Conditional Placing to raise approximately £11.3 million (US$16.0 million)

Jun 16, 2021

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Conditional Placing to raise approximately £11.3 million (US$16.0 million)

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 that it has conditionally raised approximately £11.3 million (US$16.0 million) by way of an oversubscribed placing ("Placing"). Completion of the Placing is conditional upon admission which is expected to occur at 8:00a.m on or around 22 June 2021.

Accordingly, an Admission Document dated 16 June 2021 has today been published and will shortly be available on the Company's website at www.spectralmd.com

Key Placing Statistics

Valuation prior to Admission at the Placing Price (assuming exercise of all Share Options)	£95 million
Placing price (per share of New Common Stock)	59 pence
Existing Common Stock	117,009,267
New Common Stock being placed on behalf of the Company[1]	19,067,797
Common Stock in issue immediately following Admission	136,077,064
Market capitalisation on Admission at the Placing Price[2]	£80 million
Share Options outstanding on Admission	43,549,926
Fully diluted Common Stock following Admission (assuming exercise of all Share Options)	179,626,990
Market capitalisation on Admission at the Placing Price (assuming exercise of all Share Options)[2]	£106 million
New Common Stock as a percentage of the Enlarged Share Capital	14.0 per cent.
Gross proceeds of the Placing receivable by the Company	£11.3 million
Estimated net proceeds of the Placing receivable by the Company	£9.5 million
ISIN	USU8457V1099
SEDOL	BKY4VZ9
TIDM	SMD
LEI	213800VXW1FVGWTCKL44

1. This figure includes EIS/VCT New Common Stock
2. The market capitalisation of the Company at any given time will depend on the market price of the Ordinary Shares at that time. There can be no assurance that the market price of an Ordinary Share will equal or exceed the Issue Price.

Publication date of the Admission Document	16 June 2021
Unconditional issue of the EIS/VCT New Common Stock	20 June 2021

Conditional issue of the New Ordinary Shares (other than the EIS/VCT New Common Stock)	22 June 2021
Admission and dealings commence in the Common Stock on AIM	8.00 a.m. on 22 June 2021
Expected date for CREST accounts to be credited with Depositary Interests in respect of New Common Stock	22 June 2021
Despatch of definitive share certificates for New Common Stock in certificated form (where applicable)	By 6 July 2021

Defined terms used in this Announcement carry the same meanings as those ascribed to them in the Company's Admission Document, unless the context requires otherwise.

Spectral MD is a predictive analytics group 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 system which has designated FDA Breakthrough status, the Group 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).

The Group 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 burns application for its DeepView® system.

The Group is seeking admission to AIM to provide further funding to undertake clinical trials for the DFU application, which is a larger market than burn wound assessment, in the US, UK and EU and to develop a UK-based EMEA headquarters to support CE-Mark approval and commercial expansion.

The Company has one principal trading subsidiary Spectral MD, Inc. The Company has established a permanent establishment in the UK from which it will be growing its business in the UK and EU.

For further information please contact:

Spectral MD Holdings, Ltd.	investors.spectralmd.com
Wensheng Fan, Chief Executive Officer	via Walbrook PR
Wan Lung Eng, Chief Financial Officer	
SP Angel Corporate Finance LLP (NOMAD & BROKER)	Tel: +44 (0)20 3470 0470
Stuart Gledhill/Caroline Rowe (Corporate Finance) Vadim Alexandre/Rob Rees (Sales & Broking)	
Walbrook PR Ltd (Media & Investor Relations)	Tel: +44 (0)20 7933 8780 or spectralMD@walbrookpr.com
Paul McManus/Sam Allen Alice Woodings	Mob: +44 (0)7980 541 893 / +44 (0)7502 558 258 +44 (0)7407 804 654

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, US, 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 US, 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'.