Final results

Mar 21, 2022

All key operational milestones outlined at admission to AIM achieved in a transformational year for the Company

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 audited final results for the year ended 31 December 2021.

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Operational highlights

- Key performance numbers from Expanded Proof-of-Concept ("ePOC") showing accuracies of 92% and 88% in detection of severe thermal burn injury in adults and children, respectively
- Awarded new contracts with the US Biomedical Advanced Research and Development Authority (BARDA) valued at US$40.5 million, with total funding now awarded from BARDA of over US$100 million
    - US$20.6 million Option 1A BARDA contract due to successful ePOC outcome, in March 2021
    - US$18.8 million Option 1B BARDA contract 6 months ahead of schedule, in September 2021
- Initiated second stage of burn Artificial Intelligence ("AI") clinical training study, where the research has been expanded from five to a total of ten clinical sites, and from 100 subjects to a total of 250 subjects
- Successfully completed 150 subject Diabetic Foot Ulcer ("DFU") AI training study on schedule across six clinical sites
- Appointment of Nils Windler as Chief Financial Officer

Financial highlights

1. Grant revenue of US$15.2 million, primarily from current BARDA contract
2. Adj. EBITDA US$(3.0) million, including DFU development costs
3. Cash on hand of US$16.1 million as of 31 December 2021
4. Raised gross proceeds of £11.3 million (approximately US$15.6 million) through a successful initial public offering, with the entire share capital admitted to trading on AIM on 22 June 2021

Post-period end highlights

1. Enrolled 80+ subjects across eight clinical sites in the second stage of the burn AI clinical training study, with the Company on track to meet the 250 subject enrollment target across 10-12 sites in the US by Q4 2022
2. Training DFU algorithm performance determined at 81% accuracy for broad coverage – a robust and reliable result based on results from a considerably larger study population across multiple locations and practices
3. DFU AI clinical study initiated with Royal College of Surgeons in Ireland, clinical agreement in progress and submitted for regulatory review
4. Full hand-held engineering prototype is being developed for a miniaturized version of DeepView®

Wensheng Fan, Chief Executive Officer of Spectral MD, said: *"In 2021, Spectral MD achieved all key operational milestones outlined at the time of our IPO. It has been a transformational year for the Company, from the positive readout from our clinical trials for both our burn and DFU indications, to the accelerated US Government funding for our applications and the successful IPO, raising gross proceeds of £11.3 million (US$15.6 million). I am particularly proud of the Spectral MD team which we continue to build as we position the Company for further future success.*

"The Company is well positioned to achieve further key milestones that are foundational to our planned regulatory approvals and commercialization plans. Over the course of 2022 and 2023, we will accelerate investment in key management hires and commercialization efforts to enhance the Company's readiness to obtain significant government support for placement of our devices in over 5,000 US based hospitals. We will also continue to opportunistically evaluate additional indications, market opportunities and other initiatives to further enhance our commercial success and shareholder value."

2021 Business Update and Outlook

BARDA – Biomedical Advanced Research and Development Authority

At IPO: The Company had been awarded the BARDA contract Option 1A (US$20.6 million), granted in March 2021, and Option 1B (US$18.8 million) was expected to be granted in 2022 to execute the adult and pediatric multi-center clinical training study.

Achieved: Spectral MD received the Option 1B US$18.8 million six months ahead of schedule in 2021 due to a successful ePOC outcome. The accelerated funding, which takes the total BARDA awarded contract funding into the Company to over US$100 million, will allow the Company to accelerate initiation of the second stage of the clinical training study with confidence.

Outlook: The Company expects to successfully complete the Option 1A and 1B 250 subject clinical study in 2022. Upon successful completion of the study, the Company expects to see high performing algorithm results across demographic and geographic variability in the study population. The Company is excited for the continued collaboration with BARDA, as it works together into the next contract phase.

DFU – Diabetic Foot Ulcers

At IPO: At IPO, the Company expected to meet the 150 subject enrollment goal for the DFU U.S. training study and complete the study by year end of 2021.

Achieved: The Company successfully completed the 150 subject DFU U.S. training study on schedule across six clinical sites in December 2021.

Outlook: Following successful completion of the training study, the DFU AI algorithm is being finalized, and additional newly developed product features are being incorporated. In 2022, the Company will start and expects to finish the validation study for the DFU AI algorithm in the U.S.. In Q2 2022, the Company expects to start the DFU clinical study in the EU, where the data collected will be combined and compared with U.S. data to expand DeepView® readiness in both the U.S. and CE marked regions. The Company's focus will be on the continued development of the DFU AI model as we progress into the validation study.

DHA – Defense Health Agency

At IPO: The Company intended to develop a miniaturized, fully hand-held version of DeepView®.

Achieved: The DHA awarded the Company a US$1.1 million contract in June 2021, two years earlier than expected. The Company has developed an early scientific protype of the DeepView® technology with key optical and computing capabilities in a fully handheld, portable form.

Outlook: The Company will continue to develop the early scientific prototype into a fully engineered, production- ready model to support clinical studies.

Commercialization

At IPO: The Company stated it expected to commence commercial sales in the U.S. in Q4 of 2022 and UK and Germany in H2 2023.

Achieved: The Company has made substantial advancements on the commercialization pathway for DeepView® for both DFU and burn indications in 2021. Proceeds raised from its AIM IPO, combined with two successful BARDA contracts, positions Spectral MD to accelerate commercialization and achieve key business objectives.

Outlook: The Company's primary focus in 2022 remains to develop its products towards commercialization for both DFU and burn indications. The Company will build upon its human resource capabilities and infrastructure readiness to support key commercial initiatives to distribute DeepView® in the U.S and Europe.

People/Human Resources

At IPO: At IPO, the Company had 48 full time employees. The focus for the Company was to hire personnel in all areas to permit the Company to execute its corporate objectives.

Achieved: Since IPO, the Company added 11 employees and at year end had 55 full-time employees in the US and UK, which includes key hires such as our newly appointed Chief Financial Officer and Head of UK/EU Clinical Research.

Outlook: The Company will continue to make additional hires over the course of 2022 and beyond. The new hires will be made in all areas, as needed to enable the Company to realize its technology, IP, clinical, regulatory, and commercial goals in 2022 and 2023.

Finance

At IPO: At IPO, the Company stated that it will (i) continue to fulfil its contractual obligations and meet milestones under the BARDA contract; and (ii) pursue the commercialization of the DFU application in the U.S., UK and EU.

Achieved: The Company was granted US$40.5 million of funding in 2021, including US$18.8 million post IPO, to accelerate its burn training study. In addition, through its AIM IPO it raised US$15.6 million in gross proceeds to finance clinical trials, regulatory approvals, and commercialization for our DFU indication.

Outlook: The Company has a strong current cash position of US$16.1 million which is expected to enable the Company to pursue its objectives and to enhance the prospects of its future success.

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

Spectral MD is a predictive analytics company that develops proprietary AI algorithms and optical technology to help clinicians make more accurate and faster treatment decisions in the wound care sector. Using its DeepView® Wound Imaging Solution, an internally developed AI technology and multispectral imaging which has FDA Breakthrough Device Designation status, the Company is able to distinguish between damaged and healthy human tissue invisible to the naked eye, providing 'Day One' healing assessments for burn wounds and diabetic foot ulcers (DFU). Spectral is headquartered in Dallas, Texas, USA. The Company has received substantial support from the U.S. government for its application to burn wounds from agencies such as Biomedical Advanced Research and Development Authority (BARDA), National Science Foundation (NSF), National Institute of Health (NIH) and Defense Health Agency (DHA). Spectral currently has signed contracts in respect of the period from 12 November 2009 to 31 December 2022, with a total value of US$100 million with significant potential future funding that remains to be awarded. On 22 June 2021, the Company completed an AIM IPO, raising gross proceeds of US$15.6 million, to support the further development of the DFU indication.

About DeepView®

DeepView® is a predictive analytics platform that combines AI algorithms and medical imaging for wound prediction. It is non-invasive, non-radiation, non-laser and does not require the use of injectable dye. This integration can be characterized 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 color 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. DeepView®'s proprietary optics are able to extract millions of data points or AI model features 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 53 billion pixels with ever-growing clinically validated data points.DeepView® is designed to enable clinicians to make a more accurate, timely and informed decision regarding the treatment of the patient's wound.