



Final Results

Feb 27, 2023

Strong foundations laid ahead of planned regulatory submissions in 2023

LONDON, U.K. AND DALLAS, TX, U.S. – Spectral MD Holdings, Ltd. (AIM: SMD), a predictive analytics company with proprietary AI algorithms and optical technology for faster and more accurate treatment decisions in wound care, announces its audited results for the year ended 31 December 2022.

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To view a full version of the results in PDF format [click here](#)

Operational Highlights:

US Burn Indication supported by BARDA (Biomedical Advanced Research and Development Authority)

- Awarded US\$ 8.2 million contract expansion to accelerate the commercialization pathway for DeepView™
- Burn Image Assessment Study (“BIAS”) findings reinforce DeepView™’s value proposition and clinical need:
 - In 31% of healing wounds Emergency Department (“ED”) physicians incorrectly selected immediate referral to a burn center or surgery
 - In 74% of non-healing wounds ED physicians failed to select immediate referral or surgery
- Adult enrollment in Burn AI training study completed

Diabetic Foot Ulcer (“DFU”) Indication

- Clinical Study is on track to complete enrollment by end of Q2 2023 to support DeepView™ AI-DFU FDA regulatory submission in 2023

Commercial readiness

- Strengthened senior leadership team with four key appointments: Niko Pagoulatos, Chief Operating Officer; Christine Marks, VP Marketing & Commercialization; Vince Capone, General Counsel & Company Secretary; and Mary Regan, VP of Clinical Affairs
- Won Best Technology Award at the European Mediscience Awards in June 2022

Financial Highlights:

- R&D revenue up 67% to US\$ 25.4 million (2021: US\$ 15.2 million) funding Burn indication development as well as the development of handheld prototype DeepView SnapShot® M
- Strong cash position with cash on hand of US\$ 14.2 million (2021: US\$ 16.1 million)

Post-Period Highlights:

US Burn Indication

- Pediatric enrollment in Burn AI training study has been completed in February 2023.
- Federal contract opportunity initiated for Health and Human Services Burn Wound Imaging technology. Company responded with proposal and will be evaluated for contract fulfillment.
- DeepView™ AI-3D developed to capture millimetric level wound size measurement accuracy

with single image acquisition without requiring external reference markers for seamless integration into the clinical workflow.

DFU Indication

- Successful interim results reported showing AI diagnostic accuracy improvement from 81% to 86%.
- US clinical study is on track with additional sites being incorporated in Q1 2023, providing data to support FDA and UKCA regulatory submissions.
- Initiated EU clinical study with the Royal College of Surgeons in Ireland (“RCSI”) conducted at Connolly Hospital in Dublin, Ireland.

Wensheng Fan, Chief Executive Officer of Spectral MD, said: “We are pleased with the rate of progress and development made in 2022 and have delivered strong operational results for both our Burn and DFU indications. Spectral MD also exceeded financial expectations during the period through effective cost management. Importantly, this will allow the Company to increase investment in 2023 to drive forwards our commercialization strategy for DFU.

“Our immediate strategy remains focused on commercialization planning activities. We are in regular communication with BARDA to further develop our infrastructure readiness for a federal level commercial contract and look forward to building upon our strong momentum, whilst continuing to collaborate with BARDA and our clinical partners to scale and advance our transformative technology.”

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 Holdings, Ltd. (www.spectralmd.com)

Using its DeepView™ Wound Imaging Solution, an internally developed AI technology and multispectral imaging system which 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 (DFU), with other applications being explored.

Spectral MD has to date received substantial support from the US government with contracts from institutions such as Biomedical Advanced Research and Development Authority (BARDA), National Science Foundation (NSF), National Institute of Health (NIH) and Defense Health Agency (DHA) in support of the burn application for its DeepView™ solution. Spectral MD started trading on the AIM market of the London Stock Exchange on June 22nd, 2021, after raising US \$16 million through an oversubscribed initial public offering. The Company has two principal trading subsidiaries, Spectral MD, Inc. and Spectral MD UK Limited.