



BARDA approval of additional \$18.8m funding

Sep 06, 2021

Funds will expand the DeepView training clinical study for burn wound

Total funding commitments of c. \$93m received from BARDA to date to support the development of Spectral MD's artificial intelligence and multi-spectral imaging for wound healing assessment

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 commitment of additional funding of \$18.8 million from the US Biomedical Advanced Research and Development Authority (BARDA), which will be used to expand the current clinical training study of Spectral MD's DeepView® Wound Imaging System for burn wound healing assessment.

This contract option funding of \$18.8 million under Option 1B of Spectral MD's current contract with BARDA follows the \$20.6 million awarded under Option 1A which was exercised by BARDA in March 2021 to execute the first stage of the clinical training study at five sites to train the DeepView® AI algorithm. The Option 1B funding announced today will allow Spectral MD to accelerate initiation of the second stage of this clinical training study. The second stage will expand from five to a total of ten clinical sites, and from 100 to a total of 250 clinical subjects and is expected to continue until Q4 2022. The DeepView® Wound Imaging System received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") in 2018 for its burn indication and aims to provide burn wound healing predictions on Day 1 to assist a physician's decision on treatment choices to reduce the patient's pain and suffering, improve clinical outcomes, and decrease the economic burden for the patient, hospital, and payor.

The study, which commenced on 9 August 2021, remains focused on collecting burn wound data from real-world clinical patients, representative of the US Burn population, including adult and paediatric subjects. This data will allow Spectral MD to complete the development and training of the DeepView® Wound Imaging System algorithm and finalize the system for the validation clinical study prior to submission for FDA clearance.

Spectral MD has received total funding commitments from BARDA to date of approximately \$93 million. Between 2013 and 2019, under the previous contract, the company received \$26 million in funding from BARDA. Under the current contract initiated in 2019, BARDA has to-date awarded \$66.8 million in funding, including \$27.3 million awarded in July 2019; \$20.6 million awarded under the Option 1A in March 2021; and \$18.8 million under Option 1B announced today. The initial \$27.3 million funding from BARDA has led to the development of the SnapShot DeepView Wound Imaging System into a highly portable, proprietary snapshot multi-spectrum imaging technology that can capture broad optical bands of wound tissue data in high resolution within milliseconds. This contract also contains an option to fund an additional \$22.1 million at a later date for the validation studies.

Wensheng Fan, Chief Executive Officer of Spectral MD, said: "We are grateful for the additional award of \$18.8 million from BARDA which was originally expected for March 2022. Due to the strong collaboration between BARDA, Spectral MD, and our clinical partners, we were able to have the successful kickoff of the study at the first five sites which has enabled the award of this funding earlier than anticipated. The Option 1B funding award will allow us to build a more streamlined training clinical study for the AI algorithm for DeepView®, enabling better timing and cost savings for our studies across the US, and helping to reduce the risks in clinical trials associated with COVID. BARDA's support has allowed Spectral MD to achieve many important milestones and this latest funding will further accelerate our development of DeepView."

Funding and technical support for development of DeepView® Wound Imaging System is provided by BARDA, under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. 75A50119C00033. For more information about BARDA, refer to <https://www.medicalcountermeasures.gov/>.

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.

The Company has two principal trading subsidiaries, Spectral MD, Inc. and Spectral MD UK Limited.

DeepView®

DeepView® is a predictive analytics platform that integrates AI algorithms and advanced optical technology for wound healing prediction. 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 physician 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 of appropriate candidates for surgery as well as determining what specific areas of the burn wound will require skin grafting. DeepView®'s current accuracy for burn wounds is 91 per cent., compared with current physician accuracy of 50 per cent. to 70 per cent. 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.