



Full Year Trading update and Notice of Results

Feb 01, 2022

*Unaudited cash and loss for the year ahead of expectations
Burn and Diabetic Foot Ulcer clinical studies and regulatory pathway on track*

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, provides a trading update for the year ended 31 December 2021.

The Company can confirm that both its unaudited loss for the year and negative EBITDA are expected to be materially ahead of current market expectations with the 31 December 2021 unaudited cash position also marginally ahead of expectations. This has been primarily driven by lower costs per subject associated with the Diabetic Foot Ulcer (“DFU”) clinical training study. Additionally, unaudited grant revenue, deriving from the Company’s BARDA funding contract for the Burn indication, is expected to be broadly in line with market expectations.

Notice of Results

The Company intends to publish its audited preliminary results for the year ended 31 December 2021 by the end of March.

Wensheng Fan, CEO of Spectral MD Holdings, Ltd, said: “Spectral continues to make good progress on its clinical and regulatory pathway and the Company is on track to deliver on its expected milestones notwithstanding the continued challenges of the Covid pandemic. Cash and loss for the year are both expected to have exceeded expectations, with BARDA grant revenue broadly in line with expectations. I look forward to providing further updates at the time of the preliminary results.”

Market Abuse Regulation (MAR) Disclosure

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014 as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018 (‘MAR’). Upon the publication of this announcement via Regulatory Information Service (‘RIS’), this inside information is now considered to be in the public domain.

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About Spectral MD:

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 organisations 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 92 percent in adults and 88 percent in children, 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.