

Spectral MD Holdings, Ltd. (AIM: SMD)

Company Summary

Investment Profile

1. FDA Breakthrough designation in 2018
2. c. \$100m non-dilutive funding
3. Total addressable market ~\$15bn
4. Delivering on commercialisation strategy
5. Project BioShield contract (~\$400m) potential
6. Several future product applications

Share Information

Ticker	SMD
Share Price	36.50p
Shares in issue	136m
Market Cap	£49.67m
12m Hi/Low	62.00/35.00p

(Source: The London Stock Exchange, January 2022)

12-Month Share Price



(Source: The London Stock Exchange, January 2022)

Major Shareholders (as of January 2022)

Name	%
The Spangenberg Entities	40.4
J. Michael DiMaio	18.8
University of Texas (Southwestern)	7.7
Octopus Investments plc	7.6
Jose Melendez	6.6
Laurence Hirsch	5.7

(Source: company website)

Watch the latest presentation [here](#)

Company Overview

Spectral MD (AIM: SMD) is a 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**. Clinicians can use this data to support earlier treatment decisions, leading to improved patient outcomes and lower overall treatment costs.

Quoted on AIM since on 22 June 2021, **raising \$16 million gross** in the process, Spectral MD was incorporated in 2009 as a spin out from the University of Texas Southwestern. It is located in Dallas, Texas, USA, with a registered office in Delaware, USA, and **develops proprietary AI algorithms and optical technology for faster and more accurate treatment decisions in wound care**.

Deepview® was **granted FDA Breakthrough Device Designation Status in 2018** and, according to the company's admission document, it is not common for a medical technology to have gained such prestigious acknowledgement. This status not only emphasises the FDA's recognition of DeepView®'s scientific and technological value, but also provides the Group with an expedited regulatory framework for the burn application and guaranteed Medicare reimbursement for a period of four years post FDA approval.



Who are BARDA?

The Biomedical Advanced Research and Development Authority is a US Department of Health and Human Services office responsible for the procurement and development of medical countermeasures, principally against bioterrorism, including chemical, biological, radiological and nuclear threats, as well as pandemic influenza and emerging infectious diseases. BARDA is also responsible for the procurement for Project BioShield acquisitions.



Significant Non-Dilutive Funding

Spectral has received substantial support from the US government for its application to burn wounds from agencies such as BARDA, National Science Foundation (NSF), National Institute of Health (NIH) and Defense Health Agency (DHA) to the tune of **c. \$100 million**.

In September, Spectral announced the commitment of **additional funding of \$18.8m from BARDA**, which will be used to expand the current clinical training study of the Company's DeepView® Wound Imaging System for burn wound healing assessment.

Importantly, **BARDA has no rights to ownership, no claims to IP, or other contractual entanglements**.

Delivering on Commercialisation Strategy

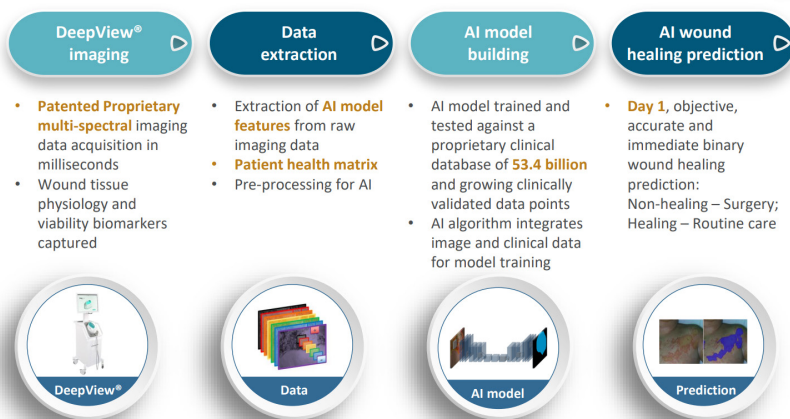
Spectral is on track and **delivering on its milestones** as part of its path toward commercialisation of the DeepView® Wound Imaging Solution. In September, the Company announced that it received \$18.8m as part of the Option 1B phase of its BARDA contract, which allowed Spectral to accelerate initiation of the second stage of its clinical training study for the burn indication. This was received ahead of time, given it was originally expected in March 2022.

In November, the Company announced two further significant milestones. Firstly, Spectral reported that early data from its multi-center clinical study indicated that **DeepView® had achieved an increased 92% accuracy** in its early wound healing assessment for thermal burns in adults, and an **88% accuracy in children**. Importantly, the results highlighted that DeepView® was responding with substantial reliability to variation in the study population. The same month, Spectral also **completed enrolment for its DFU training study**, another key milestone highlighted at IPO. The data collected from the 150 subjects will help improve DeepView®'s current 83% accuracy for DFU.

Finally, the appointment of Nils Windler as Spectral's CFO will accelerate the Company's commercialisation strategy. Attracted to Spectral by the outstanding potential of DeepView®, Nils has a **track record of delivering transformational commercialisation at high growth companies**.

What is the DeepView® Wound Imaging Solution?

DeepView® combines non-radiation multi-spectral optical technology with its AI model as well as over 66 billion clinically validated data points to produce a day 1 healing assessment of a burn or DFU. The technology is patent protected and significantly differentiated, with no other wound care solutions in the market able to compete with DeepView®'s offering.



Key Newsflow

- June:** Oversubscribed [AIM IPO](#) raises £11.3m
- July:** [Multicenter clinical study](#) initiated
- Sept:** Next phase \$18.8m [BARDA contract](#)
- Sept:** [Interim results](#)
- Nov:** [Positive clinical results](#) for burn indication
- Nov:** [Enrolment completed](#) for DFU training study
- Dec:** [Appointment of CFO](#)

Management Team

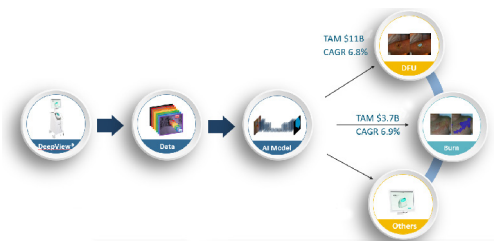


Spectral **CEO, Wensheng Fan**, is an executive, entrepreneur and innovator with **over 20 years' experience** in natural speech recognition, imaging systems, medical devices and artificial intelligence.

Prior to joining Spectral, Wensheng was a Global Vision Application Engineering Manager for Sensata Technologies (former Texas Instruments Sensors & Controls Division) with a focus on introducing imaging sensor and vision systems into automotive original equipment manufacturers for auto safety features. He was also an Engineering Manager at Philips, where he specialised in integrating natural speech recognition into the telecommunication world.

CFO, Nils Windler, has more than 20 years of finance and operations experience. Prior to joining Spectral MD, Mr. Windler served as Senior Finance Leader and Business Finance Transformation Leader at **3M**. In this role, he helped integrate the \$6.7bn acquisition of wound care solutions provider **Acelity** and its global **KCI subsidiaries** into 3M's Health Care Medical Solution Division, 3M's largest acquisition to date.

One Platform, Many Applications



Forecasts (Source: Consensus forecasts compiled by Walbrook PR)

	FY'20 (Actual)	FY'21 (Est.)	FY'22 (Est.)	FY'23 (Est.)	FY'24 (Est.)
Sales (\$m)	17.3	16.5	25.6	41.8	132.4
EBITDA (\$m)	1.4	(6.2)	(7.5)	0.3	51.1
PBT (\$m)	1.4	(6.2)	(7.5)	0.2	51.1
EPS diluted (c)	12.1	(3.4)	(4.2)	0.1	25.5