



Enrolment completed for multi-center study for Diabetic Foot Ulcers (“DFU”)

Nov 18, 2021

Data being collected from 150 adult subjects to further develop DeepView® DFU application

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 the completion of enrolment for its IRB-approved multi-center training study to support the development of its DFU application for the DeepView® Wound Imaging System. The data collected from the study will bolster the existing clinical database of DFU images and clinical data to train and increase the current 83.3% decision support accuracy of the DeepView® algorithm for DFU.

The IRB-approved multi-center study enrolled a total of 150 adult subjects and was executed successfully and on schedule across six clinical sites in the U.S. The training study with data from all study subjects is expected to complete in December 2021.

The DFU images and clinical data collected will be incorporated into the database for the development of DeepView®'s DFU algorithm. It will also inform on key datapoints that will be captured in a planned validation study, which is expected to start around late Q1 2022 following the successful completion of the training study. Importantly, data collected will support the Company's applications for FDA and CE mark approval for DeepView®'s DFU indication, one of the necessary milestones required in order to commercialise DeepView®'s DFU application which is targeted towards the end of 2022.

The completion of enrolment for the multi-center study is an important milestone for the Company and illustrates that it is delivering on its expected milestones outlined at the time of its AIM IPO in June 2021. Proceeds raised at IPO will continue to support the development of DeepView® for the DFU application with its current training study and eventual validation study.

DFU is a severe chronic diabetic complication that consists of lesions in the deep tissues associated with neurological disorders and peripheral vascular disease in the lower limbs. It is the most frequently recognised, complex and costly symptom of diabetes and can lead to limb amputation if left undiagnosed, misdiagnosed or untreated. Due to U.S. reimbursement rules, physicians are currently required to wait 30 days to designate a DFU as non-healing before using advanced wound care therapies, resulting in higher probability of infections, longer healing times and significant lifetime medical costs for the patient. DeepView®'s early healing assessment for DFU would provide a significant improvement to the current standard of care, resulting in faster application of advanced therapy, better wound healing and reduced overall hospital visits and utilisation.

Wensheng Fan, Chief Executive Officer of Spectral MD, said: *“We are pleased to now complete the enrolment for the multi-center training study to further develop DeepView® for the DFU application. DFU images and data collected from the 150 subjects will be instrumental in improving the early healing assessment of DeepView® for DFU, which currently has a clinical accuracy of 83.3%.*

“Crucially, the enrolment completion highlights that we are on track regarding the Company's expected milestones outlined at the time of our June 2021 IPO. I look forward to providing further updates for investors as we continue to develop Spectral's ground-breaking Wound Imaging System for both the DFU and burn wound indications.”

Dr. Jeffrey Thatcher, Chief Scientist of Spectral MD, said: *“Meeting our 150 subject enrolment goal is a huge step in the process of commercialising our transformative technology. The study is collecting valuable DFU wound images that will be used to build a database for the development of a Machine Learning algorithm for DFU healing assessment, as well as exploring other DFU questions using images and clinical data obtained with the DeepView® technology.”*

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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 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 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.