Admission to trading on AIM & First Day of Dealings

Jun 22, 2021

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, is pleased to announce the admission of its entire issued share capital, being 136,077,064 shares of common stock, to trading on AIM ("Admission") will take place and dealings will commence at 8.00 a.m. today under the ticker 'SMD' and ISIN 'USU8457V1099'.

The Company's Admission Document was published on 16 June 2021 and is available here: https://investors.spectralmd.com

Summary and Highlights:

- Oversubscribed Placing for gross proceeds of £11.3 million (c.US$16 million)
- The Placing was conducted at a pre-IPO fully diluted valuation of £95m
- Placing price per share of common stock of 59 pence
- Market capitalisation (at the Placing Price) of approximately £80 million on Admission
- The 19,067,797 shares of New Common Stock being placed represent c.14 per cent. of the Enlarged Share Capital
- SP Angel Corporate Finance LLP acted as Nominated Adviser, Broker and Bookrunner in relation to the Placing and has been retained as the Company's Nominated Adviser and Corporate Broker from Admission

Introduction to the Group

Using its DeepView® Wound Imaging Solution, an internally developed AI technology and multispectral imaging system which has designated FDA Breakthrough Device, 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 Company has one principal trading subsidiary, Spectral MD, Inc., and has set up a permanent establishment in the UK from which it will be growing its business in the UK and EU.

Reasons for Admission to AIM and use of the proceeds of the Placing

The Directors believe that Admission will be an important step in the Group's development as it will assist in building the profile of its business, particularly in Europe where it is looking to spearhead growth, and will provide access to wider pools of capital.

The Group believes that Admission will 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 net proceeds of the Placing of the New Common Stock of approximately £9.5 million will be used to:

- provide capital for the development of the DFU product, this will include investment in 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 jurisdictions;
- build U.S distribution; and
- provide working capital for the Group.

The benefits of Admission, in addition to the proceeds of the Placing, will include ongoing incentivisation of key employees through share based incentivisation structures and building the profile of the Group in its key international markets.

Wensheng Fan, CEO of Spectral MD Holdings, Ltd., said: *"We are delighted with the support shown by institutional investors in our AIM IPO, which is a key milestone in our commercial development. Our technology enables clinicians to make 'Day One' decisions on burn injuries which can significantly reduce patient recovery time and improve the outcome of the healing process. These funds will support further development of our DFU application, build a greater UK and European presence and help the Company gain the necessary regulatory approvals to bring the DeepView® technology into these markets.*

"We are now well funded to develop our DFU technology through to commercial launch, which positions us well in a significant and continually growing market worldwide. Diabetes affects over 30 million people in the US and more than 415 million globally.

"Spectral MD has the opportunity to support patient recovery from life-changing injuries worldwide and revolutionise the management of wound care. We look forward to keeping our shareholders updated as we deliver on that mission."

For further information please contact:

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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 US State of Delaware 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.

In 2018, the US Food & Drug Administration ('FDA') designated the DeepView® technology as a Breakthrough Device 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.

From 2013 to 2019, the Group engaged in and completed a BARDA contract, 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.

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 of 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 US 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'.