



Interim results for the six-months ended 30 June 2022

Sep 20, 2022

Extensive solution validation; accelerating commercialization readiness

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 interim results for the six-months ended 30 June 2022 (“H1 2022”).

Download

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

Operational Highlights

- Enrollment on track in the Biomedical Advanced Research and Development Authority (“BARDA”) Burn AI Training Study: 145 of the targeted 190 adult subjects (76%) and 25 of the targeted 60 pediatric subjects (41%).
- Burn Image Assessment Study (“BIAS”) findings: burn specialists and Emergency Department (“ED”) physicians significantly less accurate in assessing wound healing vs non-healing than DeepView™.
- Diabetic foot ulcer (“DFU”) AI Model created post Clinical Training Study with 81% accuracy. This is the live AI algorithm in use in the DFU Clinical Validation Study.
- Initiated DFU Clinical Validation Study in June: up to 200 adult subjects across seven potential clinical sites. Data expected to support regulatory submission.
- Filled key positions in Regulatory, Operations, Marketing, Administration, and Engineering to accelerate commercialization readiness.
- Won Best Technology Award at the European Mediscience Awards in June. Criteria for winning technology: innovative, well-funded, capable of significant commercial success.

Post-Period Highlights

- Awarded US\$ 8.2 million US Government contract expansion with BARDA to accelerate commercialization pathway for the DeepView™ technology, bringing the total government funding commitment received by Spectral MD to over \$125 million since 2013.
- Strong DFU Clinical Validation study enrollment: 56/200 subjects enrolled since June initiation, remaining on track to report results in early 2023. This represents an important study to support the Company as it prepares FDA and CE mark submissions for DeepView®’s DFU indication, planned in 2023.

Financial Highlights

- R&D revenue up 76% to US\$ 12.3 million (H1 2021: US\$ 7.0 million): accelerating BARDA funded studies.
- Cash on hand of US\$ 15.6 million on 30 June 2022 (H1 2021: US\$ 18.5 million)
- Removal of ‘Regulation S’ market trading restrictions from shares following the first anniversary on AIM.
- Expanded Analyst research coverage to include Stifel and WH Ireland, in addition to SP Angel’s existing coverage.

Wensheng Fan, Chief Executive Officer of Spectral MD, said: “The Company has made solid progress in H1 2022 and is on schedule regarding the development of, and clinical studies for, Burn, DFU, and handheld applications. With the recent addition of the US\$ 8.2 million BARDA contract

expansion, we believe that the likelihood of potential federal procurement has increased, with an expedited timeline to award.

"Over the balance of 2022 and 2023, we will remain focused on completing enrollment in both Burn and DFU clinical studies and continuing to accelerate investment into the Company's commercial readiness. We believe DeepView™ is the market leading technology that has the potential to disrupt current treatment pathways, and to improve the standard of care for many patients across multiple geographical markets and applications. We remain confident in our strategic approach and that our transformative technology is well positioned for success in providing Day One wound healing assessments."

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.

For further information please contact:

Spectral MD Holdings, Ltd.

Wensheng Fan, Chief Executive Officer
Nils Windler, Chief Financial Officer

investors.spectralmd.com

via Walbrook PR

SP Angel Corporate Finance LLP (NOMAD and Joint Broker)

Stuart Gledhill/Caroline Rowe (Corporate Finance)/Vadim Alexandre/Rob Rees (Sales & Broking)

Tel: [+44 \(0\)20 3470 0470](tel:+44(0)2034700470)

Stifel Nicolaus Europe Limited (Joint Broker) Charles Hoare / Ben Maddison / Nick Harland / Will Palmer-Brown

Tel: [+44 \(0\)20 7710 7600](tel:+44(0)2077107600)

Walbrook PR Ltd (Media & Investor Relations)

Paul McManus / Louis Ashe-Jepson
Alice Woodings

Tel: [+44 \(0\)20 7933 8780](tel:+44(0)2079338780) or spectralMD@walbrookpr.com

Mob: [+44 \(0\)7980 541 893](tel:+44(0)7980541893) / [+44 \(0\)7747 515 393](tel:+44(0)7747515393)
[+44 \(0\)7407 804 654](tel:+44(0)7407804654)

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, with total grant received to date of over US\$ 101.5 million.

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.