



Half-Year Report

Sep 13, 2021

Spectral MD has achieved all the project milestones it set to be achieved by this time in 2021 and has achieved other important milestones ahead of schedule, including early receipt of increased U.S. Government grant funding of c. US\$20 million post-IPO and progress on new burn and DFU patient studies

Revolutionary technology to transform the future of wound care

LONDON, U.K. AND DALLAS, TX, U.S – Spectral MD Holdings, Ltd. (AIM: SMD), a predictive analytics company that develops proprietary AI algorithms and optical technology for faster and more accurate treatment decisions in wound care, announces its unaudited results for the six-month period ended 30 June 2021, and provides an update on further development of the DeepView® Wound Imaging Solution.

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Wensheng Fan, Chief Executive Officer of Spectral MD, said: *“I am delighted by Spectral MD’s progress in the first half of 2021. We have exceeded the commercial milestones we set for the Company in our admission document, which we believe will position the Company for success in the important and growing wound care market. The Company has begun the next phase of our U.S. Government contract with BARDA and received the recently announced accelerated approval of BARDA’s Option 1B funding. This brings our total funding committed from BARDA since 2013 to over US\$92.8 million, including US\$39.4 million of commitment in 2021 year to date. We have successfully initiated a 250 patient multi-center burn clinical study to further develop and enhance the DeepView® Wound Imaging Solution and look forward to providing further updates as enrollment progresses. Spectral MD is on target for its second half 2021 milestones, including current enrollment of 143 patients in our DFU study, and we are on track to complete the study of 150 patients by the end of 2021. Critically, the Company is positioned to achieve milestones that are foundational for our planned regulatory approvals and commercialization plans in 2022 and 2023. I am particularly proud of the Spectral MD team which we continue to build so we can further position the Company for future success. “We are thankful for the support you have shown in our AIM IPO, and we will endeavor to continue to meet or exceed the objectives we have set for the Company.”*

Half Year Operational highlights:

- Accuracy of DeepView®’s artificial intelligence (AI) algorithms in development is currently 91 percent for burn indication and 83 percent for diabetic foot ulcers (DFU) indication, with expected further improvements
- Completed an Expanded Proof-of-Concept (ePOC) for DeepView® burn application on 124 subjects at Wake Forest Baptist Medical Center Winston-Salem, NC; University Medical Center New Orleans, LA; and Medstar Washington Hospital Center Washington D.C.
- Entered into a US\$20.6 million U.S. Government contract (Option 1A) with Biomedical Advanced Research and Development Authority (BARDA) as a result of the successful ePOC outcome
- Enrolled 117 (increased to 143 since 30 June 2021) of the targeted 150 subjects into the AI training study for ‘Day One’ DFU healing assessment and on schedule to complete the study by the end of 2021
- Increased burn and DFU data to 8.1 terabytes and 66.7 billion pixels for the deep learning algorithms training and to build a proprietary, market-leading wound image database
- Awarded a US\$1.1 million contract with U.S. Department of Defense’s Defense Health Agency (DHA) to miniaturize DeepView® for U.S. military use
- Secured a total of six U.S. patents and four foreign and international patents for the DeepView® imaging technology
- Hired 17 new employees in support of the Company’s growth and development plans, as anticipated in the IPO **Half Year Financial highlights (unaudited):**
- Raised £11.3 million (approximately US\$16.0 million) in an oversubscribed placing and entire share capital admitted to trading on AIM on 22 June 2021
- Gross revenue of US\$7.0 million

- Net loss before tax of US\$0.9 million
- Cash on hand of US\$18.5 million as of 30 June 2021 **Post-period highlights:**
- On 29 July, the Company began a multi-center clinical study to further develop its DeepView® Wound Imaging Solution for the burn application, which is anticipated to include 10 sites and 250 patients
- On 6 September, the Company announced early entry into the next phase of U.S. Government contract (Option 1B) with BARDA. This Option 1B funding totals US\$18.8 million, bringing the total U.S. Government funding since inception to US\$93 million, including US\$40.5 million in 2021
- The DFU clinical study has enrolled an additional 21 subjects (making a total of 143 subjects) across six clinical study sites in the U.S.
- The hiring of our first General Counsel who will lead the legal, compliance, ethics, corporate secretary, and human resources functions, and will support intellectual property workstreams; a lead data scientist; and additional hires anticipated to facilitate future growth

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About Spectral MD Holdings, Ltd. (www.spectralmd.com)

Using its DeepView® Wound Imaging Solution, an internally developed AI technology and multispectral imaging solution that has received FDA Breakthrough Designation for the burn indication, Spectral MD is able to distinguish between non-healing and healing human tissue invisible to the naked eye. Spectral MD currently is able to provide 'Day One' healing assessments for burn wounds and diabetic foot ulcers with other applications being explored.

Spectral MD has to date received substantial support from the U.S. government with contracts from institutions such as Biomedical Advanced Research and Development Authority, National Science Foundation, National Institute of Health and Defense Health Agency in support of the burn application for its DeepView® solution, with total grant funding received to date from all of these organizations of over \$93 million, including \$40.5 million received in 2021. This grant funding is non-dilutive to our shareholders and the Company believes it validates the important nature of our mission and technology. The Company leverages this funding to support R&D efforts that are applicable to burn, DFU and potentially other indications where DeepView can play an important role in Day 1 wound healing assessment.

The Company has two principal trading subsidiaries, Spectral MD, Inc. and Spectral MD UK Limited.

DeepView®

DeepView® is a predictive analytics platform that integrates proprietary AI algorithms and advanced optical technology for wound healing predictions. It is non-invasive, non-radiation, non-laser and does not require the use of injectable dye. This integration can be characterised into four distinct components: DeepView® imaging, data extraction, AI model building and AI wound healing prediction.

- The DeepView® imaging technology consists of patented, proprietary, multi-spectral optics and sensors that can classify wound tissue physiology and capture the viability of various biomarkers within the skin. The imaging technology extracts appropriate clinical data, processes the image, and displays a comparison of the original image next to an image with a colour overlay of the non-healing portions of the wound. The image acquisition takes 0.2 seconds, and the output takes approximately 20 to 25 seconds.
- The DeepView® data extraction consists of proprietary optics that are able to collect millions of data points from each raw image. This information is then used to build and continually improve the AI model, which is trained and tested against a proprietary database of more than 66.7 billion pixels with an ever-growing input of clinically validated data points.
- The AI algorithm then produces a predictive wound healing assessment in the form of an

objective, accurate, and immediate binary wound healing prediction. This prediction is graphically represented to the clinician through a coloured overlay of the original image that annotates the non-healing portion of the wound.

DeepView® is designed to allow clinicians to make a more accurate, timely and informed decision regarding the treatment of the patient's wound. In the case of DFUs, a non-healing assessment would provide the clinician with the appropriate justification to use an advanced wound care therapy on 'Day One' as opposed to waiting 30 days and potentially losing the patient to lack of patient follow-up or risking patient noncompliance with standard wound therapy. For burn wounds, the clinician can make an immediate and objective determination to identify appropriate candidates for surgery as well as determining what specific areas of the burn wound will require skin grafting. DeepView®'s current accuracy for determining the healing potential of burn wounds is 91 percent, compared with current physician accuracy of 50 to 70 percent. The current clinical accuracy of DeepView® is 83 percent for DFUs. Both of these accuracy percentages are expected to increase with additional R&D efforts, including clinical studies.