![Spectral AI® — Seeing the Unknown]

Intention to Float on AIM

Jun 07, 2021

Wound care AI company, focused on predictive analytics for faster treatment decisions to seek admission to AIM and raise funding through an IPO

LONDON, U.K. AND DALLAS, TX, U.S. Spectral MD Holdings, Ltd., a predictive analytics group that develops proprietary AI algorithms and optical technology for faster treatment decisions in wound care, announces its intention to seek admission of the entire issued and to be issued common stock of the Company to the AIM market of the London Stock Exchange ("**Admission**").

Spectral's DeepView® Wound Imaging Solution is an internally developed AI and multispectral imaging technology that enables the user 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, in the United States of America. The Group 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 Institutes 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$75.9 million with significant potential future funding that remains to be awarded.

DeepView® already has FDA Breakthrough Device Designation status for the burn indication and the Company is seeking to conduct a conditional placing of shares ("**Placing**") principally to provide further funding to undertake additional clinical trials for the DFU application in the U.S., UK and EU, which is a larger commercial market than burn wound assessment. The Company is also looking to develop a UK-based EMEA headquarters to support CE-Mark approval and commercial expansion.

SP Angel Corporate Finance LLP is acting as Nominated Adviser, Broker and Bookrunner in relation to the proposed Placing.

Key highlights

- Net proceeds from the IPO will be used by the Company to:- provide capital for the development of DFU technology which will include investment in additional clinical studies supporting the indication along with progressing regulatory filings;- build a European presence from which to progress specific European regulatory approvals and subsequently to implement the Group's sales strategy to sell the Group's DeepView® product into various targeted European jurisdiction;- build a U.S distribution network; and- provide working capital for the Group.
- Admission and commencement of dealings on AIM expected to take place in late June 2021

The Company will publish an Admission Document which will be available in due course on the Company's website: https://www.spectralmd.com/

Wensheng Fan, CEO of Spectral MD Holdings, Ltd., said: *"We are very pleased to announce our intention to float on AIM. We will use the proceeds from the fundraise to undertake additional clinical trials for the DFU application which will allow us to tap into a significant and continually growing market worldwide, with diabetes affecting over 30 million people in the US and more than 415 million worldwide.*

"Our technology enables clinicians to make 'Day One' decisions on burn injuries which can significantly decrease patient recovery time and the outcome of the healing process. The admission to AIM will enable us to further develop our DFU application, build a greater UK and European presence, and gain the necessary regulatory approvals to bring the DeepView® technology into these markets.

"We look forward to welcoming support from investors which will help expand our technology to new applications and support patient recovery from life changing injuries worldwide."

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About Spectral MD Holdings, Ltd. (www.spectralmd.com**)**

Background and history

Spectral MD Holdings, Ltd. was established through the technology transfer department of the University of Texas Southwestern with its operating subsidiary being incorporated in the State of Delaware, U.S., in 2009. The Group's initial focus was to provide clinicians with the ability to understand and predict pressure ulcers for bed-ridden patients. NSF grants supported these endeavours until the Group's focus shifted to providing healing assessments for burn wounds.

From 2013 to 2019, the Group engaged in and completed a BARDA contract valued at US$26 million, referred to as BARDA Burn I, to investigate the use of its technology as a surgical-triage tool for burn victims in a mass casualty event.

In 2018, the FDA designated the DeepView® technology with Breakthrough Device Designation status for its burn indication. It is not common for a medical technology to have gained such prestigious acknowledgement and therefore this status not only emphasises the FDA's recognition of DeepView®'s scientific and technological value, but also provides the Group with an expedited regulatory framework for the burn application and expectation of Medicare reimbursement for a period of four years post FDA approval.

Stemming from the completion of BARDA Burn I, the Group focused its technology on the integration of multi-spectral imaging and AI algorithms and began exploring other clinical applications, such as DFUs and level of amputation selection. In July 2019, the Group entered into a second contract with BARDA, referred to as BARDA Burn II, to further develop the DeepView® technology as a medical countermeasure for mass casualty events. The performance period for this contract is four and a half years and is valued at up to US$89 million across all its phases.

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 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.
- 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.
- The AI algorithm then produces a wound healing prediction 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 follow-up or risking patient noncompliance with standard wound therapy. The current clinical accuracy of DeepView® is 83 per cent. for DFUs. For burn wounds, the clinician can make an immediate and objective determination for 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. DeepView® demonstrates a much higher diagnostic accuracy for burn wounds and DFUs.

The Market – Unmet clinical need

To the Group's knowledge, there are no diagnostic imaging products that provide clinicians with an objective and immediate assessment of a wound's healing potential and which benefit from the application of AI. Currently, healthcare professionals rely on their experience and subjective assessments to determine if wounds, such as burn injuries and DFU, will respond to therapeutic treatment.

Burns

In the U.S. and UK, respectively, there are approximately 490,000 and 87,000 burn victims who receive emergency medical treatment each year. Burn victims have varying degrees of tissue damage upon initial admission to the emergency room and burn surgeons must evaluate tissue viability as either healing or non-healing to determine what areas of the burn wound must be surgically excised for grafting. Management has identified that clinicians have a 50 to 70 per cent. accuracy in assessing the viability of burned tissue. Physicians typically admit the patient for a period of up to 21 days to wait for the viable tissue to present itself as healing or non-healing before taking the patient to surgery. Unfortunately, this "wait and see" period comes at an above average cost for the facility and duress for the burn victim. Currently, the average hospital stay is 8.1 days with an average cost of approximately US$24,000. DeepView® provides the physician with a 'Day One' healing assessment and enables the physician to triage the patient to the appropriate setting sooner. In addition, the technology assists the physician in accurately determining which areas of the burn wound are appropriate for excision and grafting.

DFU

Diabetes (type 1 and type 2) affects over 30 million people in the US alone and more than 415 million people worldwide. 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.

There is a large and growing number of diabetic patients who suffer from DFU, with over 4 million, 0.2 million and 1 million receiving treatment in the U.S., UK and EU respectively every year. However, there is currently no effective diagnostic pathway for DFU patients in the U.S., the UK or EU. In the U.S., patients must undergo standard wound care therapy for 30 days prior to receiving advanced wound care therapy (negative pressure wound therapy, synthetic skin substitute grafts, and hyperbaric oxygen therapy).

Many of these chronic wounds will not respond to standard wound care therapy and would have benefited from advanced wound care therapy on 'Day One'. Further complicating this clinical issue, management has identified that clinicians' wound healing predictions have a 50 per cent. accuracy rate. DeepView®'s primary objective is to provide physicians with a healing prediction that enables them to therapeutically intervene earlier in the patient's care pathway. Unfortunately, diagnostic tools to assess the healing potential of DFUs, such as trans-cutaneous oxygen measurement (TCOM), ankle-brachial index (ABI), and doppler ultrasounds do not provide a wound healing prediction. These systems are often inaccurate and only provide a range of values that indirectly correlate to wound healing. All current systems claiming to be effective in determining DFU healing potential measure only one physiologic parameter, however, the Company believes that a single parameter cannot effectively discriminate healing from non-healing DFUs. The American Heart Association stated in a 2019 scientific summary that "No single vascular test has been identified as the most important predictor of wound healing or major amputation for the threatened limb". In the U.S., DFU patients have an annual cost of up to US$63,100 per patient and see an outpatient provider, on average, 15.5 times per year. Non-healing DFUs in the UK are reported as being four times more expensive than DFUs that heal. DeepView® aims to reduce waiting times, minimise patient costs and lower the probability of infections by offering advanced wound care therapy on 'Day One'.