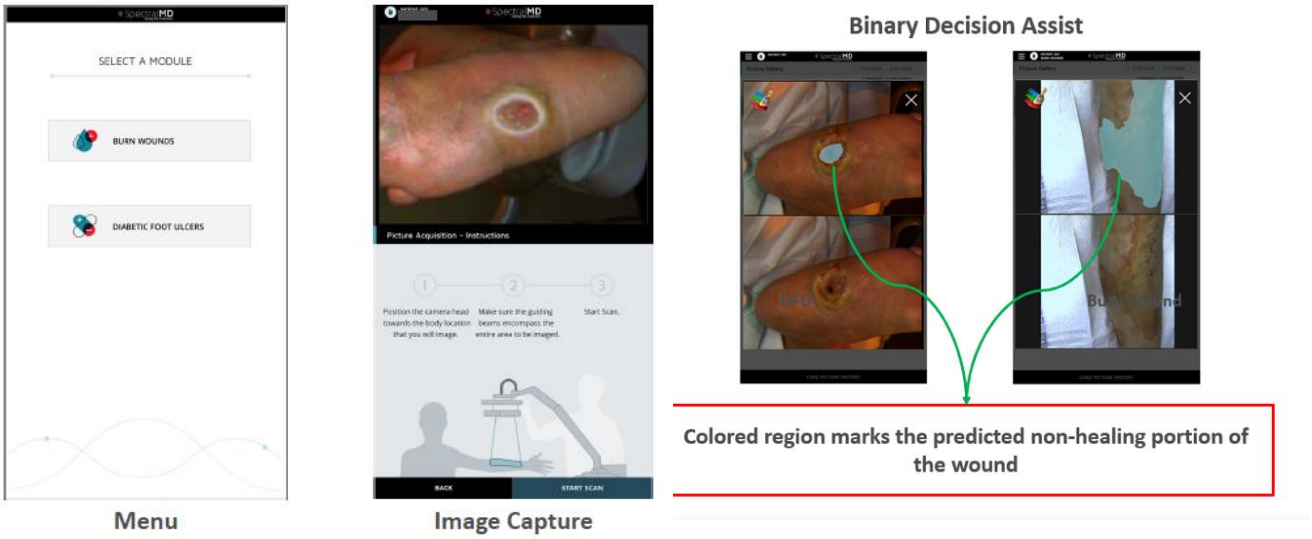
Figure 1: DeepView® product schematic



Source: Spectral AI

The system generates an image of the wound with a coloured overlay indicating regions which are deemed non-healing or healing. Clinicians can use this data to support treatment decisions. DeepView® could also help triage burn patients for surgery and help surgeons plan the required circumference of skin grafts to cover non-healing regions of a burn. In the case of DFUs, DeepView® could support the decision to initiate advanced wound care therapy on Day 1 as opposed to waiting 30 days.

Figure 2: DeepView® protocol and output



Source: Spectral AI

Ease of use should drive clinical adoption

DeepView® has been designed with clinician input and user feedback to incorporate the needs of healthcare professionals and patients. The device is simple to install and use which should drive the utility of the system.

Table 5: DeepView system designed to support clinical adoption

Reproducible	The developers have incorporated flexibility into the system to accommodate image capture variability, which is common between users, without affecting output.
User friendly	The camera module is attached to an articulated arm that can be easily manoeuvred to capture images in any area of the body. Correct use of the system is a simple, intuitive procedure which is guided by instructions via the touchscreen-based display.
Mobility	The device is mobile therefore can be easily moved between wards or consultation rooms. The system is powered through a standard mains electricity plug but can also run on a battery for several hours in the case of a power outage.
Strong safety profile	The procedure is non-invasive and requires no contact with the patient and does not use ionising radiation or radioactive tracers. DeepView Snapshot is classed by the US FDA as a Class 1 medical device
Instant, simple to interpret results	Users receive the output of the system in under a minute. Results are displayed via a clear report with coloured regions marking the predicted non-healing portion of the wound.

Compiled by SP Angel

Proprietary MSI system enables broad capture of information

A key element of the DeepView® system is the camera head. This incorporates the SnapShot MSI system, which is involved in image capture, whilst a proprietary broad-spectrum LED illumination system generates the wavelengths required for detection of the optical biomarkers. The SnapShot MSI system consists of four MSI cameras which collect eight specific wavelengths. Each wavelength was selected to support the assessment of certain physiological characteristics related to wound healing, such as haemoglobin concentration and oxygen saturation. These wavelengths of light are either absorbed into the skin or reflected back into the sensor to be measured. The use of the MSI system is an improvement over standard colour cameras as the MSI camera can capture information from both the visible and near-infrared spectrum. This enables additional information to be derived from wound images, such as the ability to differentiate between different tissue types.

Intellectual Property

Spectral AI believes its IP portfolio provides adequate protection from competition which would have to incur high costs to circumvent the patents. The Company's IP estate falls into nine key areas and the Company continues to extend its patent portfolio both in the US and in additional geographies. The Company has ten issued and allowed US patents with five patent applications pending. The Group has 10 issued and allowed international patent with 29 pending applications.

Formation of Spectral IP, Inc subsidiary

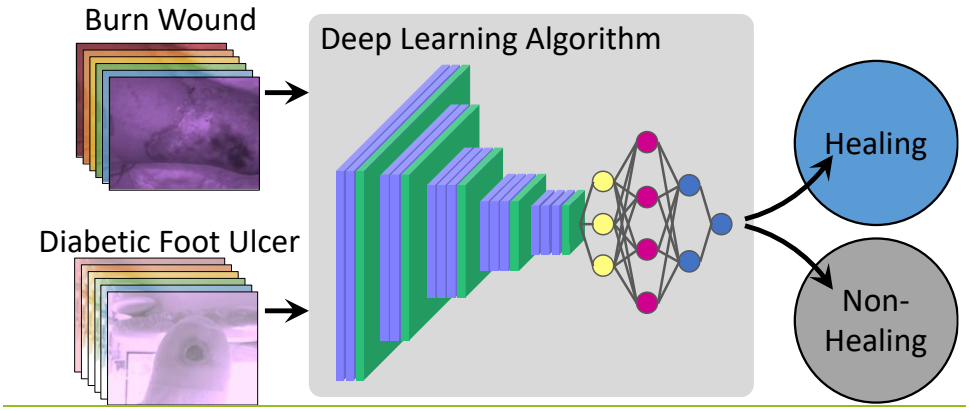
In March, MDAI announced the formation of a wholly owned subsidiary Spectral IP, Inc which will be focused on advancing IP relevant to the broader AI ecosystem, with a specific emphasis on healthcare. The formation of a new subsidiary comes after a comprehensive review of the Company's IP portfolio identified additional opportunities which could generate value by developing or acquiring IP applicable to the broader AI ecosystem. Spectral IP received a $1m investment structured as a note payable with a one-year maturity, an interest rate of 8%, and requiring earlier prepayment if Spectral IP is spun off to the Company's shareholders or sold.

DeepView® predictive algorithm overview

Optical biomarkers provide predictive wound healing assessment

Different tissues have distinctive spectral signatures, such as reflection and absorption in response to certain wavelengths of light. These spectral signatures can generate an optical biomarker specific to a tissue type and/or condition. Such biomarkers can then be further characterised to add a predictive function such as whether a wound will heal by standard of care treatments or require advanced therapies. This concept forms the basis of the DeepView® system which can detect and identify optical biomarkers within a wound image and form a predictive assessment of healing potential.

Figure 3: DeepView® algorithm schematic



Source: Spectral AI

AI is trained with validated clinical data owned by MDAI

A key component of the DeepView® system is the use of AI for image analysis. Predictive algorithms require training datasets to calibrate the algorithm to consistently generate the desired output, in this case the healing potential of the wound. Training the algorithm on a large database of biopsy data improves the predictive function of the AI when assessing a novel wound in a real-world setting. To optimise the predictive function of DeepView®, Spectral AI has amassed a significant medical database, consisting of c. 263bn pixels of Burn and DFU data. The Group has access to a significant number of clinical images as well as c.900 tissue biopsies collected from c.120 wounds. This data includes images and tissue biopsies taken from patient wounds at different time points with different outcomes, such as those which did not heal by standard of care within 30 days.

The access to a large library of images underpinned by tissue biopsy data, the gold standard for tissue characterisation, provided a solid benchmark to train the DeepView® predictive algorithm. To train the system for burn wounds, tissue biopsies are taken at specific positions of the wound. Each biopsy is analysed by burn surgeons and pathologists to determine its depth, composition and regenerative potential. The biopsy vector is then correlated with the corresponding vector on the wound image (e.g. did not heal by standard of care within 30 days). This should support the clinical performance of DeepView® in generating accurate wound healing profiles of previously unseen wounds. A similar process is employed for DFU wounds. Wounds are assessed by specialists to generate a benchmark based on wound progression or healing between the time of initial evaluation and the follow up assessment.

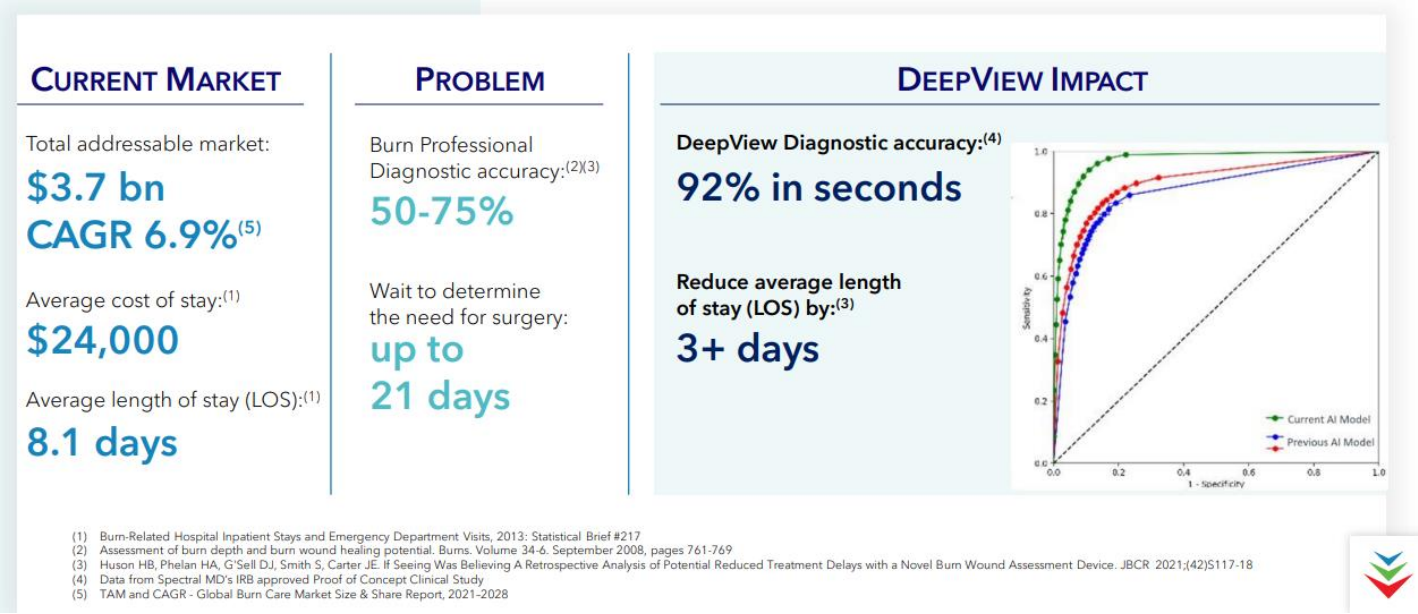
DeepView Burn programme

Summary

The DeepView® Burn Application aims to support clinicians by providing a predictive analysis of whether a wound is likely to heal when a patient first presents at a clinic or hospital. Currently, patients are subjected to a period of "watchful waiting" to evaluate if the burn wound will heal with or without further interventions. It can take up to 21 days to determine the healing potential of the wound.

Accuracy is currently at 92% with the product currently in a pivotal trial prior to seeking US regulatory approval, expected in FY25E. UK approval was received in FY24E. This accuracy is far higher than conventional wound assessments (typically between 50%-75% accuracy) which are highly subjective and reliant on clinician experience. Furthermore, a period of watchful waiting is usually required prior to the progression to advanced treatments or surgery. Project development to date has been supported by non-dilutive grant contracts from the US government with the Group receiving its largest contract award of $150m under Project Bioshield in September 2023.

Figure 4: Burn Wound Market Opportunity



Company presentation

Burn Validation Study underway with results expected in 2024

At the start of 2024, MDAI announced first patient enrolment in a pivotal study, funded by BARDA. The trial is evaluating DeepView AI®-Burn as an imaging technology for burn size and healing assessment. The study is being conducted in US burn centres and emergency departments and is expected to enrol up to c.240 adults and paediatric patients (ClinicalTrials.gov ID: NCT06131203). According to ClinicalTrials.gov, the primary endpoint of the study is to demonstrate that the sensitivity of DeepView AI® is superior to burn centre healthcare professional bedside examination whilst maintaining non-inferior specificity compared to burn healthcare professionals. The pivotal study follows the completion of a training study which showed that the DeepView AI® system has 92% accuracy in determining healing vs. nonhealing tissue in burn wounds.

US Regulatory approval expected in 2025

Upon completion of the Burn Validation Study, Spectral AI is looking to submit an application to the FDA regarding the use of DeepView® for burns in early 2025, with a marketing approval decision expected towards the end of the year. Commercial sales are expected to commence in FY26E. Given the substantial commitment from BARDA to date and the successful approval of prior generations of DeepView®, we are of the view that the regulatory approval carries less risk.

UK clearance received for DeepView AI®-Burn

In February, Spectral AI announced UKCA marking for DeepView AI®-Burn. DeepView AI®-Burn is indicated to be registered for clinical use in the UK for individuals aged eighteen years and older. UKCA-marking is the product certification system to ensure that medical devices sold in the UK comply with the relevant technical standards and requirements. The Company noted that it is looking to deploy six devices in the UK for customer evaluation with revenue generation expected in the second half of the year. UKCA marking is a significant milestone for Spectral AI as it enables the Group to begin selling the DeepView AI®-Burn system in the UK. The placement of devices at UK sites should provide real world evidence regarding the clinical utility of the asset. Furthermore, the approval should support partnership discussions in other regions where UKCA marking is recognised, such as the UAE.

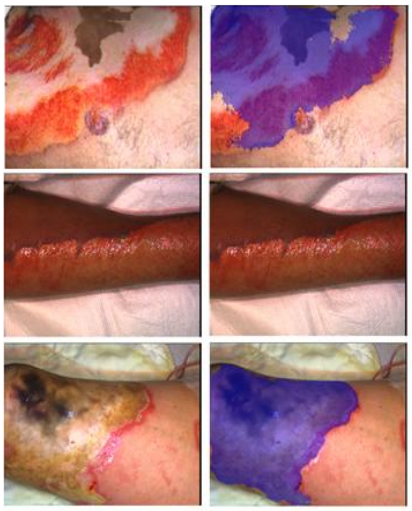
Development and commercial activities funded by BARDA

On 27th September 2023, Spectral AI announced it has been awarded a new contract valued at up to $150m by BARDA (contract number 75A50123C00049). The contract award marks a major milestone for Spectral AI as it supports the commercialisation of the product including federal procurement and deployment into US hospitals for both routine burn care and as a medical countermeasure for use in burn mass casualty incidents.

The base part of the contract ($55m) enables MDAI to expand its validation trial to emergency room and trauma centres, alongside specialist burn centres. This provides an opportunity to generate data for a broader addressable market as there are c.5,400 emergency rooms and trauma centres in the US, alongside 134 specialist burn centres.

The contract also includes options with an additional total value of $94m and can be exercised for additional product development, procurement, and deployment of DeepView® at US emergency departments, trauma centres and burn centres in a phased approach. The contract follows awarded BARDA contracts totalling $123m, of which $101m has been committed to date. Together with this new contract, it brings the total potential support from BARDA to nearly $251m.

Figure 5: DeepView® Burn output



Source: Spectral AI

Strong relationship bodes well for future BARDA support

Spectral AI has received significant commitment from the US Government to support the development of the DeepView® system. BARDA funding is recognised as R&D revenue by the Company on a cost-plus-fee basis. MDAI bills BARDA monthly for the completion of activities under the grant with payment received the following month.

The Company was awarded BARDA PBS in September 2023 to further support development of DeepView® Burn to market clearance as well as procurement and commercial activities. The Base element provides $55m for further development and testing and is expected to run between Q3-23 to Q1-26. The option element totals $94m and is to support procurement and deployment and runs for several years. The award of BARDA PBS follows the successful completion of two prior contracts, (BARDA Burn I and BARDA Burn II) totalling $101m.

Given the Group's strong relationship with BARDA and the award of prior commitments, we expect Spectral AI to qualify for the additional options of BARDA PBS. Furthermore, we believe that MDAI is well positioned to receive additional funding options outside of the scope of the BARDA PBS.

Table 6: $250m committed by BARDA since 2013

	Estimated Value
BARDA Burn I Base	$13m
BARDA Burn I Options	$13m
BARDA Burn II Base	$27.3
Option 1A and B	$39.4
Option 1 B expansion	$8.2
Options 2	$21.9*
BARDA PBS Base	$55m
BARDA PBS Options	$94m

**This was rolled into the BARDA PBS Base contract*

Source: Admission Document; Company Announcements ; SP Angel Estimates

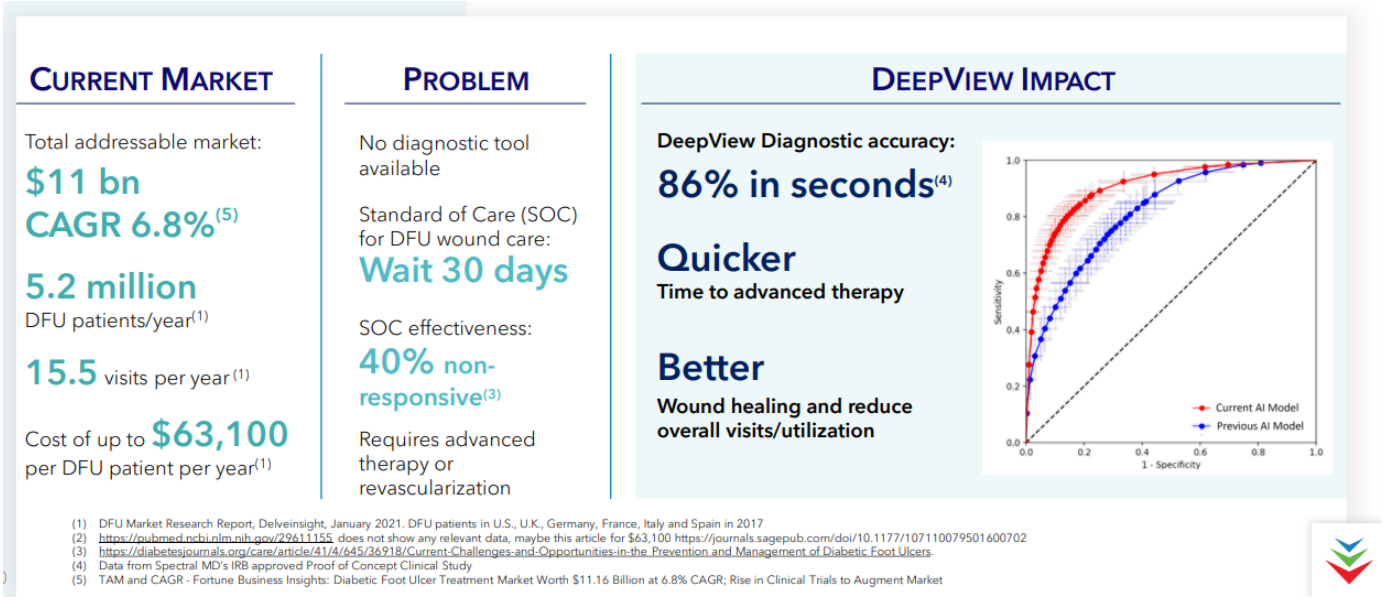
DeepView® DFU Application

Alongside DeepView® Burn, Spectral AI is developing a method to provide clinicians with an earlier and more accurate prediction of the wound healing potential of Diabetic Foot Ulcers (DFUs). DFUs are sores found on the lower leg or feet of an individual with diabetes. They are thought to affect up to 10% of diabetes sufferers and are associated with increased morbidity, mortality, and healthcare costs.

Need for more accurate and earlier diagnosis to support treatment

DFU assessments and subsequent treatment decisions are usually driven by a naked-eye-assessment by a clinician/podiatrist, a highly subjective technique reliant on clinician experience. Currently, patients who present with a DFU receive standard wound care treatments. This is followed by a four-week period of "watchful waiting" to see if wound healing is occurring. Advanced therapies are only applied if the wound is deemed to be not healing after this period. Using DeepView to predict healing potential of a DFU at day one should support treatment decisions and improve healing rates.

Figure 6: Diabetic Foot Ulcer Market Opportunity



Source: Company presentation

Pivotal DFU study expected to complete in 2024

The Company is progressing a clinical validation study for DeepView® in assessing Diabetic Foot Ulcers (DFUs). The study aims to expand the Company's DFU image and physiologic data database, enhance the DeepView® AI algorithm and support regulatory submissions in the US and Europe. The study is gathering data from up to 200 adult subjects at fourteen clinical sites and is expected to complete later this year.

Positive interim data

The validation study is progressing well with positive interim data showing a five-percentage improvement in the accuracy of DeepView. The ability of DeepView to correctly predict at day one whether a DFU will halve in size by week four (aka diagnostic accuracy) was 86% (previously: 81%). Sensitivity (true positive rate) and specificity (true negative rate) was 89% and 83%, respectively.

US regulatory clearance expected in 2025

Following the completion of the pivotal study, we expect Spectral AI to prepare submissions for US, EU and UK approval of the DeepView® DFU application. We expect the Company to submit applications to the US FDA this year with an approval expected towards the end of 2025 with first US sales expected in early 2026. The Company expects the DeepView® DFU Application to be classified as a Class II device and follow the FDA's De Novo clearance pathway. Whilst difficult to predict a regulatory approval decision, the clearance of two prior generations of DeepView® and the Group's regular dialogue with the FDA suggest a low likelihood of a regulatory setback.

UK approval expected in 2024

Whilst progressing the US pathway, Spectral AI will look to file UKCA marking for UK clearance and CE mark approval for EU. We believe that data from the US Training and Validation studies should be adequate to support UKCA and CE-mark approval. The Group has received a recommendation from the Health Products Regulatory Authority in Ireland for the DFU Application to be classified as a Class IIa designation for CE Mark approval in the EU. We expect a submission for UKCA marking to occur in FY24 with an approval decision at or around the end of the year with commercial sales set to begin in FY25E. CE mark submission is expected to occur in FY25E with approval expected in late FY25E/ early FY26E with sales to follow later on in the year.

Post marketing studies planned to drive clinical adoption

Following CE-marking, we expect the Group to perform post-market studies evaluating the device in key regions, such as UK, Germany, Italy and France. These studies, expected to enrol c.35-50 patients, would provide real-world safety and efficacy data for the region in question. Data from these studies should support market access such as achieving positive recommendations from local reimbursement agencies or organisations such as the National Institute for Health and Care Excellence (NICE) who advise the NHS on the value of new technologies. Furthermore, the studies would be conducted by local KOLS whose advocacy for the device should support sales within the region.

Additional opportunities

New disease indications for DeepView

Spectral AI is exploring the use of the DeepView® system to provide predictive wound assessment for additional indications. MDAI is targeting conditions with large addressable populations with a need for improved wound care management. The use of DeepView® could support planning for invasive procedures, such as amputation or stents, and follow-up assessments to evaluate the efficacy of the procedure.

Spectral AI believes that follow-on applications would not require a change to the DeepView® hardware. Therefore, new applications could be uploaded to existing machines. Each follow-on application would require regulatory approval with clinical studies required to collect patient data to train the algorithm and demonstrate clinical benefit. Areas of interest include:

1. **Pre-/post-surgical applications:** Spectral AI is evaluating the use of DeepView® to support surgeons in preoperative planning, such as the decision of the extent of lower limb amputation. An application can be designed to provide a post-operative perfusion assessment for peripheral interventions, such as a stent, to indicate if the intervention is functioning. Surgery is a high-cost area and we expect the Group could negotiate substantial reimbursement rates and higher application fees should the application be commercialised.

2. **Wound bed preparedness:** Evaluating whether debridement (removal of dead/necrotic tissue) is sufficient and assessing what type of wound dressing to use.

3. **Critical limb ischemia (CLI):** CLI is a serious condition whereby obstruction of the arteries reduces blood flow to limbs. Mis-managed or untreated, CLI can result in amputation. Similarly to DFU and Burn Applications, DeepView® could be used to determine disease severity and treatment decisions for CLI.

US government funding development of portable DeepView

Alongside BARDA, Spectral AI has received grant funding from other areas of the US Government to support the development of the DeepView™ system. The Company was recently awarded a new contract from the Defense Health Agency (DHA) and the US Army Medical Material Development Activity (USAMMDA). The contract is valued at c.$500k and aims to support the development of DeepView SnapShot®, a handheld version of DeepView™, the Group's wound healing assessment system. The contract brings the total non-dilutive funding for the development of DeepView SnapShot® to c.$6m, following contract awards in April 2023 ($4m) and June 2021($1.1m).

A handheld version of DeepView™ would provide the military with a system which could be deployed at remote locations, such as field hospitals, to support patient triage, diagnosis, and resource management for burn injuries. This could reduce the need to transport patients to more established hospitals to complete these tasks, which would require additional cost and time. Success in this project could open up the potential for military procurement contracts.

Commercialisation

Sales model offers two revenue streams

We expect Spectral AI to offer the DeepView® system to customers as a capital equipment purchase for the DeepView system (the imaging device) and an annual software licence fee for use of the predictive software for a given disease indication (Burn or DFU). The licensing fee includes maintenance, image hosting, algorithm updates.

Looking to increase reimbursement to drive adoption

A high reimbursement rate, driven by the improved diagnostic information offered by DeepView®, would present an attractive case to customers to buy and use the system. Current reimbursement codes typically relate to technique appointment time but do not compensate for the AI element. If Spectral AI can demonstrate significant clinical benefit over conventional techniques, the Group will be well-placed to negotiate an additional or higher reimbursement rate for the use of the AI element of DeepView®.

US commercialisation

Given the Company's knowledge of the domestic wound care market, we expect the Company to build an in-house sales force for the US market. In terms of DeepView® Burn Application, we expect the Company to target emergency departments at hospitals as well as specialist burn centres. We estimate this to be a market of c.5,400. Alongside commercial sales, we expect the units procured under BARDA PBS to be positioned at these sites and form part of the installed base.

In terms of DFU, MDAI will initially focus on sales to podiatry clinics in populous states with a high prevalence of diabetes, such as Texas and Florida. These clinics typically see high volumes of DFU cases. The Group also looks to target organisations which treat large volumes of diabetic patients, such as hospital outpatient departments and wound care centres. We estimate there to be c.12,000 of these sites in the US.

DeepView® Burn Application could significantly reduce hospital stay

Initially, MDAI aims to seek reimbursement for DeepView Burn under the existing reimbursement (DRG) codes for evaluating burn inpatients. In the medium term, the Company aims to apply for Centre's for Medicare & Medicaid Services (CMS) New Technology Add-On Payment (NTAP). NTAP provides additional payment for approaches deemed to offer a substantial clinical improvement. As DeepView Burn has US FDA Breakthrough Device Designation this should fulfil the requirement. An NTAP code would provide additional payment to the burn DRG codes, which should drive adoption.

MDAI is well placed to negotiate a high reimbursement rate for DeepView® Burn due to the increased cost-benefit, such as reduction in patient stay against current standard-of-care. Physicians currently rely on a wait-and-see approach of c.21 days to determine the need for surgery, resulting in higher probability of infections, additional costs, longer hospital stay, and over-excision of viable skin. A retrospective economic analysis performed at University Medical Centre New Orleans evaluated 80 burn patients and demonstrated that DeepView® could reduce the average length of stay 4.9 days per burn patient. Based on the 80 patients in the study this could lead to cost savings of $2m per year.

DeepView® DFU Application system can add value to customers

Similar to DeepView Burn, the Company anticipates rolling out DeepView DFU under existing reimbursement (CPT) codes such as CPT 93923, which has a national payment rate of c.$133. Once selling systems, the Company aims to gather clinical evidence and apply for a unique CPT code application. Given the clinical benefit of an earlier diagnosis, we believe that DeepView DFU could justify a higher reimbursement code. Using DeepView could enable earlier interventions with advanced wound care treatments for wounds deemed non-healing rather than waiting 30 days. This should improve healing rates and reduce treatment costs. Furthermore, the use of DeepView® could enable clinicians to initiate advance wound therapies at an earlier point. These treatments usually carry a higher reimbursement cost, enabling the clinicians to recoup higher fees per patient compared to standard wound therapy.

European commercialisation

MDAI will initially focus on UK sales before rolling out into the EU. Similar to the US, the target customer base is expected to be primary care centres, including podiatry clinics, outpatient wound centres and other care facilities which see a high-volume of diabetic/DFU patients. Spectral AI is looking to establish a presence in the UK to manage the product launch and commercial activities within the UK and EU. We expect the Company to operate a hybrid approach of sales to customers as well as engaging with specialist medical device distributors with local experience to increase market penetration in key regions.

European reimbursement

For the UK, MDAI intends to use its clinical evidence and health economic analysis for post-market approval and seek reimbursement from the NHS. After gaining more market presence, the Company intends to apply for NICE certification. In the EU, reimbursement varies between European geographies. Therefore, Spectral AI looks to engage with market access and reimbursement consultants with local experience to achieve adequate coverage in each region. We expect the Group to perform small studies in key regions to demonstrate the cost-benefit of using DeepView® to healthcare providers. This data should support discussions with local agencies responsible for making reimbursement and procurement recommendations.

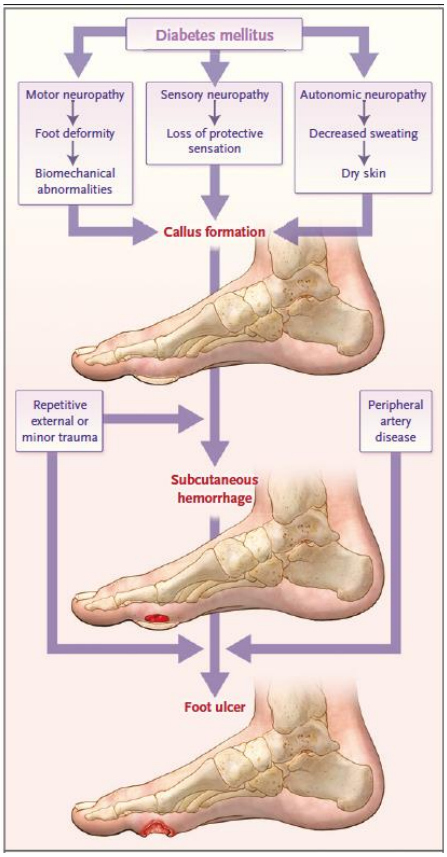
Additional geographies

The near-term focus of the Group is to drive commercial sales in the US and Europe. However, the Group recognises that there are other regions that are worthwhile entering. Once sales are established in the US and Europe, the Group looks to initiate sales in China followed by other high value markets, such as the Middle East where UKCA marking is acknowledged.

Market sector: Diabetic foot ulcers

DFU overview

Figure 7: Formation of DFU



Source: Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017 Jun 15;376(24):2367-2375. doi: 10.1056/NEJMra1615439. PMID: 28614678.

Diabetic Foot Ulcers (DFU) are wounds found on the lower leg and feet of diabetic patients. They are a common complication of patients with diabetes and peripheral arterial disease. It is thought that the annual risk of a diabetic patient developing a DFU may be 4%, with c.34% of diabetic patients estimated to develop at least one DFU over the course of their lifetime. This is considerable given there is an estimated c.463m adult diabetic individuals globally, which is expected to rise to 700m by 2045 (International Diabetes Foundation).

The presence of DFUs has a severe impact on patient livelihood due to the loss of mobility. Furthermore, DFU patients may have a two-fold increase in mortality compared to diabetic patients without a DFU[3]. With inadequate or delayed treatment, a DFU may fail to heal. This increases the likelihood of severe infection occurring which may require amputation. Amputation is a major surgical procedure with a severe impact on patient quality of life. The five-year mortality rate for patients who have received a lower extremity amputation for a DFU is c.50%[4]. In the US, c.1% of DFU patients undergo lower extremity amputations making DFUs a leading cause of nontraumatic amputations[5].

The economic burden of caring for DFU is significant. Of the total cost of treating diabetes in the US (c.$237b), c.30% is associated with care for diabetic foot disease[6]. The cost of treating a DFU patient in the US is between $8k to $17k, dependant on the level of infection and severity of the wound. This rises to c.$63k if a major amputation is required[7]. In the UK, there are c.4.5m people with diabetes. In 2015, the NHS is estimated to have spent between £972m–£1.13b on care related to DFUs and amputation in diabetes. This was equivalent to 0.72%–0.83% of the annual NHS budget. The mean cost to the NHS for treating a DFU is c.£7,800/year. The cost of care for a healed DFU was £2,140 which increased to £8,800 for an unhealed DFU. Costs doubled to £16,900 for a DFU which required amputation[8]. The cost comparison between a healed DFU and one which requires amputation highlights the importance of accurate treatment decisions to support wound healing.

[3] Boyko E. J., Ahroni J. H., Smith D. G., Davignon D. Increased mortality associated with diabetic foot ulcer. Diabetic Medicine. 1996;13(11):967–972.
[4] Lavery LA, Hunt NA, Ndip A, Lavery DC, Van Houtum W, Boulton AJM. Impact of chronic kidney disease on survival after amputation in individuals with diabetes. Diabetes Care. 2010;33(11):2365–9.
[5] Oliver TI, Mutluoglu M. Diabetic Foot Ulcer. [Updated 2020 Aug 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537328/
[6] Armstrong DG, Swerdlow MA, Armstrong AA, Conte MS, Padula WV, Bus SA. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. J Foot Ankle Res. 2020;13(1):16. Published 2020 Mar 24. doi:10.1186/s13047-020-00383-2
[7] Delveinsight; Diabetic Foot Ulcer (DFU); Market Insights, Epidemiology, and Market Forecast—2030; Published: January 2021
[8] Guest JF, Fuller GW, Vowden P. Diabetic foot ulcer management in clinical practice in the UK: costs and outcomes. Int Wound J. 2018 Feb;15(1):43-52. doi: 10.1111/iwj.12816. Epub 2017 Dec 15. PMID: 29243399.

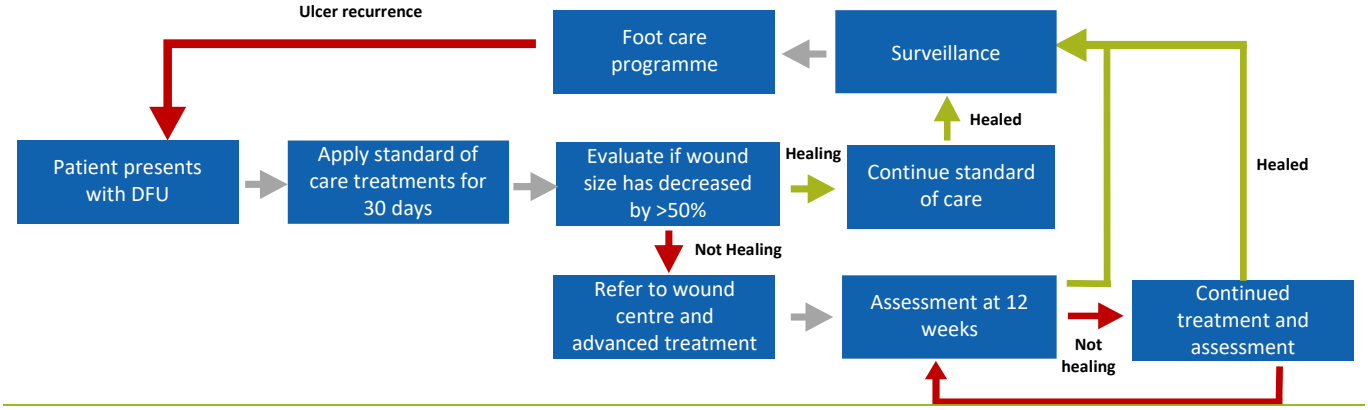
Lack of DFU diagnostic tools to assess wound healing

Despite the prevalence of DFUs, there is a lack of options available to clinicians to accurately assess wound healing when a patient first presents. One of the keys to DFU treatment is early diagnosis and referral to a multidisciplinary team as a quick intervention increases the probability of healing and reduces risk of amputation.

In the US, patients with a DFU are usually referred to a specialist, typically a podiatrist who assesses the wound and initiates treatment. In the first 30 days of treatment the podiatrist performs standard of care treatments, such as wound debridement, application of antimicrobials to prevent infection and relieving pressure on the DFU (wound offloading). If the DFU has not healed by 50% at Day 30, the wound is considered non-healing and the patient is referred to a specialist wound centre. Advanced wound therapies are applied, such as bioengineered skin substitutes, negative pressure wound therapy or arterial stents. If the wound is deemed non-healing at 12 weeks, further advanced treatment is continued.

The use of DeepView® could help clinicians with treatment decisions at Day 1. This could enable earlier interventions with advanced wound care treatments for wounds deemed non-healing rather than waiting 30 days. This should improve healing rates and reduce treatment costs.

Figure 8: US DFU Clinical care pathway



Source: Derived from Company Admission Document (Technical report) and Ousey K et al. J Wound Care. 2018 May

Market sector: Burns

In the US, c.489,000 burn patients seek medical attention per year (CDC: National Hospital Ambulatory Medical Care Survey: 2017 Emergency Department Summary Tables). Of these, c.53,220 patients are admitted into hospital due to burn injuries. Inadequate or a delay in treatment decisions can increase wound healing times and risk of infection and scar formation. This may increase costs due to additional days required in hospital as well as a need for cosmetic treatment or surgery due to scarring.

Lack of Burn diagnostic tools to assess wound healing

There is a lack of diagnostic tools available to support initial assessment of burn wounds. Burn patients are assessed by clinicians or burn specialists who apply skin grafts and subject the patient to a period of "watchful waiting" to evaluate if the burn wound will heal with or without further interventions, such as surgery. This period usually lasts between four to seven inpatient hospital days but can take up to 21 days to determine the healing potential of the wound.

Current treatment decisions are reliant on subjective assessments

For the burn assessment, the clinician relies on their experience with prior burn wounds to establish a treatment pathway for the patient. This assessment is based on the clinician's experience with prior wounds. Therefore, treatment decisions can be highly subjective and tend to vary between clinicians. For burn specialists, the accuracy of predicting whether a wound will heal at Day 21 without further intervention is c.70%. This falls to c.50% for non-specialists. Given that there are only 134 specialist burn centres in the US compared to 5,336 hospitals nationwide it is likely that initial assessments will be performed by a non-specialist. With a current clinical accuracy of c.90%, the use of the DeepView® system could provide a more accurate method to both specialist and non-specialist clinicians to predict wound healing at the point when a patient is admitted.

DeepView® can reduce hospital stay and support resource management

The DeepView® Burn Application is well-placed to support clinicians in delivering a more accurate and timely diagnosis for triage and therapeutic intervention. The average length of hospital stay for a burn patient is 8.1 days at a cost of $24k. Data from a Proof-of-concept study indicated that DeepView® has potential to reduce average length of stay by 4.9 days which could save c.$14.5k/stay.

Skin grafts are often applied to burn wounds to support wound healing. To prepare the wound for skin graft, nonviable tissue must be removed. The delineation between viable and nonviable tissue can be difficult to discern which can lead to unnecessary excision of healthy skin. DeepView® can be used to accurately delineate between viable and non-viable tissue. This can help guide clinicians in pre-surgical planning for skin grafts. By accurately delineating between viable and nonviable tissue, DeepView® could also reduce the amount of skin graft used per patient. This is especially important in the event of a potential disaster where a significant number of patients present with burn injuries. In this case, the efficient use of skin graft supplies can ensure a larger number of patients can receive adequate care.

Financials

FY23 results summary

Spectral AI recently released its results for the year ended 31 December 2023 (FY23A) and fourth quarter (Q4-23).

- FY23A R&D revenues were $18.1m (FY22A: $25.4m), ahead of Company guidance of $17.4m. Year on year decline reflects a decrease in activity due to the completion of work under the BARDA Burn II contract and the transition to the new BARDA PBS contract. R&D revenues for Q4-23 were $5.3m (Q1-24: $6.1m) as MDAI began activities under BARDA PBS (awarded in September 2023).

- The Company reiterated FY24E R&D revenue guidance of $28.0m.

- FY23 gross profit margin improved to 43.6% (FY22A: 42.7%) with Q4-23 gross margins of 46.1% (Q4-22: 41.1%). This reflects the start of BARDA PBS in September 2023 which has a higher reimbursement rate than BARDA Burn II.

- General & administrative expenses increased to $20.9m (FY22: $13.5m), reflecting increased headcount and investment to support non-BARDA/Burn related activities such as regulatory, commercial and clinical activities for DFU.

- FY23 operating losses of $13.0m (FY22: $2.6m loss) reflect reduced R&D revenues and increased operating expenses. FY23 net losses of $20.9m (FY22: $2.9m) included $8.3m of non-recurring transaction costs associated with the Nasdaq merger (FY22: $nil). Net losses for Q4-23 were $3.5m (Q4-22: $1.7m).

- Cash at period end was $4.8m (September 30, 2023: $7.3m; December 31, 2022: $14.2m). In Q1-24, MDAI received $5m via a fixed price prepaid advance and standby equity purchase agreement (SEPA) as part of a total advance of $12.5m. MDAI also received net proceeds of c.$2.8m via a committed equity facility (announced December 2023) with MDAI eligible to draw a further $3.0m prior to utilising the SEPA facility.

Table 7: FY23 results review

December year end ($m)	2022A	2023A
Total Revenue	**25.4**	**18.1**
COGS	**(14.5)**	**(10.2)**
Gross profit	**10.8**	**7.9**
Gross profit margin (%)	*42.7%*	*43.6%*
Total Operating expenses	**(13.5)**	**(20.9)**
Operating Profit (losses)	**(2.6)**	**(13.0)**
Pre-tax profit (losses)	**(2.8)**	**(20.8)**
EBITDA	**(2.1)**	**(12.3)**
Change in cash	**(1.8)**	**(9.3)**
Cash at end of period	**14.2**	**4.8**

Source: Spectral AI financial reports and SP Angel estimates

Forecasts

We summarise our key assumptions for our estimates below:

DeepView Burn

- We expect modest UK sales for DeepView Burn to begin in H2-24E.
- US approval for DeepView Burn is expected in FY25E with commercial sales in FY26E.
- European sales for DeepView Burn are expected to occur in FY26E.
- DeepView Burn System Units are to be sold in the US at $75,000 (increasing 5% y/y) with an associated annual SaaS licensing/maintenance fee (Application revenue) of $25,000. We estimate margins of 40% and 75% for the system unit and licence fee, respectively. Pricing in EU & UK is expected to be c.80% of US.

R&D Revenue

- Grant funding is recognised as R&D revenue by the Company on a cost-plus-fee basis. Revenues from these contracts are recognised as costs are incurred, such as the completion of activities related to the Burn clinical study or manufacturing scale up. We assume margins of 46%, in line with Q4-23 margins (46.1%) which saw the initiation of BARDA PBS.
- We expect Spectral AI to complete the base period ($55m) of Project BioShield over FY24E and FY25E which is supporting clinical, regulatory and manufacturing scale up activities for DeepView Burn.
- We expect Spectral AI to progress through the additional options of Project BioShield, receiving an additional $95m. We expect this to be split between 200 System unit sales ($15m) and $80m R&D revenue spread across FY26E-FY28E to support additional health economics, procurement and clinical activities.
- PBS procurement is expected to begin in FY26E with 200 system units sold between FY26 and FY30E. PBS DeepView® Burn System Units are priced at $75k and are expected to be incorporated into the total installed base.
- We expect an additional $4m in grant funding in FY25E to support DeepView miniaturisation.

DeepView DFU

- We expect UK approval for DeepView DFU to occur in FY24E with sales beginning in FY25E. US commercialisation is expected to begin in FY26E whilst EU sales are set to begin in FY27E.
- DeepView Burn System Units are to be sold in the US at $75,000 (increasing 5% y/y) with an associated annual SaaS licensing/maintenance fee (Application revenue) of $25,000. Pricing in Europe & UK is expected to be c.80% of US

Other

- We expect the Company to receive $18.3m in FY24E via convertible facilities announced in December 2023 ($5.8m) and March 2024 ($12.5m).
- We estimate the fully diluted share count at the end of FY24E to be 28.7m. This excludes 8.4m in out of the money warrants with an exercise price of $11.50.

US Revenue

DeepView Burn

We expect initial US Burn sales to commence in FY26E with the sale of 38 systems, rising to 66 in FY27E, the first full year of sales. The total market size for DeepView Burn consists of hospitals and burn centres which we estimate to be 5,470. In FY26E we also expect the first 30 system units to be procured under Project Bioshield. We expect these units to form part of the total installed base of System Units and attract a licencing fee. US Burn sales is expected to result in revenues of $5.0m in FY26E and $10.4m in FY27E. By the fifth year of sales (FY30E) the Company is expected to achieve revenues of $40m.

DeepView DFU

DFU sales are also expected to begin in FY26 with 36 systems sold, rising to 72 the following year. By the fifth year of sales, we expect revenues of $46m with an installed base of 650 machines. We expect MDAI to focus on selling into podiatry practices, hospital emergency rooms and wound care clinics as these see a high volume of DFU patients. We estimate there to be c.12k of these sites in the US.

Table 7: US revenue forecast

Product Revenue Forecast	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Deepview AI - Burn								
Hospitals	5,336	5,336	5,336	5,336	5,336	5,336	5,336	5,336
Hospitals y/y growth %	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Burn Centres	134	134	134	134	134	134	134	134
Burn Centres y/y growth %	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Total Addressable Market (#)	5,470	5,470	5,470	5,470	5,470	5,470	5,470	5,470
Total market size growth	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Penetration (%)	*0.7%*	*1.2%*	*1.8%*	*2.5%*	*3.0%*	*3.5%*	*4.0%*	*4.0%*
System Units sold (#)	38	66	96	137	164	191	219	219
Adding Project Bioshield System Units (#)	68	96	156	197	184	191	219	219
System Units installed base (#)	68	164	320	516	701	892	1,111	1,330
System Units installed base penetration (%)	*1.2%*	*3.0%*	*5.8%*	*9.4%*	*12.8%*	*16.3%*	*20.3%*	*24.3%*
System Unit price ($)	82,688	86,822	91,163	95,721	100,507	105,533	110,809	116,350
System Unit Revenue ($m)	**3.2**	**5.7**	**8.7**	**13.1**	**16.5**	**20.2**	**24.2**	**25.5**
Base Licensing/Maintenance Fee ($m)	27,563	28,941	30,388	31,907	33,502	35,178	36,936	38,783
Base Annual Licensing fee revenue ($m)	**1.9**	**4.7**	**9.7**	**16.5**	**23.5**	**31.4**	**41.0**	**51.6**
US revenue ($m)	**5.0**	**10.4**	**18.4**	**29.6**	**40.0**	**51.6**	**65.3**	**77.0**

Source: SP Angel forecasts

Table 8: US revenue forecast

Product Revenue Forecast	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Deepview AI - DFU								
Podiatrist Practices	4,493	4,493	4,493	4,493	4,493	4,493	4,493	4,493
Wound care clinics	2,200	2,200	2,200	2,200	2,200	2,200	2,200	2,200
Emergency rooms	5,336	5,336	5,336	5,336	5,336	5,336	5,336	5,336
Total Addressable Market (#)	12,029	12,029	12,029	12,029	12,029	12,029	12,029	12,029
Penetration (%)	*0.3%*	*0.6%*	*1.0%*	*1.5%*	*2.0%*	*2.5%*	*3.0%*	*3.0%*
System Units sold (#)	36	72	120	180	241	301	361	361
System Units installed base (#)	36	108	229	409	650	950	1,311	1,672
System Units installed base penetration (%)	*0.3%*	*0.9%*	*1.9%*	*3.4%*	*5.4%*	*7.9%*	*10.9%*	*13.9%*
System Unit price ($)	82,688	86,822	91,163	95,721	100,507	105,533	110,809	116,350
System Unit Revenue ($)	**3.0**	**6.3**	**11.0**	**17.3**	**24.2**	**31.7**	**40.0**	**42.0**
Base Licensing Fee ($)	27,563	28,941	30,388	31,907	33,502	35,178	36,936	38,783
Application Revenue ($)	**1.0**	**3.1**	**6.9**	**13.0**	**21.8**	**33.4**	**48.4**	**64.8**
US revenue ($)	**4.0**	**9.4**	**17.9**	**30.3**	**45.9**	**65.2**	**88.4**	**106.8**

Source: SP Angel forecasts

UK and EU revenue

DeepView Burn

With UKCA marking approval achieved we expect modest initial commercial sales to begin at or around the end of the year. We expect EU sales to begin in FY26E with a focus on larger markets such as Germany, France, Italy and Spain. By the fifth year of sales (FY28E) the Company is expected to achieve revenues of $11m on a total installed base of 212 systems. We expect MDAI to sell DeepView Burn systems units into hospitals which we estimate there to be c.8,500 across UK/EU.

DeepView DFU

UK DFU sales are estimated to begin in 2025 beginning with EU sales beginning in FY26E. By the fifth year of sales (FY29E) the Company is expected to achieve revenues of $15m on a total installed base of 287 systems. Sourcing accurate data regarding the number of podiatry clinics across Europe was difficult, so we took the prevalence of DFUs in each country and assumed that one DeepView DFU system would be bought per 100 patients.

Table 9: UK/EU revenue forecast

Product Revenue Forecast	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Deepview AI - Burn										
Germany/Austria	2,137	2,137	2,137	2,137	2,137	2,137	2,137	2,137	2,137	2,137
UK	1,148	1,148	1,148	1,148	1,148	1,148	1,148	1,148	1,148	1,148
France/BENELUX	3,092	3,092	3,092	3,092	3,092	3,092	3,092	3,092	3,092	3,092
Italy	1,051	1,051	1,051	1,051	1,051	1,051	1,051	1,051	1,051	1,051
Spain/Portugal	1,016	1,016	1,016	1,016	1,016	1,016	1,016	1,016	1,016	1,016
Total Addressable Market (#)	8,444	8,444	8,444	8,444	8,444	8,444	8,444	8,444	8,444	8,444
Penetration (%)	*0.1%*	*0.2%*	*0.5%*	*0.8%*	*1.0%*	*1.3%*	*1.5%*	*2.0%*	*2.0%*	*2.0%*
System Units sold (#)	5	17	42	63	84	106	127	169	169	169
System Units installed base (#)	5	22	64	128	212	317	444	613	782	951
System Units installed base penetration (%)	*0.1%*	*0.3%*	*0.8%*	*1.5%*	*2.5%*	*3.8%*	*5.3%*	*7.3%*	*9.3%*	*11.3%*
System Unit price ($)	60,000	63,000	66,150	69,458	72,930	76,577	80,406	84,426	88,647	93,080
System Unit Revenue ($)	**0.3**	**1.1**	**2.8**	**4.4**	**6.2**	**8.1**	**10.2**	**14.3**	**15.0**	**15.7**
Base Licensing Fee ($)	20,000	21,000	22,050	23,153	24,310	25,526	26,802	28,142	29,549	31,027
Base Annual Licensing fee revenue ($)	**0.1**	**0.5**	**1.4**	**3.0**	**5.2**	**8.1**	**11.9**	**17.3**	**23.1**	**29.5**
UK/EU revenue ($)	**0.4**	**1.5**	**4.2**	**7.4**	**11.3**	**16.2**	**22.1**	**31.5**	**38.1**	**45.2**

Source: SP Angel forecasts

Table 10: UK/EU revenue forecast

Product Revenue Forecast	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Deepview AI - DFU									
Germany	221,312	221,312	221,312	221,312	221,312	221,312	221,312	221,312	221,312
UK	78,716	78,716	78,716	78,716	78,716	78,716	78,716	78,716	78,716
France/BENELUX	79,601	79,601	79,601	79,601	79,601	79,601	79,601	79,601	79,601
Italy	81,178	81,178	81,178	81,178	81,178	81,178	81,178	81,178	81,178
Spain/Portugal	241,877	241,877	241,877	241,877	241,877	241,877	241,877	241,877	241,877
Total patients with DFUs	**702,683**	**702,683**	**702,683**	**702,683**	**702,683**	**702,683**	**702,683**	**702,683**	**702,683**
Penetration (%)	*0.1%*	*0.3%*	*1.0%*	*1.2%*	*1.5%*	*2.0%*	*2.5%*	*3.0%*	*3.0%*
Patients	703	2,108	7,027	8,432	10,540	14,054	17,567	21,080	21,080
System Units sold (#)	7	21	70	84	105	141	176	211	211
System Units installed base (#)	7	28	98	182	287	428	604	815	1,026
System Unit price ($)	63,000	66,150	69,458	72,930	76,577	80,406	84,426	88,647	93,080
System Unit Revenue ($)	**0.4**	**1.4**	**4.9**	**6.1**	**8.0**	**11.3**	**14.9**	**18.7**	**19.6**
Base Licensing Fee ($)	21,000	22,050	23,153	24,310	25,526	26,802	28,142	29,549	31,027
Application Revenue ($)	**0.1**	**0.6**	**2.3**	**4.4**	**7.3**	**11.5**	**17.0**	**24.1**	**31.8**
UK/EU revenue ($)	**0.6**	**2.0**	**7.1**	**10.6**	**15.4**	**22.8**	**31.9**	**42.8**	**51.5**

Source: SP Angel forecasts

Project BioShield

We expect DeepView® units to be procured by BARDA under the PBS contract, beginning in FY26E. Under the Base period, we expect Project BioShield to acquire 30 system units in FY26E. The contract indicates a further 170 system units can be acquired as part of the three additional options of the contract. We expect procurement to be fulfilled by FY30E. We estimate the price per unit to be $75k. The total revenue for Project BioShield procurement is estimated to be $15m.

Given the total amount of funding that BARDA has awarded to date, and the history of the company of striking federal contracts we expect that there is scope or the procurement of additional system units or grant funding as part of an additional contracts. However, we have not included these in our current estimates.

Table 11: Project BioShield forecast

Product Revenue Forecast	2026E	2027E	2028E	2029E	2030E
System Units sold (#)	30	30	60	60	20
System Unit price ($)	75,000	75,000	75,000	75,000	75,000
System Unit Revenue ($)	**2.3**	**2.3**	**4.5**	**4.5**	**1.5**

Source: SP Angel forecasts

R&D revenue expected through to FY30E

In September 2023, MDAI was awarded BARDA PBS. The base period of this contract ($55m) is supporting clinical validation work and US FDA clearance of DeepView® Burn for commercial marketing and distribution purposes. This contract follows the previous BARDA contract (BARDA Burn II). We expect the base element of the PBS contract to be deployed across FY24E and FY25E. We anticipate additional grant funding ($4m) to be received in FY25E to support development of the portable DeepView Snapshot. We expect the remainder of BARDA PBS ($90m) to be received from FY26E to FY30E.

Overheads

Costs for the Group are expected to be driven by General & Admin as well as Clinical & R&D and Sales & Marketing costs. Clinical and R&D expenses for Burn are primarily recognised within COGS. These are mostly direct costs related to the BARDA Burn and Project Bioshield contracts which are recognised as R&D revenue.

We expect additional Clinical/R&D costs as MDAI begins to conduct its own R&D and clinical programmes as the Group continues to build out its clinical database and conduct post-marketing studies to drive adoption and further validate the use of DeepView® in DFU and additional wound care indications, such as peripheral arterial disease. Sales & Marketing is expected to grow as the Group begins its first full year of commercialisation of the DeepView® system. We expect a modest reduction in operating expenses in FY25E ($20.6m vs FY24E: $21.9m) as the DFU clinical trial programme is completed, offset by an increase in sales & marketing as the Company expands its commercialisation activities.

Valuation

DCF valuation

We believe that the best method for valuing Spectral AI is through discounting cash flows (DCFs) as near-term earnings forecasts do not reflect the Group's long-term growth trajectory. For example, the Group is yet to receive US FDA approval for DeepView® and begin commercial sales.

In support of our DCF model we produced ten years of forecasts, from 2024E to 2033E inclusively. This forecast period incorporates the rollout of DeepView for both DFU and Burn indications and the Project BioShield programme.

We used a discount rate of 15% and our terminal value is calculated using a long-term free cash flow growth rate of 4%.

Our DCF model, described below, indicates a fair value of $305.0m implying a $10.60 target price.

Table 12: Discounted cash flow

DCF (Dec year end)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Operating CF	**(6.8)**	**(3.3)**	**0.5**	**9.2**	**11.8**	**14.1**	**31.3**	**53.6**	**82.6**	**107.1**
Capex	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Tax (net)	-	-	-	(1.8)	(2.5)	(3.2)	(7.6)	(13.2)	(20.6)	(26.8)
FCF	**(6.9)**	**(3.4)**	**0.4**	**7.2**	**9.1**	**10.7**	**23.6**	**40.2**	**61.8**	**80.0**
Discounted FCF	**(6.9)**	**(3.0)**	**0.3**	**4.7**	**5.2**	**5.3**	**10.2**	**15.1**	**20.2**	**22.7**
NPV	73.9									
TV	215.0									
EV	288.9									
Net Cash/(Debt)	16.1									
Fair Value ($m)	**305.0**									
Fully diluted shares (m)	28.7									
Target Price ($)	**10.6**									
Current share price ($)	2.4									
Discount rate	*15%*									
Terminal growth rate	*4%*									

Source: Bloomberg, Spectral AI financial reports and SP Angel estimates

Peer Group analysis

We generated a peer group of life sciences companies which are developing diagnostics or offering services and/or products with a focus on wound care or digital health. We compared their current enterprise value to revenues estimated for FY26E, the first year of US commercial sales.

Spectral AI's FY26E EV/Sales (0.6x) remains below the median (2.7x) FY26E EV/Sales for the group indicating that the Company remains undervalued against its peers. The median EV/Sales for the peer group broadly corroborates with the target price which we derived from our DCF ($10.60).

Table 13: Peer Group analysis

					BEst Sales						EV / Sales					
Company name	Ticker	MCAP	EV	Price	FY24	FY25	FY26	FY27	FY28	FY29	FY24	FY25	FY26	FY27	FY28	FY29
Average	**Average**	**783.1**	**747.6**	**32.4**	**190.3**	**230.9**	**266.7**	**272.8**	**305.7**	**351.6**	**5.1**	**4.4**	**3.8**	**3.3**	**3.0**	**2.7**
Median	**Median**	**438.7**	**364.1**	**8.1**	**75.2**	**123.7**	**136.9**	**109.5**	**125.6**	**138.5**	**5.1**	**2.8**	**2.7**	**2.5**	**2.2**	**1.9**
Spectral AI Inc	**MDAI US**	**34.5**	**29.6**	**2.2**	**28.4**	**33.1**	**47.5**	**66.6**	**82.7**	**95.9**	**1.0**	**0.9**	**0.6**	**0.4**	**0.4**	**0.3**
Mimedx Group	MDXG US	1,108.1	1,076.6	8.0	357.4	355.8	402.2	451.5	496.0	552.0	3.0	3.0	2.7	2.4	2.2	2.0
Mediwound	MDWD US	147.5	143.7	13.1	24.1	23.8	33.7	53.5	85.7	125.0	6.0	6.0	4.3	2.7	1.7	1.1
Adv. Medical Sol.	AMS LN	519.2	454.0	2.6	184.4	172.6	185.0	200.7	211.5	248.0	2.5	2.6	2.5	2.3	2.1	1.8
Vericel Corp	VCEL US	2,469.6	2,448.1	49.5	239.3	240.8	295.2	385.7	471.3	575.3	10.2	10.2	8.3	6.3	5.2	4.3
Organogenesis	ORGO US	348.4	343.5	3.4	454.7	456.0	488.0	522.0	-	-	0.8	0.8	0.7	0.7	x	x
Polynovo Ltd	PNV AU	964.5	943.8	1.3	67.1	65.3	85.8	107.7	118.4	142.1	14.1	14.5	11.0	8.8	8.0	6.6
Iradimed Corp	IRMD US	544.2	496.5	44.9	72.0	72.0	80.1	-	80.1	80.1	6.9	6.9	6.2	x	6.2	6.2
Butterfly Network	BFLY US	214.4	105.0	1.0	72.9	74.9	82.5	-	82.5	82.5	1.4	1.4	1.3	x	1.3	1.3
EKF Diagnostics	EKF LN	149.5	146.3	0.4	71.1	72.0	78.3	84.9	84.9	84.9	2.1	2.0	1.9	1.7	1.7	1.7
Caredx Inc	CDNA US	498.6	297.4	8.2	266.6	260.7	285.6	-	285.6	285.6	1.1	1.1	1.0	x	1.0	1.0
Irhythm Technologies	IRTC US	3,566.6	3,562.6	112.2	580.9	578.5	680.8	769.2	881.8	1,051.0	6.1	6.2	5.2	4.6	4.0	3.4
Renalytix AI	RENX LN	53.0	55.9	191.6	7.7	781.4	948.2	1,132.7	1,348.9	1,560.7	7.3	0.1	0.1	0.0	0.0	0.0
Neuropace	NPCE US	378.7	384.6	17.5	75.2	74.6	88.7	111.4	132.8	135.0	5.1	5.2	4.3	3.5	2.9	2.8
Better Therapeutics	BTTX US	0.7	8.4	0.2	x	3.8	-	-	-	-	x	2.2	x	x	x	x

Source: Bloomberg BEst Estimates, Spectral AI financial reports and SP Angel estimates

Table 14: Income Statement

Income Statement ($)	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Commercial Revenue	-	0.4	2.1	17.5	36.6	62.7	95.9	132.3	180.1	234.6	280.5
Product Revenue growth	-	-	*421.3%*	*727.8%*	*109.1%*	*71.5%*	*53.0%*	*37.9%*	*36.1%*	*30.2%*	*19.6%*
R&D Revenue	18.1	28.0	31.0	30.0	30.0	20.0	-	-	-	-	-
Total Revenue	**18.1**	**28.4**	**33.1**	**47.5**	**66.6**	**82.7**	**95.9**	**132.3**	**180.1**	**234.6**	**280.5**
Total Revenue growth	*(28.8%)*	*57.3%*	*16.6%*	*43.4%*	*40.2%*	*24.2%*	*16.0%*	*37.9%*	*36.1%*	*30.2%*	*19.6%*
COGS	**(10.2)**	**(15.3)**	**(17.8)**	**(25.9)**	**(34.5)**	**(41.0)**	**(43.6)**	**(56.0)**	**(73.4)**	**(92.9)**	**(106.1)**
Gross profit	**7.9**	**13.1**	**15.3**	**21.6**	**32.1**	**41.7**	**52.3**	**76.3**	**106.7**	**141.6**	**174.4**
Gross profit margin (%)	*43.6%*	*46.0%*	*46.3%*	*45.5%*	*48.2%*	*50.4%*	*54.5%*	*57.7%*	*59.2%*	*60.4%*	*62.2%*
Total Operating expenses	**(20.9)**	**(21.9)**	**(20.6)**	**(23.0)**	**(24.8)**	**(31.5)**	**(39.6)**	**(46.0)**	**(53.7)**	**(59.2)**	**(67.1)**
Operating Profit (Loss)	**(13.0)**	**(8.8)**	**(5.3)**	**(1.4)**	**7.4**	**10.1**	**12.7**	**30.3**	**53.0**	**82.4**	**107.4**
Operating Margin (%)	*(71.9%)*	*(31.1%)*	*(16.0%)*	*(2.9%)*	*11.1%*	*12.3%*	*13.3%*	*22.9%*	*29.4%*	*35.1%*	*38.3%*
Interest Income (expense)	0.2	-	-	-	-	-	-	-	-	-	-
Other Income (expenses)	(8.0)	-	-	-	-	-	-	-	-	-	-
Pre-tax profit	**(20.8)**	**(8.8)**	**(5.3)**	**(1.4)**	**7.4**	**10.1**	**12.7**	**30.3**	**53.0**	**82.4**	**107.4**
Tax rate (%)	*0.0%*	*0.0%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*	*25.0%*
Tax	(0.0)	-	-	-	(1.8)	(2.5)	(3.2)	(7.6)	(13.2)	(20.6)	(26.8)
Profit after tax	**(20.9)**	**(8.8)**	**(5.3)**	**(1.4)**	**5.5**	**7.6**	**9.5**	**22.7**	**39.7**	**61.8**	**80.5**
Foreign currency translation adjustment	12,000.0	-	-	-	-	-	-	-	-	-	-
Total comprehensive (loss) income applicable to common stockholders	**(20.8)**	**(8.8)**	**(5.3)**	**(1.4)**	**5.5**	**7.6**	**9.5**	**22.7**	**39.7**	**61.8**	**80.5**
Earnings (loss) per share - basic - $	(1.28)	(0.38)	(0.23)	(0.06)	0.24	0.33	0.41	0.98	1.71	2.66	3.46
Earnings (loss) per share - diluted - $	(1.28)	(0.31)	(0.18)	(0.05)	0.19	0.27	0.33	0.79	1.38	2.15	2.80
-	-	-	-	-	-	-	-	-	-	-	-
Shares outstanding - basic	16.3	23.2	23.2	23.2	23.2	23.2	23.2	23.2	23.2	23.2	23.2
Shares outstanding - diluted	16.3	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7

Source: Spectral AI financial reports and SP Angel estimates

Table 15: Cash Flow

Cash Flow Statement ($)	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
EBIT	**(13.0)**	**(8.8)**	**(5.3)**	**(1.4)**	**7.4**	**10.1**	**12.7**	**30.3**	**53.0**	**82.4**	**107.4**
Depreciation & Amortisation	0.7	0.7	0.8	0.8	0.8	0.8	0.8	0.9	0.9	0.9	0.9
EBITDA	**(12.3)**	**(8.1)**	**(4.5)**	**(0.6)**	**8.2**	**11.0**	**13.6**	**31.2**	**53.9**	**83.3**	**108.3**
Share option related charges	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Other non cash items	4.1	-	-	-	-	-	-	-	-	-	-
Working capital movements	1.5	(0.0)	(0.0)	(0.1)	(0.2)	(0.5)	(0.7)	(1.1)	(1.5)	(2.0)	(2.4)
Operating CF	**(5.4)**	**(6.8)**	**(3.3)**	**0.5**	**9.2**	**11.8**	**14.1**	**31.3**	**53.6**	**82.6**	**107.1**
Net Interest	0.2	-	-	-	-	-	-	-	-	-	-
Capex	-	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Tax (net)	(0.0)	-	-	-	(1.8)	(2.5)	(3.2)	(7.6)	(13.2)	(20.6)	(26.8)
FCF	**(5.2)**	**(6.9)**	**(3.4)**	**0.4**	**7.2**	**9.1**	**10.7**	**23.6**	**40.2**	**61.8**	**80.0**
Acquisitions/Disposals	(8.0)	-	-	-	-	-	-	-	-	-	-
Share issues	3.4	-	-	-	-	-	-	-	-	-	-
Proceeds from exercise of stock options	0.3	-	-	-	-	-	-	-	-	-	-
Debt movement	(0.5)	-	-	-	-	-	-	-	-	-	-
Other	0.7	18.2	-	-	-	-	-	-	-	-	-
Change in cash	**(9.4)**	**11.3**	**(3.4)**	**0.4**	**7.2**	**9.1**	**10.7**	**23.6**	**40.2**	**61.8**	**80.0**
Cash at beginning of period	14.3	4.9	16.1	12.7	13.1	20.3	29.4	40.1	63.7	103.8	165.6
Cash at end of period	**4.9**	**16.1**	**12.7**	**13.1**	**20.3**	**29.4**	**40.1**	**63.7**	**103.8**	**165.6**	**245.6**

Source: Spectral AI financial reports and SP Angel estimates

Key risks

As a healthcare company with a product undergoing late stage clinical trials, Spectral AI is exposed to risks inherent to the sector. We view risks related to the regulatory pathway and commercialisation as most relevant for the Company.

Government commitment

Development of the DeepView® system has been significantly supported by government grants, primarily from BARDA. Spectral AI expects to receive additional financing from BARDA to support development and placement of DeepView® systems for burns. Should BARDA reduce or discontinue financial support we expect there to be a requirement for additional working capital to support the commercialisation activities. Given the agency's support to date, including the recent BARDA PBS contract, and the unmet need for burn support in the case of a catastrophic event, we expect Spectral AI to continue to receive committed contracts from BARDA.

Pricing and Reimbursement

Pricing and reimbursement schemes will play an important factor in product-uptake once DeepView® reaches the market. As a novel technology, there is no current reimbursement code. If Spectral AI's technology is designated an insufficient Medicare reimbursement code or if there is a delay in awarding a code this could adversely affect sales. Spectral AI is using an external reimbursement consultant to perform reimbursement landscape testing. The Company has already identified a pre-existing code for a similar treatment which the Directors expect their technology to be priced at or above due to the additional information the technology provides, such as wound healing assessment at Day 1. In Europe, the reimbursement landscape varies between regions therefore Spectral AI looks to engage with market access and reimbursement consultants with local experience to achieve adequate coverage in each region. We expect the Group to perform small studies in key regions to demonstrate the cost-benefit of using DeepView® to healthcare providers. This data should support discussions with local agencies responsible for making reimbursement and procurement recommendations, such as Haute Autorité de Santé in France or NICE in the UK. Alongside this, the Group looks to enlist Key Opinion Leaders (KOLS) in each region to advocate the use of the technology.

Clinical trial risk

The outcome of clinical trials cannot be pre-determined and there is no guarantee that Spectral AI's technology will meet the endpoint of future clinical trials. Trials may raise safety and/or efficacy issues and there may be requests for additional clinical data by the FDA. The DeepView® platform has a strong safety profile and has been tested on a number of patients. The procedure is non-invasive and requires no contact with the patient and does not use ionising radiation or radioactive tracers.

Commercial risk

Spectral AI has not previously generated commercial revenues and is yet to launch the DeepView® system into its target markets. Commercial launch of the device may be delayed, and/or adoption may be slower than originally anticipated. Other imaging solutions with wound management applications have not been particularly successful in the market but that may be because they offer little more than reproducible wound measurement systems and do little to improve diagnosis and treatment or reduce cost. DeepView® appears to address these shortcomings of other systems and we would expect it to have greater appeal.

Regulatory pathway

Spectral AI requires regulatory approval to bring its products to market and must adhere to strict regulations on safety and efficacy. Different countries have different approval processes and timelines, and the Company may have to incur costs for receiving regulatory approval. There is no assurance the Company will receive regulatory approval and there may be significant delays in the review process. Unsuccessful or delayed approval would have a detrimental effect on the Company's finances. The Company maintains a positive dialogue with the FDA and the Directors remain confident of DeepView® receiving approval for both Burn and DFU. Spectral AI benefits from an experienced management team which has considerable experience in project management and regulatory activities. Furthermore, the Group has achieved FDA 510(k) clearance for two prior generations of the DeepView® solution and recently received UKCA approval for clinical use in the UK.

Key Management

Richard Cotton, Non-Executive Chairman

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. His experience covers all financial management and value creation activities from R&D, to manufacturing and commercial in international organizations. He has significant experience in the development and successful execution of strategy, corporate finance and M&A, capital markets and governance. Richard also serves as Financial Advisor to Novumgen Ltd., a specialty pharmaceuticals company, amongst other NED / advisory roles. Mr. Cotton was Chief Financial Officer of FTSE250 animal health Group Dechra Pharmaceuticals plc, and prior to that Chief Financial Officer of medical device and drug formulation business Consort Medical plc. He was also Finance Director of Vitec Group plc, Group Finance Director at Wagon plc and Group Finance Director of McLeod Russel plc. Prior to this he held senior finance roles in Alcoa Inc. Fellow of the Chartered Institute of Management Accountants, Mr. Cotton holds a BA (Hons) in Business Studies from Kingston University.

Peter M. Carlson, CEO

Mr. Carlson has served as CFO of Spectral AI since January 2024. Prior to Spectral AI, he served as CFO of MiMedx Group, Inc., a pioneer and leader in the advanced wound care space, where he led numerous strategic, financing, operational initiatives that helped stabilize and strengthen the company for its next chapter of growth. Prior to MiMedx, Mr. Carlson served as Chief Operating Officer at Brighthouse Financial, Inc., and played an essential role in establishing Brighthouse as a separate public company after its spin-off from MetLife, Inc., where he worked for eight years as Chief Accounting Officer. Previously, Mr. Carlson was the Controller at Wachovia Corporation and an audit partner for a Big Five accounting firm, Arthur Andersen LLP. Mr. Carlson serves as a Board Member at White Mountains Insurance Group and as a trustee for Wake Forest University.

Vince Capone, CFO and General Counsel

Mr. Capone has served as General Counsel and Corporate Secretary at Spectral AI since March 2022. Mr. Capone has an extensive background in representing technology companies and he has a proven track record as a business-focused and results-oriented leader in driving corporate growth and development. He began his career at KPMG LLP before practicing corporate and securities law. He has more than 20 years of broad legal experience both at Morgan Lewis, LLP, then as a Partner at Reed Smith, LLP. Prior to Spectral AI, he was President of a New York-based private equity fund investing in global life sciences and technology companies. Mr. Capone serves as a senior advisor to Alexet Capital Associates, LLC and is a board member of the Ryan Lesher Foundation, a non-profit organization assisting families in Bucks County, Pennsylvania. Additionally, while currently inactive, he was a certified public accountant in Pennsylvania. Mr. Capone earned both his J.D. and M.B.A. degrees from Temple University and his B.S. degree in Accounting from The Pennsylvania State University.

Niko Pagoulatos, COO

Niko Pagoulatos, Ph.D. is a technology executive and innovator with 25+ years of experience in engineering, clinical and business aspects of specialized medical ultrasound imaging. Dr. Pagoulatos is a team-oriented and results-driven leader with extensive experience and a strong track record in building and leading cross-functional teams to successfully commercialize innovative medical technologies with global clinical impact. Prior to joining Spectral AI, Dr. Pagoulatos held multiple executive roles at EchoNous, a global healthcare AI-focused medical ultrasound innovation company. Prior to EchoNous, Dr. Pagoulatos held director and advanced research and development engineering roles at FUJIFILM SonoSite, the world leader in point-of-care ultrasound, DYSIS Medical, a company focused on early detection and diagnosis of cervical disease using biophotonics, and Siemens Healthcare. Dr. Pagoulatos earned his B.S. in Physics from the University of Athens in Greece and completed his graduate studies at the University of Washington in Seattle, where he earned a M.S. in Bioengineering in addition to a M.S. and Ph.D. in Electrical Engineering.

Wensheng Fan, Chief Innovation Strategist

Wensheng Fan is a Co-Founder and the first employee of Spectral MD. Over the past 11 years he has served as CTO and COO, before becoming the CEO of Spectral MD for four years. He is an executive, entrepreneur, and innovator with over 20 years of experience in natural speech recognition and imaging systems. Mr. Fan held various leadership roles in strategy, engineering, and operations with Sensata Technologies and Philips. He also has a long history of experience in business development and cross-functional team leadership, being a founder and/or early core member of multiple successful start-up companies. Under his leadership, Spectral MD's DeepView® was granted FDA Breakthrough Device designation and is well on its way to disrupting the field of healthcare and medical technology. Mr. Fan received his B.S.E.E. degree from Tsinghua University in Beijing, China and M.S.E.E. degree from Northeastern University in Boston.

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Recommendations are based on a 12-month time horizon as follows:

Buy - Expected return >15%
Hold - Expected return range -15% to +15%
Sell - Expected return < 15%