

## Annual Report and Accounts for the year ended 31 December 2021



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### Introduction

I am delighted to report on the Company's first annual results since IPO in June 2021. 2021 was a transformational year for Spectral MD with the Company achieving all key operational milestones. The Company is now well positioned to succeed in further milestones that are foundational to our planned regulatory approvals and commercialization plans.

We successfully raised gross proceeds of £11.3 million (US\$ 15.6 million) at IPO and retained a strong cash position at year end of US\$ 16.1 million. Over the course of 2022 and 2023, we will use the proceeds to finance clinical trials, regulatory approvals, development and commercialization for our Diabetic Foot Ulcer (DFU) indication. Our Burn indication continues to be well supported through non-dilutive US Government funding.

### 2021 Business Update

The Company's achievements since IPO and plans for 2022 and beyond are set out below.

#### Finance

- At IPO: Upon listing, Company stated that it will:
  - continue to fulfil its contractual obligations and meet milestones under the BARDA contract and
  - pursue the commercialization of the DFU application in the US, UK and EU.
- Achieved: The Company was granted US\$ 40.5 million of funding in 2021, including US\$ 18.8 million post IPO, to accelerate its burn training study. In addition, through its AIM IPO it raised US\$ 15.6 million in gross proceeds to finance clinical trials, regulatory approvals, and commercialization for our DFU indication.
- Outlook: The Company has a strong current cash position of US\$ 16.1 million which is expected to enable the Company to pursue its objectives and to enhance the prospects of its future success.

### Commercialization

- At IPO: The Company stated it expected to commence commercial sales in the US in Q4 of 2022 and UK and Germany in H2 2023.
- Achieved: The Company has made substantial advancements on the commercialization pathway for DeepView<sup>®</sup> for both DFU and burn indications in 2021. Proceeds raised from its AIM IPO, combined with two successful BARDA contracts, positions Spectral MD to accelerate commercialization and achieve key business objectives.
- Outlook: The Company's primary focus in 2022 remains to develop its products towards commercialization for both DFU and Burn indications. The Company will build upon its human resource capabilities and infrastructure readiness to support key commercial initiatives to distribute DeepView<sup>®</sup> in the US and Europe.

### BARDA - Biomedical Advanced Research and Development Authority

- At IPO: The Company had been awarded the BARDA contract Option 1A (US\$ 20.6 million), granted in March 2021, and Option 1B (US\$ 18.8 million) was expected to be granted in 2022 to execute the adult and pediatric multi-center clinical training study.
- Achieved: Spectral MD received the Option 1B US\$ 18.8 million six months ahead of schedule in 2021 due to a successful expanded proof of concept (ePOC) outcome. The accelerated funding, which takes the total BARDA awarded contract funding into the Company to over US\$100 million, allows the Company to accelerate initiation of the second stage of the clinical training study with confidence.

## Chairman's Statement

#### continued

Outlook: The Company expects to successfully complete the currently planned Option 1A and 1B 250 subject clinical study in 2022. Upon successful completion of the study, the Company expects to see high performing algorithm results across demographic and geographic variability in the study population. The Company is excited for the continued collaboration with BARDA, as we work together into the next contract phase.

#### **DFU – Diabetic Foot Ulcers**

- At IPO: The Company expected to meet the 150 subject enrollment goal for the DFU US training study and complete the study by year end.
- Achieved: The Company successfully completed the 150 subject DFU US training study on schedule across six clinical sites in December 2021.
- Outlook: Following successful completion of the training study, the trained DFU AI algorithm performance has been determined, and additional newly developed product features are being incorporated. In 2022, the Company will start and expects to finish the validation study for the DFU AI algorithm in the US. In the second half of 2022, the Company expects to start the DFU clinical study in the EU, where the data collected will be combined and compared with US data to expand DeepView<sup>®</sup> readiness in both the US and CE marked regions. The Company's focus will be on the continued development of the DFU AI model as we progress into the validation study.

#### **DHA - Defense Health Agency**

- At IPO: The Company intended to develop a miniaturized, fully hand-held version of DeepView<sup>®</sup>.
- Achieved: The DHA awarded the Company a US\$ 1.1 million contract in June 2021, two years earlier than expected. The Company has developed an early scientific protype of the DeepView<sup>®</sup> technology with key optical and computing capabilities in a fully handheld, portable form.
- Outlook: The Company will continue to develop the early scientific prototype into a fully engineered, production- ready model to support clinical studies.

#### People and Human Resources

- At IPO: The Company had 48 full-time employees and the focus was to hire personnel in all areas to permit the Company to execute its corporate objectives.
- Achieved: Since IPO, the Company has added 11 employees and at year end had 55 full-time employees in the US and UK, which includes key hires such as our newly appointed Chief Financial Officer and Head of UK/EU Clinical Research.
- Outlook: The Company will continue to make additional hires over the course of 2022 and beyond. The new hires will be made in all areas, as needed to enable the Company to realize its technology, IP, clinical, regulatory, and commercial goals in 2022 and 2023.

## Chairman's Statement

continued

### Outlook

2022 is set to be an exciting year for Spectral MD. In November 2021, we welcomed Nils Windler as CFO of the Company and his expertise in the commercialization of high growth companies will be greatly valued.

In 2021, we were awarded new contracts worth US\$ 40.5 million with the US Biomedical Advanced Research and Development Authority (BARDA) and total funding awarded from BARDA is now over US\$ 100 million. We have initiated the second stage of the burn Artificial Intelligence ("AI") clinical training study, where the research has been expanded from five to a total of ten clinical sites, and from 100 subjects to a total of 250 subjects and is on track to meet the 250 subject enrollment target across 10-12 sites in the US by Q4 2022.

We remain committed to creating shareholder value in the business as we look to commercialize DeepView<sup>®</sup> for DFU and burn indications, and continue to realize the milestones and business objectives set out at IPO. I look forward to continuing to update shareholders as we progress.

In closing, I would like to thank everyone of Spectral MD's employees for the benefits they are creating for prospective patients globally, and for the value they are creating for the Company and our shareholders. I look forward to updating our shareholders as we progress.

Martin Mellish Chairman

### TO THE MEMBERS OF SPECTRAL MD

I am pleased to present the audited final results for the twelve months ended 31 December 2021 for Spectral MD, Holdings, Ltd. 2021 was a year focused on sizable expansion, and development of our DeepView® technology and operations.

- In the year ended 31 December 2021 and the immediate post-period, the Company made substantial progress towards its goal of seeking FDA approval and commercialization of its DeepView<sup>®</sup> Wound Imaging Technology.
- The Company's results, across key performance metrics, reflect both the committed dedication to our mission and operational discipline.
- Strong financial and clinical top line results, showing excellent AI performance metrics, give the Company great confidence in the DeepView<sup>®</sup> technology. We believe it will be instrumental in disrupting current treatment pathways and improving the standard of care for many patients across multiple geographical markets, and in multiple applications.

We look forward to building upon our strong momentum, whilst continuing to collaborate with BARDA and our clinical partners to scale and advance our transformative technology.

### FINANCIAL REVIEW

The Company met its 2021 milestones for both its Burn and DFU applications and was able to end the year with a higher-than-expected cash position of US\$ 16.1 million (2020: US\$ 5.1 million). While grant revenue of US\$ 15.2 million (2020: US\$ 17.3 million) was broadly in line with market expectations, expenses of US\$ 19.2M (2020: US\$15.9 million) were lower, leading to a better-than-expected negative adjusted EBITDA of US\$ (3.0) million (2020: US\$ 3.7 million). The unfortunate circumstances of COVID-19 and resulting limitations of travel and in-person-meetings forced us and our partners to utilize remote technology to accomplish our goal, with a corresponding reduction in costs. Furthermore, we were able to utilize our US. resources to drive UK related milestones given the challenging COVID-19 environment in the UK and EU, which also contributed to lower expenses.

In June 2021, we successfully raised US\$ 15.6 million as part of our IPO on the AIM market of the London Stock Exchange. Those funds are designated for clinical trials, regulatory approvals, and commercialization efforts for our DFU application through to 2023. Despite the COVID-19 circumstances, we completed the enrollment of our DFU training study as planned. Grant revenue from BARDA remains our largest source of revenue. Following the award of the first option of our BARDA Burns contract (US\$ 20.6 million) in March 2021, we have been successful in securing additional funding of US\$ 18.8 million through the second option of this contract in early September 2021, six months ahead of schedule.

### **BURN INDICATION**

#### Funding

Spectral MD has received substantial support from the US. government with contracts from institutions such as BARDA, National Science Foundation("NSF"), National Institute of Health ("NIH") and DHA in support of the burn application for its DeepView<sup>®</sup> solution. Total grant funding awarded to date from these organizations is over US\$ 100 million, including US\$ 40.5 million awarded during 2021. This grant funding is non-dilutive to our shareholders, and the Company believes it validates the important nature of its mission and technology.

Following the successful completion of the ePOC multi-center clinical study in Q1 of 2021, the Company received two additional grants, US\$ 20.6 million in March 2021 and US\$ 18.8 million in September 2021, to bolster the Company's existing clinical database to train the AI algorithm, and to improve the DeepView® technology in early burn wound healing assessment. The US\$ 20.6 million contract awarded under Option 1A was exercised by BARDA in March 2021 to execute the first stage of the clinical training study to train the DeepView® AI algorithm at five sites. The contract option funding of US\$ 18.8 million under Option 1B of the Company's current contract with BARDA was granted six months ahead of schedule, which enables Company to accelerate the initiation of the second stage of this clinical training study with confidence.

continued

This Option 1B second stage will expand the study 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. In the year ended 31 December 2021 and immediately post period, enrollment in the expanded clinical training study is strong and on schedule across eight clinical sites.

The updated US Government Broad Agency Announcement announced in November 2021 effectively closed the door for potential competitors to Spectral MD for burn healing assessment technologies.

#### Clinical study results

The results from the ePOC multi-center clinical study were presented at three scientific presentations at the Southern Region Burn Conference held from 4-7 November 2021, in New Orleans, Louisiana. The top-line results showed an excellent Al performance metric. The results of the first multi-center study using Spectral MD's burn imaging technology included 124 adult and pediatric participants.

In adult participants, the performance showed 92% accuracy, with cross-validation from the AI model for identification of non-healing burn regions. This represents an improvement on the previously reported accuracy of 91% for the DeepView<sup>®</sup> Wound Imaging Solution in early healing assessment of adults.

In pediatric patients the AI performance showed 88% accuracy, underlining how the technology is responding with significant reliability to variability in the study population. Based on these strong results, the Company has bolstered its infrastructure to facilitate the expansion of the study to additional sites and has begun enrollment in a larger study in order to complete the AI algorithm's development.

#### **FDA** communication

In the year ended 31 December 2021, the Company submitted an FDA pre-submission request. This advises the FDA that the Company will expand the clinical data set to include burn wound data from emergency departments. The Company believes that the site-of-service for the DeepView<sup>®</sup> Wound Imaging technology will be utilized in both burn care centers and emergency departments. Expanding our data set to both burn care centers and emergency departments. Expanding our data set to both burn care centers in the US, in fulfilment of BARDA's mass casualty countermeasures mission. The Company is excited to expand its focus to emergency departments, as it believes that DeepView<sup>®</sup> is well positioned to have a substantial impact on burn wound treatment in this setting.

### **DFU INDICATION**

In November 2021, the Company completed enrollment for its Institutional Review Board (IRB) approved multi-center training study to support the development of its DFU application for the DeepView<sup>®</sup> Wound Imaging System. The study enrolled a total of 150 adult subjects and was executed successfully and on schedule across six clinical sites in the US.

The DFU images and clinical data collected are currently being incorporated into the database for the development of DeepView<sup>®</sup>'s DFU algorithm. The data will also inform on key datapoints that will be captured in a planned validation study, and the incorporation of additional newly developed features. Data collected throughout the study will support the Company's applications for FDA and CE mark approval for DeepView<sup>®</sup>'s DFU indication - one of the necessary milestones required to commercialize DeepView<sup>®</sup>'s DFU application. The completion of enrollment for the multi-center study is an important milestone and illustrates how the Company is delivering on the expected milestones it outlined at the time of its AIM IPO in June 2021.

The development of the DeepView<sup>®</sup> system for the DFU application and the user interface software have seen substantial progress in 2021. Verification and validation of the user application software for DFU along with the DFU system specification capabilities were completed by the end of 2021.

continued

## DEFENSE HEALTH AGENCY (DHA)

On 23 June 2021, the Company was awarded a two-year, US\$ 1.1 million, Sequential Phase II Small Business Technology 5 Transfer (STTR) contract by the DHA within the US. Department of Defense. This funding enables the Company to research and develop a fully portable, handheld version of the DeepView<sup>®</sup> solution. The Company has previously been awarded STTR Phase I and Phase II contracts from the DHA. In July 2021, the Company held a kick-off meeting with DHA to review the two-year project timeline. It is anticipated that Stage One of the study will focus on system development, Stage Two will develop a fully handheld prototype and Stage Three will be a clinical study with the Burn Center at University Medical Center New Orleans to validate the system prototype. The Sequential Phase II contract will fund all three referenced stages.

In the 12-month period ended 31 December 2021, the Company has made considerable progress in the development of the miniaturized DeepView<sup>®</sup> technology. The Company has developed an early scientific prototype of the DeepView<sup>®</sup> technology with key optical and computing capabilities in a fully handheld, portable form. Upon review in a joint meeting with the DHA, both the Company and DHA are committed to developing this into a more engineered, production-ready prototype to support upcoming clinical studies. The Company is on track to meet the milestones for the study and looks forward to the continued progression of the miniaturized version of the DeepView<sup>®</sup> technology.

# PROPRIETARY AND CLINICALLY VALIDATED WOUND IMAGE DATABASE FOR AI DEVELOPMENT

As of 31 December 2021, approximately 8.1 terabytes and 174 billion pixels worth of proprietary DFU and burn data have been acquired and utilized for the deep learning algorithms training. This presents a significant barrier to entry to would-be competitors in wound care healing assessments.

## INTELLECTUAL PROPERTY (IP) DEVELOPMENT

The Company places a significant emphasis on obtaining and protecting its intellectual property. In 2021, the Company filed a total of 15 new applications, including 12 foreign applications (national phase filings in the Snapshot and DFU families), two international PCT applications (wound healing prediction with optical biomarkers, and histology/burns), and one new provisional application (updated Snapshot disclosure using single aperture and multiplexed illumination).

Four new patents were allowed or issued in 2021, including a US. patent in the Snapshot family, a China National patent in the Multi-spectral Imaging (MSI) tissue classification family, and Japan and European patents in the original MSI+ Photoplethysmography (PPG) tissue classification family. The granted European patent has been validated in Belgium, Germany, France, and the UK.

The Company has the following eight active patent application families:

- Burn/Wound classification on MSI and PPG
- Tissue classification on MSI and PPG
- Amputation site analysis on MSI, machine learning and healthcare matrix
- DFU healing potential prediction and wound assessment on MSI, machine learning and healthcare matrix
- High-precision, multi-aperture, MSI snapshot imaging
- Wound assessment on MSI, optical biomarkers, and machine learning
- Burn/Histology assessment on MSI and machine learning
- High-precision single-aperture snapshot imaging with multiplexed illumination

continued

### PEOPLE AND ORGANIZATION

Continuing to build a focused and highly skilled team is critical to our growth. The Company added 27 employees during the fiscal year 2021 and currently has 55 full-time employees in the US and UK and has and will continue to make additional hires over the course of 2022 and beyond. The new hires will be made in all areas, though in particular in operations, sales, marketing, and government contracts. This will further enable the Company to meet its technology, IP, clinical, regulatory, and commercial goals in 2022 and 2023.

In December 2021, the Company was pleased to announce the appointment of Nils Windler as Chief Financial Officer. Mr. Windler specializes in healthcare and life sciences and has more than 20 years' finance and operations experience. In addition, Mr. Windler has a successful track record of leveraging his financial, operations and sales experience to drive revenue growth and to enhance profitability and has overseen organizational transformation at the previous companies at which he has served. He also has built a considerable reputation and expert knowledge having worked for multiple global organizations and has been responsible for business transformation at high growth companies. We are confident that his strong financial acumen, proven track record, and deep understanding of our industry makes him an ideal fit to lead Spectral MD's financial team. I look forward to working closely with Nils to accelerate commercialization, to execute our business initiatives, and to pursue our routes to markets.

In 2022, the Company successfully filled, amongst others, the critical position of Vice President of Marketing and Commercialization as well as Director of Regulatory Affairs. Maria Cadic, Vice President of Operations, decided to leave the Company for personal reasons.

### **BUSINESS OUTLOOK**

The Company continues to believe that it has developed a unique diagnostic imaging solution that has no direct competition in the assessment of wound healing potential. Given the large addressable DFU market and the potential of the BARDA contract, the Company is optimistic that DeepView® has the potential to disrupt current treatment pathways, and to improve the standard of care for many patients across multiple geographical markets and applications. During 2021, the Company achieved several important milestones, and it remains highly focused on its goal of commercializing its transformative DeepView® technology. The Company is confident that it will continue to build upon the expansion and development it experienced in 2021. We are well-placed to address challenges and opportunities, based on underlying financial strength, a resilient organization, a validated technology, and a diversified business model.

#### Burn

We look forward to successfully completing the Options 1A and 1B 250 subject clinical study. Upon successful completion of the study, the Company expects to see high performing algorithm results across demographic and geographic variability in the study population. The Company is excited for the continued collaboration with BARDA, as we work together into the next contract phase. Spectral MD is in constant communication with BARDA to further develop our human resource leadership and infrastructure readiness for a federal level commercial contract. The Company is committed to up scaling its operations and infrastructure to support BARDA's procurement needs to distribute the DeepView® technology into clinics in the US.

#### DFU

In 2022, the Company will start, and expects to finish, the validation study for the DFU AI algorithm in the US. Further, in the second half of 2022 the Company expects to start the DFU clinical study in the EU, where the data collected will be combined and compared with US data to expand DeepView<sup>®</sup> readiness in both the US. and CE marked regions. The Company is optimistic about the potential to accelerate the development of the DFU application and to expand into the UK and EU.

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#### DHA

The Company believes that the recently awarded DHA contract has potential for US. Government procurement by the US. military and first responders as well as other militaries in the world, as permitted by law. A fully hand-held version of DeepView® not only expands the market to the US. military, but also has the potential to enable in-home use for DFU and other consumer applications, beyond the anticipated DHA applications. In 2022, we will continue to build upon the great progress achieved in 2021, towards the realization of a miniaturized device. The Company will continue to develop the early scientific prototype into a more engineered, production-ready prototype to support clinical studies. The Company is on track to meet the milestones for the study and looks forward to the continued progression of the miniaturized version of the DeepView® technology.

#### Commercialization

The Company's primary focus for 2022 is the accelerated commercialization for both DFU and burn indications. We look forward to the planned validation study, now expected to start in Q2 2022. 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 to commercialize DeepView®'s DFU application. The Company is firmly focused on developing its resource infrastructure in a timely manner to prepare for the needs of a potential procurement contract with the US federal government. The Company expects that realization of each milestone will create significant value for the Company in commercializing its technology.

#### Financial

Throughout 2021, the Company demonstrated its financial stability and the value which it can generate, even during a pandemic environment. The Company will continue to build on the Option 1A and 1B funding under the BARDA contract throughout the rest of 2022 and into 2023 to drive the clinical training study of the DeepView<sup>®</sup> Wound Imaging Solution. The Company has a strong cash position of US\$ 16.1 million at 31 December 2021, which will enable it to pursue its objectives and to realize its commercial opportunities.

#### **R&D** outlook

Based on the existing platform in development for chronic DFU and acute burn wounds, the Company sees the potential to expand into other wound types such as Venous Leg Ulcers, Critical Limb Ischemia, and Amputation. Furthermore, future generations of the Company's algorithm potentially enable its utilization in the early detection and prevention of wounds, supporting wound treatment decision making, and in the provision of valuable information in the follow up evaluation of the therapy efficiency as well as in the insurance reimbursement process.

### **CLOSING STATEMENTS**

The Company has made substantial advances towards commercialization of DeepView<sup>®</sup> for both burn and DFU indications. Gross proceeds raised at the time of IPO of US\$ 15.6 million combined with two successful BARDA contract awards positions Spectral MD to accelerate commercialization and achieve key business objectives in 2022.

We believe a critical metric in this phase of our Company's history is ongoing government grant support, primarily from BARDA, but also from other sources. This non-dilutive grant funding, over US\$ 100 million which has been awarded since the Company's inception and of which US\$ 40.5 million which was awarded in 2021, enables Spectral MD to conduct important R&D efforts, and to develop and improve the Company's AI and optical technology performance. We believe that these R&D efforts also materially enhance the likely success of our future regulatory and commercial prospects.

Our primary focus is on achieving the core business objectives which we set out for the Company in its AIM admission document. We continue to opportunistically evaluate additional indications, market opportunities and other initiatives that may enhance our potential for commercial success and shareholder value.

Wensheng Fan Chief Executive Officer

### ABOUT SPECTRAL MD

Spectral MD is a predictive analytics company 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 and multispectral imaging technology which has FDA Breakthrough Device Designation status, the Company 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). Spectral MD is headquartered in Dallas, Texas, USA. The Company has received substantial support from the US government for its application to burn wounds from agencies such as Biomedical Advanced Research and Development Authority (BARDA), National Science Foundation (NSF), National Institute 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\$ 100 million with significant potential future funding that remains to be awarded. On 22 June 2021, the Company completed an AIM IPO, raising gross proceeds of US\$ 15.6 million, to support the further development of the DFU indication.

## ABOUT DEEPVIEW®

DeepView<sup>®</sup> 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 characterized into four distinct components: DeepView<sup>®</sup> imaging, data extraction, AI model building and AI wound healing prediction.

The DeepView<sup>®</sup> imaging technology consists of patented proprietary multi-spectral optics and sensors which 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 color 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<sup>®</sup>'s proprietary optics can 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 174 billion pixels with ever-growing clinically validated data points.

DeepView<sup>®</sup> is designed to enable clinicians to make a more accurate, timely and informed decision regarding the treatment of a wound and, as a result, improves patient outcomes in terms of speed and ease of diagnosis, efficiency of care and shortened length of hospital stay.

## Product Overview and Strategy

Spectral MD is a predictive analytics Company that develops proprietary optical technology and Al algorithms to help clinicians make more accurate and faster treatment decisions in the wound care sector. Using its DeepView<sup>®</sup> Wound Imaging Device, an internally developed multispectral imaging device which has designated FDA Breakthrough status, the Company 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). DeepView<sup>®</sup>'s output is specifically engineered to allow the physician 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 the current approach that involves waiting up to 30 days to see how the wound develops before making a clinical assessment. The accuracy of DeepView<sup>®</sup> is 81 percent. for DFUs compared to current clinical accuracy of 50 percent. For burn wounds, the clinician can make an immediate and objective determination for appropriate candidates for surgery as well determining what specific areas of the burn wound will require skin grafting. DeepView<sup>®</sup>'s current accuracy for burn wounds is 92 percent for adults, compared with current physician accuracy of 50 to 70 percent.

#### Commercialization:

#### US

The Company intends to sell the DeepView<sup>®</sup> technology to inpatient and outpatient sites of care throughout the US. Podiatry practices are typically the first line of specialty care for DFUs in the US, but vascular and cardiology companies and outpatient wound centers also treat wounds. Sales will initially target podiatry practices presiding in areas with high prevalence of diabetes such as the south and southeastern areas of the US. Large hospital systems with outpatient wound care centers will also be targeted as they serve a large volume of DFU patients. The solution will have two revenue streams, a SaaS (software as a service) model and a capital sale component. The SaaS model will feature a fixed annual software licensing fee and a variable per-image fee that includes maintenance, image hosting, access to the artificial intelligence algorithms and access to algorithm updates. The capital sale component will be competitively priced to not become a barrier for independent practices and clinics.

The Company started to build up its Sales and Marketing team in 2022 to market DeepView<sup>®</sup> technology to US customers in 2023. For the burn indication, the primary customer base will be emergency departments located in approximately 5,400 federal and community hospitals throughout the US. Commercial sales are expected to commence in 2023 for the DFU application and 2024 for burns, although the burns application is expected to continue to attract considerable government funding through BARDA, having recently elected to enter Option 1B.

#### UK and EU4

The Company expects to engage contract sales organizations to distribute DeepView<sup>®</sup> throughout the UK and EU4. Preliminary discussions with distributors are expected to occur during 2023 to determine which organization possesses the key relationships and insights for selling diagnostic systems within their respective countries. The Company will focus its commercial strategy on the UK and Germany in the second half of 2023, with France, Italy and Spain to follow in 2024. Similar to the US, the primary customer base for the DFU application in Europe will be outpatient wound centers and secondary sites of care that have a high-volume of DFU patients. The Company also expects to engage a market access consulting firm to help navigate the various regional tender and contracting entities within each country.

#### Reimbursement:

#### US

While the Centers for Medicare and Medicaid Services' (CMS) repeal of the Medicare Coverage of Innovative Technologies rule in November 2021 was disappointing, Spectral MD does not see a material impact to its commercialization plans as the Company has line of sight to other reimbursement mechanisms.

## Product Overview and Strategy

continued

The Company also expects to apply for CMS' New Technology Add-On Payment (NTAP) as its Breakthrough Designation already fulfils CMS' requirement for demonstrating substantial clinical improvement. NTAP is a payment mechanism that allows hospitals to be reimbursed at an amount additional to the standard fixed payment fee. This will be a positive impact for the burn application but will not apply to DeepView<sup>®</sup>'s DFU application.

In the US, coverage for Medicare and Medicare Advantage patients is governed by 12 local administrative contractors with responsibility for establishing policies for their respective geographies. Each of these contracted entities have separate policies for Non-invasive Physiologic Studies of the Lower Extremity Arteries. These policies dictate coverage for technologies used in wound healing prediction, such as ankle-brachial index testing, doppler ultrasounds and trans-cutaneous oxygen measurement. Upon FDA approval, the Company will seek an amendment to the existing policy to cover use of DeepView® for wound healing prediction. Furthermore, the Company intends to collect and publish clinical and economic data from the validation study to support coverage and reimbursement from public and private payers in the US. Central to this strategy is the direct engagement with reimbursement consultants who have deep professional experience in coverage policies and the evidence requirements to obtain coverage for diagnostic imaging technology. In parallel with the public payer strategy, the Company will approach private payers, such as Blue Cross/Blue Shield, Cigna, Humana, and United Health to acknowledge and cover the use of DeepView® for DFU wound healing prediction.

The National Medicare Physician payment for CPT code 93923 for 2020 is US\$ 134 per use. The use of CPT code 93923 in an outpatient would map to ambulatory patient code (APC 5721) with an average national reimbursement of US\$ 140 per use. In the in-patient setting, payment for the use of DeepView<sup>®</sup> would be included in the Diagnosis Related Group payment to the hospital and the physician would bill the professional portion of the CPT code. Commercial payment rates are dependent on pre-negotiated and contracted rates between the individual practice and insurance carrier. In addition to the pre-existing code (93923), the Company is seeking a reimbursement code to account for the AI analysis of DeepView<sup>®</sup>. The Company estimates the reimbursement of the AI analysis to be between US\$ 300 and US\$ 500 per scan. At this rate, the use of the DeepView<sup>®</sup> technology is expected to provide an economic benefit to a typical podiatry clinic from the first year of sale. There is scope to increase this rate in certain indications, such as surgical planning, whereby the use of the Company's technology remains cost-effective against current standard of care.

#### UK and EU4

The Company recognizes and understands that the reimbursement landscape for the UK and EU4 varies within each geography. The disparity in the levels of economic and clinical evidence required to support coverage and reimbursement for DeepView® across multiple geographies poses a risk to Spectral MD's commercialization. The Company plans to mitigate this risk using three tactics: develop relationships with Key Opinion Leaders and develop clinical study engagement in future commercially targeted territories (UK and Germany), engage market access/reimbursement consultants with experience in evidence requirements for coverage, and seek input from and engage regulatory organizations such as the National Institute for Health and Clinical Excellence and the Institute for Quality and Efficiency in Healthcare in Germany. These mitigating tactics share one binding purpose: to ensure that the appropriate level of clinical and economic evidence is proactively and accurately captured throughout the entirety of the clinical study. Furthermore, the Company plans to hire experienced personnel in the UK to drive the Company's regulatory efforts to ensure timely commercialization.

#### Regulatory Pathway:

The Company has had multiple interactions with the FDA since 2013 and has obtained 510(k) clearance for the first two generations of the DeepView<sup>®</sup> technology. DeepView<sup>®</sup> GEN 1 employed photoplethysmography and was 510(k) cleared in 2013 and DeepView<sup>®</sup> GEN 2, which employed PPG and multi-spectral imaging was FDA cleared in 2017. With the ongoing support of BARDA, these two previous iterations were not commercialized due to the integration of artificial intelligence algorithms and improved optics throughout 2018 and 2019 in order to further enhance the utility of the system.

## Product Overview and Strategy

continued

The development of this improved technology enabled the Company to achieve FDA Breakthrough Device Designation status for the technology's burn application. FDA Breakthrough Device Designation devices allow for expedited regulatory approval pathways and a dedicated line of communication with reviewing members of the FDA. The Company has recently engaged with the FDA for pre-submission meetings to ensure that the regulatory pathway and data collection for the technology to meet the FDA's requirements. The Company will pursue FDA clearance (De Novo) for the DFU application in 2023 and expects FDA approval in the same year.

The Company will submit for FDA clearance of the burn application in the fourth quarter of 2023 in accordance with the projected timeline for the BARDA contract. The Company is in the process of selecting a of notified body to schedule Quality Management System (QMS) certification audit in compliance with ISO 13485:2016 Medical Device Single Audit Program (MDSAP) under the US and Canadian jurisdictions. Certification is expected in the first Quarter of 2023. In parallel, the Company is scheduling the DeepView<sup>®</sup> wound imaging system Technical Documentation audit necessary to obtain the CE Mark & UKCA certificates to allow market access in the European Union and United Kingdom.

#### Strategic Partnerships:

Spectral MD has developed strategic partnerships with multiple clinical and academic partners. In the US, the Company is currently engaged with ten leading research hospitals that are enrolling subjects in the Burn AI Training Study. In the EU and UK, the Company has engaged in a clinical partnership with the Royal College of Surgeons Ireland, as well as key opinion leaders to provide the company greater knowledge in the wound care sector. These institutions provide the Company with the opportunity to collaborate with leading wound care providers to develop effective early stage wound assessment technology.

The results presented cover FY21. The presentational currency for SpectralMD Holdings, Ltd. and its subsidiaries (together, the "Company") is the US Dollar.

## **INCOME STATEMENT**

#### Revenue

The company recognized research and development revenue of US\$ 15.2 million in the financial year ended 31 December 2021 ("FY21") related to its non-dilutive research and development contracts with BARDA and DHA.

#### **Cost of Sales**

The cost of sales associated with BARDA and DHA research and development activity was US\$ 8.2 million for FY21.

#### **Operating Expenses**

During FY21, operating expenses totaled UUS\$ 11.3 million. The major items of expenditure were general and administrative costs of US\$ 11.3 million (FY20: US\$ 6.5 million) which included US\$ 5.1 million in employee-related costs (FY20: US\$ 3.8 million), US\$ 2.7 million in subcontractors, legal, accounting, and other professional fees (FY20: US\$ 1.3 million), US\$ 2.3 million in insurance, marketing, materials, rent, and other administrative costs (FY20: US\$ 1.4 million), and DFU development-related expenses totaled US\$ 1.2 million for FY21 (FY20: US\$ 0, program began in FY21).

#### Other Income (Expense)

Other income totaled US\$ 0.1 million during FY21 (FY20: US\$ 0.04 million expenses) related to the change in fair value of warrant liability partially offset by foreign exchange transaction losses and interest expenses.

### **BALANCE SHEET**

#### **Cash and Cash Equivalents**

Cash and cash equivalents totaled US\$ 16.1 million at the end of FY21 (FY20: US\$ 5.1 million) related to the company completing its initial public offering on AIM in FY21 raising net proceeds of US\$ 14.6 million after deducting US\$ 1.0 million offering expenses.

#### **Accounts Receivable**

Accounts Receivable totaled US\$ 1.4 million at the end of FY21 (FY20: US\$ 2.7 million). This change was mainly driven by one FY20 invoice to BARDA where payment was received in FY21.

#### **Prepaid Expenses and Other Current Assets**

Prepaid Expenses and Other Current Assets totaled US\$ 0.9 million at the end of FY21 (FY20: US\$ 0.09 million).

#### **Non-current Assets**

Non-current assets consisted of US\$ 0.03 million (FY20: US\$ 0.00 million) in equipment as well as US\$ 0.04 million (FY20: US\$ 0.03 million) other non-current assets at the end of FY21.

#### Accounts Payable

Accounts Payable totaled US\$ 1.7 million (FY20: US\$ 3.8 million) at the end of FY21.

#### Accrued Expenses

Accrued Expenses totaled US\$ 2.4 million (FY20: US\$ 1.1 million) at the end of FY21.

## **Financial Review**

continued

#### **Notes Payable**

Notes Payable totaled US\$ 0.6 million (FY20: US\$ 0.0 million) at the end of FY21 and consisted of US\$ 0.4 million (FY20: US\$ 0.8M million) remaining liability of a promissory note entered in FY20 with JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program ("PPP") of the US government, an insurance financing agreement with a remaining principal of US\$ 0.2 million (FY20: US\$ 0.0 million) as well as a note for the purchase of software with a remaining principal of US\$ 0.01 million (FY20: US\$ 0.0 million).

#### **Warrant Liability**

In conjunction with the closing of company's initial public offering on the AIM market in FY21, the company issued 762,712 warrants, with a strike price of US\$ 0.89 and a ten-year life, to SP Angel, who acts as nominated advisor and broker of the company for the purposes of the AIM rules. The fair value was calculated to be US\$ 0.2M (FY20: US\$ 0.5 million) at the end of FY21.

#### **Non-current liabilities**

The company had no non-current liabilities at the end of FY21.

## **Risk Management**

The Company continues to assess, monitor, and mitigate the risks in the business. The principal risks, and the current assessment of the risk status and mitigation effectiveness are listed in the table below.

Risk	Description	Risk Status	Mitigation	Mitigation Effectiveness
BARDA	Burn development is heavily dependent on BARDA funding	Unchanged	Maintaining strong relationships and project focus	Effective – entered Option 1A commencing March 2021 and Option 1B in September 2021
DHA	Development of a handheld device is reliant on funding	Unchanged	Maintaining strong relationships and project focus	Effective – entered Phase II contract in June 2021
Loss of a major customer	No commercial sales have been made, almost all revenue from fixed fees and costs payable by BARDA	Unchanged	Maintaining a strong relationship with BARDA and expect diversification of customers in future years following commercialization	Effective – entered Option 1A commencing March 2021 and Option 1B in September 2021
Commercial	The DeepView <sup>®</sup> system has yet to be launched into the US., UK, EU and other markets and so adoption and market penetration can only be estimated	Unchanged	Maintaining strong relationships and project focus	Effective – expanding London office, establishing an EU presence in Dublin, Ireland, and engaging with potential CRO's in both EU and UK; hired a VP of Commercialization and Marketing who started in April 2022
Research and development	Complex scientific research is necessary in the life sciences and medical device development sector	Unchanged	Recruiting and retaining highly skilled employees	Effective – hired 27 new employees with world leading capabilities in 2021
Product development timelines	Unpredictability of the rate of patient recruitment into clinical trials	Unchanged	Maintaining strong relationships and project focus	Effective – on schedule with trials

## Risk Management

### continued

Risk	Description	Risk Status	Mitigation	Mitigation Effectiveness
Regulatory approvals and compliance	Obtain various regulatory approvals (including the FDA and EMA approvals)	Unchanged	Conducting thorough clinical and product market research and maintaining strong relationships with regulatory authorities	Effective – engaged in regular discussion to update FDA and established partnerships with world leading expert teams of scientific and regulatory affairs staff, including the recently hired Director of Regulatory Affairs
Technological change	Changing customer requirements and the introduction of products or services or enhancements embodying new technology	Unchanged	Continues to invest in technical developments and apply for patents	Effective – issued additional patents in 2021

## **Board of Directors**



#### Martin Mellish

#### Independent Non-Executive Chairman (Aged 64)

Martin Mellish has served as founding director of Aspen Advisory Services Ltd., since 1994. Aspen is a London-based private office overseeing investments in North America, Europe, and Asia. Mr. Mellish serves as non-executive director of Nucana Ltd (NASD: NCNA; member, Audit Committee) a clinical-stage biopharmaceutical company focused on improved chemotherapy agents, and Levitronix Technologies Inc. (Chair, Audit Committee) a technology company handling high-purity fluids for the semiconductor and life science industries, among other non-executive directorships. He is a member of the International Advisory Council of the Massachusetts General Hospital (MGH), Boston.

He holds an M.Sc. from the Master of Health Care Delivery Science program at Dartmouth; an SM (Management) from the Massachusetts Institute of Technology and an M.Sc. (Accounting) from Northeastern University.

## Wensheng Fan

#### **Chief Executive Officer (Aged 53)**

Wensheng Fan is a Co-Founder and the first employee of Spectral MD. Over the past 11 years he has served as CTO and COO, before becoming the CEO of Spectral MD. He is an executive, entrepreneur, and innovator with over 20 years of experience in natural speech recognition and imaging systems. Mr. Fan held various leadership roles in strategy, engineering, and operations with Sensata Technologies and Philips. He also has a long history of experience in business development and cross-functional team leadership, being a founder and/or early core member of multiple successful start-up companies. Under his leadership, Spectral MD's DeepView<sup>®</sup> was granted FDA Breakthrough Device designation and is well on its way to disrupting the field of healthcare and medical technology.

Mr. Fan received his B.S.E.E. degree from Tsinghua University in Beijing, China and M.S.E.E. degree from Northeastern University in Boston.



## Erich Spangenberg

### Non-Executive Director (Aged 62)

Erich Spangenberg is a serial entrepreneur and industry luminary in the patent business. Mr. Spangenberg is the Chief Executive Officer and founder of IPwe, a company which uses blockchain and artificial intelligence to create the intellectual property asset class. Mr. Spangenberg founded nXn Partners, a company that is focused on predictive analytics. He was also the founder and Chief Executive Officer of IPNav, a pioneer and leader in patent monetization, and a company that generated over half a billion dollars in licensing, settlement, or enforcement revenues for its clients.

Mr. Spangenberg is a former investment banker (having held positions at Donaldson, Lufkin, and Jenrette) and corporate lawyer (working for Jones Day). From investment banking he joined the corporate world, where he was the president of Smartalk Teleservices and Acclaim Ventures Group.

Mr. Spangenberg was a Periclean Scholar at Skidmore College, a Distinguished Graduate in his master's degree program at The London School of Economics and was on Law Review at Case Western Reserve University, where he earned his JD.



## **Board of Directors**

continued



### **Richard Cotton**

#### Independent Non-Executive Director (Aged 61)

Richard Cotton has a wealth of experience in senior financial roles in life sciences and other sectors, including broadcast and photographic, automotive, filtration and metals. His experience covers all financial management and value creation activities from R&D, to manufacturing and commercial in international organizations. He has significant experience in the development and successful execution of strategy, corporate finance and M&A, capital markets and governance.

Mr. Cotton was Chief Financial Officer of FTSE250 animal health Group Dechra Pharmaceuticals plc, and prior to that Chief Financial Officer of medical device and drug formulation business Consort Medical plc. He was also Finance Director of Vitec Group plc, Group Finance Director at Wagon plc and Group Finance Director of McLeod Russel plc. Prior to this he held senior finance roles in Alcoa Inc.

Fellow of the Chartered Institute of Management Accountants, Mr. Cotton holds a BA (Hons) in Business Studies from Kingston University.



## Cynthia Cai

#### Independent Non-Executive Director (Aged 58)

Dr. Cynthia Cai is an executive and investor with over twenty-five years of experience in the healthcare and life science industry. Extensive experience in equity investment, board membership, marketing, and business development. In-depth understanding of global biotech and life science business, widely recognized as having a unique ability to bridge collaboration between scientists and businesses, between the eastern and western worlds.

Dr. Cai is the founder and president of Tharton Consulting, which provides investment and management consulting services. She is also a venture partner of Viva BioInnovator, an equity investor in biotech innovation with novel solutions to cross multiple therapeutic areas. Before that, she served as senior advisor to Northern Light Venture Capital, led its healthcare investment effort in the United States. Previously Dr. Cai had progressive leadership roles with Agilent Technologies, as global associate vice president of marketing, she was responsible for its billion-dollar Chromatography, Automation, and Mass Spec. business.

Dr. Cai serves on the board of directors for Spectral MD (London: SMD), Arthrosi Therapeutics, F5 Therapeutics, AceLink Therapeutics, Exarta Therapeutics, and Amberstone Biosciences. She is also a member of the board for the Science History Institute in Philadelphia.

Dr. Cai earned a B.A. and M. Eng. from Tsinghua University in Beijing, received her Ph.D. in Chemistry from the University of Massachusetts, and an MBA from The Wharton Business School of the University of Pennsylvania.

## **Board of Directors**

continued



### **Gerry Beaney**

#### Independent Non-Executive Director (Aged 62)

Gerry Beaney is currently a consultant to growth companies seeking strategic advice or funding for expansion. He has carried out senior executive roles in the corporate finance sector for over 25 years. During 2018, he was the Chief Executive Officer of Northland Capital Partners Limited, an institutional stockbroker based in London, and prior to this acted as Northland's Head of Corporate Finance between 2014 and 2018. From 1997 to 2013, Mr. Beaney was a Partner and Head of Capital Markets at Grant Thornton UK LLP which grew to become the largest independent nominated adviser to AIM companies under his leadership.

Prior to 1997, Mr. Beaney held various roles with Grant Thornton in the UK and New York City. He is a member of the Institute of Chartered Accountants of Scotland and was a member of the American Institute of Certified Public Accountants between 1991 and 2016. He holds a Bachelor of Accountancy Degree from the University of Glasgow.

This report was approved by the Board on 6 May 2022 and signed on behalf of the Board by:

Martin Mellish Chairman

The Directors present their annual report on the affairs of the Company, together with the consolidated financial statements and auditor's report for the year ended 31 December 2021. The Corporate Governance Statement set out on pages 18-45 forms part of this report.

### CORPORATE DETAILS

SpectralMD Holdings, Ltd. is a public limited company incorporated and registered in the US state of Delaware under the General Corporation Law of the State of Delaware (Registration #4348471). The address of the registered office is 1209 Orange Street, Wilmington, Delaware, 19801.

### DIRECTORS

The Directors, who served in office during the year and as date of signing these financial statements were as follows:

- Martin Mellish (15 June 2021 appointment effective as of 22 June 2021)
- Wensheng Fan (15 June 2021 appointment effective as of 22 June 2021)
- Erich Spangenberg (15 June 2021 appointment effective as of 22 June 2021)
- Richard Cotton (15 June 2021 appointment effective as of 22 June 2021)
- Cynthia Cai (15 June 2021 appointment effective as of 22 June 2021)
- Gerry Beany (15 June 2021 appointment effective as of 22 June 2021)

Details of the Directors' membership of committees are shown on pages 32-33.

The Company Secretary is Vincent S. Capone, the Company's General Counsel.

#### PRINCIPAL ACTIVITIES

The Company 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<sup>®</sup> Wound Imaging Solution, an internally developed AI technology and multispectral imaging which has FDA Breakthrough Device Designation status, the Company 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).

#### **GOING CONCERN**

The Company is in the development phase of its business and has not generated commercial revenue besides grant revenue from US government agencies. On 31 December 2021 the Company has available cash resources of US\$ 16.1 million.

In considering the appropriateness of this basis of preparation, the Directors have reviewed the Company and Company working capital forecasts for a minimum of 12 months from the date of the approval of this financial information. Based on their consideration the Directors have a reasonable expectation that the Company has adequate resources to continue in the foreseeable future and that carrying values of intangible assets are supported. Thus, the adoption of the going concern basis of accounting in preparing this financial information is considered appropriate.

## FUTURE DEVELOPMENTS AND RESEARCH AND DEVELOPMENT ACTIVITIES

Future developments and research and development activities are discussed in the Strategic Report on page 9.

continued

### FINANCIAL RESULTS

Financial results are detailed in the Financial Statements and accompanying notes beginning on page 46.

### **EMPLOYEE POLICIES**

Employee policies are discussed in the Strategic Report on page 8.

## POLITICAL CONTRIBUTIONS AND CHARITABLE CONTRIBUTIONS

Neither the Company nor any of its subsidiaries made any political donations or incurred any political expenditure during the year ended 31 December 2021 (FY20: nil).

## DIRECTORS' INTERESTS

The interests in the share capital of the Company of those Directors serving on 31 December 2021 and as at the date of signing of these financial statements, all of which are beneficial, were as follows:

Director	On 31 December 2021 Ordinary Shares of 0.01p each	On 31 December 2020 Ordinary Shares of 0.01p each
Erich Spangenberg	54,929,513	0
Wensheng Fan	1,500,000	0
Richard Cotton	338,984	0
Gerry Beaney*	16,950	0

\* Gerry Beaney's holding increased to 30,283 shares of common stock at the date of this report.

### SUBSTANTIAL SHAREHOLDERS

As of 31 December 2021, the following interests in 3% or more of the issued Ordinary Share capital had been notified to the Company:

		Percentage of Issued Share
Shareholder	Number of Shares	Capital
ELS 1960 Family, L.P.*	48,974,723	35.99%
John Michael DiMaio	25,546,686	18.77%
Board of Regents of the University of Texas System for the Benefit		
of the University of Texas Southwestern Medical Center	10,500,000	7.72%
Octopus Investments plc	10,337,282	7.60%
Jose Melendez	9,000,000	6.61%
Link Mar (Nominees) Limited	8,351,947	6.13%
Laurence Hirsch	7,821,010	5.75%
Erich Spangenberg*	5,954,790	4.38%

\* Ownership by Erich Spangenberg

continued

# STATEMENT OF DIRECTORS' RESPONSIBILITIES IN RESPECT OF THE FINANCIAL STATEMENTS

The directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulation. The directors have prepared the financial statements in accordance with accordance with auditing standards generally accepted in the US (GAAS). The directors approve the financial statements only upon their satisfaction that the financial statements present a true and fair view of the state of affairs of the Company and of the profit or loss of the Company for that period. In preparing the financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently
- state whether applicable GAAS standards have been followed, subject to any material departures disclosed and explained in the financial statements
- make judgements and accounting estimates that are reasonable and prudent; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business.

The directors are also responsible for safeguarding the assets of the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities. The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and enable them to ensure that the financial statements comply with GAAS.

### DIRECTORS' INDEMNITIES

The Company has maintained insurance in the form of a qualifying third-party indemnity provision throughout the year for its directors and officers against the consequences of actions brought against them in relation to their duties for the Company. This provision was in force through the financial year and remains in force as at the date of approval of the financial statements which were prepared in accordance with GAAS.

### INDEPENDENT AUDITORS

KPMG has expressed their willingness to continue in office as auditors and a resolution to reappoint them will be proposed at the forthcoming Annual General Meeting.

### DISCLOSURE OF INFORMATION TO THE AUDITORS

The Directors who hold office at the date of approval of this report confirm that so far as they are each aware, there is no relevant audit information of which the Company's auditors are unaware, and each Director has taken all the steps that they ought to have taken as a Director in order to make themselves aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

### CORPORATE GOVERNANCE

The Company's statement of corporate governance can be found in the Corporate Governance Statement on pages 18-45. The Corporate Governance Statement forms part of this Report of the Directors and is incorporated into it by cross-reference.

### ANNUAL GENERAL MEETING

The resolutions to be proposed at the forthcoming Annual General Meeting will be set out in a separate notice to the shareholders.

continued

### RECOMMENDATION

The Board considers that the resolutions to be proposed at the Annual General Meeting are in the best interests of the Company and it is unanimously recommended that shareholders support these proposals as the Board intends to do in respect of their own holdings.

This report was approved by the Board on O6 May 2022 and signed on behalf of the Board by:

Martin Mellish

Chairman

Dear Shareholder,

I am pleased to present the Corporate Governance Statement of the Board of Directors of Spectral MD Holding Ltd for the financial year ended 31 December 2021. The Directors recognize the importance of good corporate governance and intend that the Company will apply the principles of the Quoted Companies Alliance Corporate Governance Code ("QCA Code") in so far as they are appropriate given the Company's size and stage of development. A statement detailing both how the Company complies with the QCA Code is outlined below.

## Principle One: Business Model and Strategy

The Board has adopted a strategy for the Company's development which is summarized below.

#### Overview

Spectral is a predictive analytics company that develops proprietary optical technology and AI algorithms to help clinicians make more accurate and faster treatment decisions in the wound care sector. Using its DeepView<sup>®</sup> Wound Imaging Device, an internally developed multispectral imaging device which has designated FDA Breakthrough status, the Company 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). DeepView<sup>®</sup>'s output is specifically engineered to allow the physician 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 the current approach that involves waiting up to 30 days to see how the wound develops before making a clinical assessment. The accuracy of DeepView<sup>®</sup> is 81 percent. for DFUs compared to current clinical accuracy of 50 percent. For burn wounds, the clinician can make an immediate and objective determination for appropriate candidates for surgery as well determining what specific areas of the burn wound will require skin grafting. DeepView<sup>®</sup>'s current accuracy for burn wounds is 92 percent, compared with current physician accuracy of 50 to 70 percent.

#### **Investment Case**

There are no diagnostic imaging devices that provide clinicians with an objective and immediate assessment of a wound's healing potential. Currently, healthcare professionals rely on their experience and subjective assessments to determine if wounds such as burn injuries and diabetic foot ulcers will respond to therapeutic treatment.

In the US and UK, respectively, there are over 490,000 and 87,000 burn victims who receive emergency medical treatment each year. 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" approach to assessing burn wounds comes at a higher-than-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<sup>®</sup> provides the physician with a 'Day One' healing assessment and enables the physician to not only triage the patient to the appropriate setting sooner, but also, the device assists the physician in accurately determining which areas of the burn wound are appropriate for excision and grafting.

Diabetes (type 1 and type 2) affects over 34 million people in the US alone and more than 460 million people worldwide. DFU is the most frequently recognized complex and costly symptom of diabetes which can lead to limb amputation if left undiagnosed, misdiagnosed or untreated.

There are over 5.2 million diabetic foot ulcers patients in the US and Europe every year. In the US, patients must undergo standard wound care therapy for 30 days prior to receiving advanced wound care therapy. In the US, DFU patients have annual costs that are often three times more expensive than the typical patient and see their medical provider, on average, 15.5 times per year. Nonhealing DFUs in the UK are reported as being four times more expensive than DFUs that heal.

continued

#### **Future Growth Strategy**

The Company expects that in the short term it will generate additional revenue from grants received from BARDA in connection with performance of the Company's BARDA contract. From 2013 to 2019, the Company completed the BARDA Burn I contract valued at US\$ 26 million to investigate the use of its device as a surgical-triage tool for burn victims in a mass-casualty event. In July 2019, the Company entered into the BARDA Burn II contract, to further develop the DeepView<sup>®</sup> device as a medical countermeasure for mass casualty events. The Company has now entered Option 1a of BARDA Burn II, valued at US\$ 20.6 million and Option 1B valued at US\$ 18.8 million.

Upon receiving regulatory approval, the Company intends to sell the DeepView<sup>®</sup> device to inpatient and outpatient sites throughout the US. Sales will initially target podiatry practices presiding in areas with high prevalence of diabetes such as the south and south-eastern US. Large hospital systems with outpatient wound care centers will also be targeted as they serve a large volume of DFU patients. The device will be sold as capital equipment and will have an annual subscription fee based on the number of applications the device is used for.

The Company started to build up its Sales and Marketing team in 2022 to market DeepView® technology to US customers in 2023. For the burn indication, the primary customer base will be emergency departments located in approximately 5,400 federal and community hospitals throughout the US. Commercial sales are expected to commence in 2023 for the DFU application and 2024 for burns, although the burns application is expected to continue to attract considerable government funding through BARDA, having recently elected to enter Option 1B.

The key challenges to the business and strategy are addressed in the Principle Four below.

### Principle Two: Understanding Shareholder needs and Expectations

The Board recognizes its significant responsibility towards the Company's shareholders and is committed to maintaining good communication and investor relations and having a constructive dialogue with all its shareholders. The Chief Executive Officer will hold regular meetings with institutional shareholders to keep them updated on the Company's performance, strategy and management and provide periodic briefings to analysts who cover the industry.

The Board have engaged Walbrook PR to provide investor relations services allowing all investors to have the opportunity to ask questions and provide feedback via Walbrook PR – either by phone or email at SpectralMD@walbrookpr.com. Through Walbrook, the Board will also allow all investors to attend Company investor presentations (held physically or virtually) and to submit questions to the management.

In addition, all shareholders are encouraged to attend the Company's Annual General Meeting and any other Special Meetings which are held throughout the year. Proper consideration will be given to conducting these meetings in locations relevant to the Company's activities whether in person or in virtual format. Factors to be considered include the location of the Company's shareholders, the Company's operations, with the health and safety of participants being of paramount importance.

The Board will use the Company's website (spectralmd.com) to provide access to current information about the Company's activities.

### Principle Three: Stakeholder Responsibilities

The Board recognizes that the long-term success of the Company is reliant upon the efforts of the employees of the Company and its customers, stakeholders, suppliers and regulators. The Board has identified its key stakeholders and has put in place a range of processes and systems to ensure that there is close Board oversight and contact with these groups and seeks feedback from them whenever possible.

continued

#### **Employee Annual Assessment Process**

All employees of the Company participate in a structured Company-wide annual assessment process which is designed to ensure that there is an open and confidential dialogue with each person to assess performance and set goals for the forthcoming year. The mutual feedback process ensures that the Company can communicate developments in the business to ensure employees' efforts are coordinated with Company strategy.

#### FDA consultation/BARDA meetings

The Company has had multiple interactions with the FDA since 2013 directly overseen by the Chief Executive Officer with a dedicated management team responsible for the Company's regulatory processes including the Breakthrough Device Designation regulation. The Company has recently engaged with the FDA for informational pre-submission and pre-submission meetings to ensure that the regulatory pathway and data collection for the system meet the FDA's requirements.

Since 2013, the Company's relationship with BARDA has been managed through formal monthly "Project-Core-Team" meetings consisting of leadership representation from BARDA and officers of the Company (including the Chief Executive Officer). There are additional meetings and communications by phone or email to ensure that the Company is fulfilling the contractual requirements of the contract.

#### Suppliers and Manufacturing partners

The Board ensures that all key relationships with customers and suppliers are the responsibility of, or are closely supervised by, one of the Directors or senior management.

The Company currently outsources all its manufacturing through a contract manufacturing service, Cobalt Production Solutions ("Cobalt") based in Plano, Texas. Cobalt is involved with manufacturing the DeepView GEN 3 system and will continue to do so for the foreseeable future.

In addition to Cobalt, the Company integrates several other highly specialized contract manufacturers in the areas of optics, system design, and electronics. The Company employs experienced regulatory and quality control personnel to ensure that manufacturing processes and quality management systems are in compliance with FDA and CE Mark regulations and standards. As the Company expands into the European market, the Company will consider manufacturing systems in the EU in preparation for commercialization. The Company does not have plans to develop its own manufacturing facility at this time.

### Principle Four: Risk Management

The Audit Committee is responsible to the Board for ensuring that procedures are in place and are being followed to identify, evaluate and manage the significant risks faced by the Company. The Audit Committee reviews the risks on a regular basis and will discuss them quarterly at board level and formally in the Annual Report. The following principal risks have been identified:

#### Specific risks relating to terms of key contracts

The Company currently has agreements with each of: (i) BARDA; and (ii) the Defense Health Agency ("DHA") to support continued funding and development of the next generation of the DeepView<sup>®</sup> wound imaging device.

#### BARDA

The base period of the BARDA contract expired at the end of April 2021, however BARDA has exercised Option 1A in March 2021, and Option 1B in September 2021, to provide funding to initiate the Burn Training study. BARDA may exercise further options to extend the term of the contract subject to contract milestones and decision gates. While the Company has no reason to believe that these further options will not be exercised, and whilst these contracts have been renewed or extended historically, there is no guarantee that the contracts will be extended. As these contracts are very significant to the Company, a decision by BARDA not to exercise further options could have an adverse impact on the Company's business, prospects, results of operations and financial condition.

continued

While the government has a right to terminate the BARDA contract, the government generally does not terminate funding awards unless there is reason, such as: the funding contract becomes too costly or proving impossible, the agency seeks to avoid a dispute with another branch of government, or the agency has decided to restructure its contractual arrangements and perform work in-house. Thus, it is unlikely that BARDA will terminate its contract with Company. If, however, BARDA terminates the contract, the Company may be entitled to settlement costs for payment for work already performed, but not yet paid for; costs incurred in anticipation of performance; and costs arising from termination and settling the termination, for example. While such Termination Settlement is available, the termination of the BARDA contract is considered low risk.

To mitigate this risk, the Company maintains a very close relationship with BARDA, through a project team made up of senior management including the CEO and the Head of Regulatory Affairs. Project milestones and scope are closely controlled by the Company to ensure the development goals presented to BARDA are achieved in full, and that momentum towards the development's completion is maintained. In the very unlikely event that BARDA did terminate the contract, the Company would review the adoption of suitable mitigation measures including rescheduling of the Burns development program, cost savings, and raising funds from alternative sources to complete the development, depending on the progress of the Burns development and DFU development and commercialization.

#### DHA

The DHA Department of Defense Small Business Technology Transfer (STTR) Phase II contract expired on 26 January 2021. The Company entered a supplemental Phase II contract in July of 2021 that will extend until October 2023 to pursue research and development of commercial applications. Though the Company has no reason to believe that it will not be offered a Phase III contract, and while DHA contracts have been renewed or extended historically, there is no guarantee that the contract will be extended after the base period. As this contract is a key contract for the Company, non-extension of the contract could have an adverse impact on the Company's business, prospects, results of operations and financial condition.

To mitigate this risk, the Company maintains a very close relationship with DHA, through a project team made up of senior management including the Chief Executive Officer and the Head of Regulatory Affairs. Project milestones and scope are closely controlled by the Company to ensure the development goals presented to DHA are achieved in full, and that momentum towards the development's completion is maintained. In the very unlikely event that DHA did not extend the contract, the Company would review the adoption of suitable mitigation measures including rescheduling of the Burns development program, cost savings, and raising funds from alternative sources to complete the development, depending on the progress of the Burns development and DFU development and commercialization.

#### Loss of a major customer

The Company has not made any commercial sales and receives almost all its revenue from fixed fees and costs payable by BARDA. While the Company believes it has a very good working relationship with BARDA, the loss of the Company's contract with BARDA may have an adverse impact on the Company's business, prospects, results of operations and financial condition. The Company expects diversification of customers in future years once it begins commercial sales activity.

Risk mitigation is described above in relation to BARDA and the DHA.

#### **Commercial Risk**

The DeepView system has yet to be launched into the US, EU and other markets and so adoption and market penetration can only be estimated. Widespread adoption of new medical device technologies typically follows early adoption and promotion by key opinion and thought leaders in the relevant sectors. Whilst the Directors are optimistic about the Company's prospects, there is no certainty that anticipated outcomes and sustainable revenue streams will be achieved

continued

The Company has taken steps to mitigate this risk by establishing a strong relationship with the Skin Wounds, and Trauma (SWaT) Research Centre of the Royal College of Surgeons in Ireland (RCSI)& University of Medicine and Health Sciences, a well-respected institution in the field. The Company will be able to leverage this relationship to access other institutions and individuals that should increase awareness and early adoption of the systems both in the EU and US. Further, the Company has established an Advisory Board of key opinion leaders to ensure that the DeepView developments result in commercializable products. The Burns application has received FDA breakthrough designation which will also provide strong promotional benefits in commercialization, and access to advantageous treatment reimbursement rates.

#### **Research and Development Risk**

The Company will be operating in the life sciences and medical device development sector and will look to exploit opportunities within that sector. The Company will therefore be involved in complex scientific research and industry experience indicates that there may be a risk of delay or failure to produce results. To obtain the necessary regulatory approvals required to commercialize the Company's products, the Company will need to conduct clinical trials and demonstrate successful outcomes against an agreed comparator. There is a risk that safety and efficacy issues may arise when the products are tested. There is also a risk that there will be delays to the development of the products or that unforeseen technical problems arise as the Company's technology becomes increasingly automated. These risks are common to all new medical products and there is also a risk that the clinical trials may not be successful.

The Company is mitigating such risks through the recruitment and retention of highly skilled and experienced senior managers and other employees with world leading capabilities in science, product and business development, project management and regulatory affairs to realize high performing technologically breakthrough products on schedule, and to the satisfaction of clinicians and regulatory authorities.

#### Product development timelines

Product development timelines are at risk of delay, particularly since it is not always possible to predict the rate of patient recruitment into clinical trials. There is a risk therefore that product development could take longer than presently expected by the Directors. If such delays occur the Company may require further working capital.

The Directors shall seek to minimize the risk of delays by careful management of projects and have strongly embedded processes and systems of program management to provide this. In the development of earlier generations of the DeepView product, the Company has demonstrated its ability to plan and execute its development projects in a timely manner.

#### Regulatory approvals and compliance

The Company will need to obtain various regulatory approvals (including the FDA and EMA approvals) and otherwise comply with extensive regulations regarding safety, quality and efficacy standards in order to market its future products. These regulations, including the time required for regulatory review, vary from country to country and the review and approval processes can be lengthy, expensive and uncertain. While efforts will be made to ensure compliance with government standards, there is no guarantee that any products will be able to achieve the necessary regulatory approvals to promote that product in any of the targeted markets and any such regulatory approval may include significant restrictions on the uses for which the Company's products can be promoted and used.

To ensure that the Company has the best possibility of receiving appropriate regulatory approvals to market its products, it has conducted thorough clinical and product market research through key clinical opinion leaders and institutes to refine its technology offering and to ensure that it produces and overwhelmingly compelling clinical case for regulatory approval and adoption. Further, the Company has established a process of active engagement with the regulatory authorities in determining the optimal regulatory pathway to approval, to minimize the regulatory lead time and to ensure the satisfaction of the safety, quality and efficacy standards expected by those authorities. The Company has established world leading expert teams of scientific, product and business development, project management and regulatory affairs staff to maximize the likelihood of success.

continued

#### Technological change

The markets for the Company's products and services are characterized by changing technology and customer requirements. Changing customer requirements and the introduction of products or services or enhancements embodying new technology may render the Company's existing products and services obsolete, unmarketable or competitively impaired and may exert downward pressures on the pricing of existing products and services.

One of the Company's key competitive advantages is that it is currently the only AI-enabled wound imaging system that translates raw physiological image data into an output that is directly correlated to a wound healing prediction. The Company intends to continue to invest in technical developments in order to mitigate the impact of future competition. The Company has also registered a portfolio of patents to defend its technological lead over other market offerings in the relevant clinical space.

### Principle Five: A Well-Functioning Board of Directors

The Board comprises the Independent Non-Executive Chairman, Martin Mellish, the Chief Executive Officer, Wensheng Fan, and four other Non-Executive Directors: Erich Spangenberg, Dr. Cynthia Cai, Gerry Beaney and Richard Cotton. All NEDs, except for Erich Spangenberg, are independent. Erich Spangenberg, including the Spangenberg Entities, is the largest shareholder of the Company, owning approximately 40 percent. of the Company's total issued share capital and was Chairman of the subsidiary prior to Admission. Mr. Spangenberg and his related entities have signed the Relationship Agreement which further governs his relationship with the Company and the Board.

The QCA Code recommends that at least two members of the board are non-executive Directors determined by the Board to be independent in character and judgement and free from relationships or circumstances which may affect, or could appear to affect, their judgement. The Company complies with this requirement with four non-executive Directors determined by the Board to be independent.

The Board meets at least every two months and at any other time deemed necessary for the good management of the business and at a location agreed between the Board members. It has established Audit, Remuneration and Nominations Committees, particulars of which appear under Principle Nine. Each Director has agreed to devote as much time as is required to carry out the roles and responsibilities that the Director has agreed to take on.

Notwithstanding that the Directors are based in various jurisdictions the Company will aim to ensure that face-to-face meetings occur where practicable and subject to ongoing regulations relating to the Covid-19 pandemic.

The Directors are subject to re-election intervals as prescribed in the Company's Certificate of Incorporation, the effect of which is that no director may serve a term longer than three years without standing for re-election by the Company's Shareholders at a general meeting.

### Principle Six: Appropriate Skills and Experience of the Directors

The Company has put in place a board structure that can best provide the strategic advice and leadership required.

The Board currently consists of six Directors, who are supported by an experienced senior management team and an Advisory Board.

The Directors are of the view that the Company does not currently require a Board-level Chief Financial Officer given its current stage of development. Nils Windler, the Company's Chief Financial Officer, is invited to attend all Board meetings and audit, remuneration and nomination committee meetings as required. In addition, the NEDs have appropriate financial experience: Richard Cotton previously served as Chief Financial Officer of FTSE250 listed Dechra Pharmaceuticals plc, whilst Gerry Beaney and Martin Mellish bring considerable public company advisory and audit committee experience, respectively.

continued

As the Company grows and develops, the Board will keep its corporate governance framework under review to ensure it remains appropriate for the size, complexity and risk profile of the Company.

Currently, the Board has an appropriate balance of sector, financial, and public markets skills and experience and brings a range of skills and capabilities to the Company. The Board members are kept up to date on a regular basis on key issues and developments pertaining to the Company as well as their responsibilities as members of the Board and have access to management as required.

## Principle Seven: Evaluation of Board Performance

Internal evaluation of the Board, its committees and individual Directors is seen as an important component of good governance. This will be undertaken on an annual basis in the form of peer appraisal, facilitated by self-assessment questionnaires and discussions to determine the effectiveness and performance in each individual's role. The criteria against which effectiveness is considered will be aligned to the strategy of the Company and management forecasts and budgets that are already in place. Development needs of individuals will form part of the appraisal process.

The Board may consider an externally facilitated review in the future.

In addition, NEDs' independence will be reviewed on an ongoing basis.

### Principle Eight: Corporate Culture

The Board recognizes that its decisions regarding strategy and risk will influence the corporate culture of the Company as a whole and that this will impact the performance of the Company. The Board is very aware that the tone and culture set by the Board will have an effect on all aspects of the Company as a whole and the way that employees behave. A large part of the Company's activities are centered on its interaction with government departments as well as addressing its healthcare customer needs. Therefore, the importance of sound ethical values and behaviors is crucial to the ability of the Company to successfully achieve its corporate objectives. The Board places great importance on this aspect of corporate life and seeks to ensure that this flows through all that the Company does. The Board assessment of the culture within the Company at the present time is one where there is respect for all individuals, there is open dialogue within the Company and there is a commitment to provide the best service possible to all the Company's key customers while being sensitive to the needs of all stakeholders.

In addition, the Company takes a zero-tolerance approach to bribery and corruption and is committed to acting professionally, fairly and with integrity in all business dealings and relationships wherever they occur. The Company implements effective systems to counter bribery and corruption, and as part of this has adopted an anti-bribery and anti-corruption policy. The policy provides guidance to those working for the Company on how to recognize and deal with bribery and corruption issues and the potential consequences and applies to all persons working for the Company or on its behalf in any capacity, including employees at all levels, Directors, Officers, consultants and agents.

Furthermore, the Directors believe that serving the Company's target market of hospitals and other care and treatment centers, brings with it a level of public scrutiny in procurement that is transparent and easily accessible to the Board and external advisers that oversee the Company's activities.

### Principle Nine: Maintenance of Governance Structures and Processes

Ultimate authority for all aspects of the Company's activities rests with the Board with the respective responsibilities of the Chairman and Chief Executive Officer arising as a consequence of delegation by the Board. The Chairman is responsible for the effectiveness and leadership of the Board, promoting a culture of openness and debate by facilitating the effective contribution of NEDs and ensuring constructive relations between Executive and Non-Executive Directors. The Chief Executive Officer is responsible for ensuring that the Directors receive accurate, timely and clear information. Management of the Company's day-to-day business resides with the Chief Executive Officer. As stated in Principle Two, primary contact with shareholders has been delegated by the Board to the Chief Executive Officer who may further delegate it with the consent of the Board.

continued

NEDs are appointed not only to provide independent oversight and constructive challenges to the Executive Directors and senior management but also to provide strategic advice and guidance. There is a rigorous and transparent procedure for the appointment of new Directors to the Board. The search for Board candidates is conducted, and appointments made, on merit, against objective criteria and with due regard for the benefits of diversity on the Board. The Company also maintains an Advisory Board for the purpose of providing additional insight and expertise in the areas in which the Company operates.

During 2021, the Company held five meetings prior to its admission to the Alternative Investment Market of the London Stock Exchange (the "AIM Listing") which were attended by all of the then Directors, Wensheng Fan and Erich Spangenberg. Following the AIM Listing, the attendance record of the Directors during that period of office is as follows:

Director	Times held/attendance
Gerry Beaney	6/6
Cynthia Cai	6/6
Richard Cotton	6/6
Wensheng Fan	6/6
Martin Mellish	6/6
Erich Spangenberg	6/6

The Board has delegated specific responsibilities to the Audit, Remuneration, and Nomination Committees to support the Board and improve effectiveness. The Committees have the necessary skills and knowledge to discharge their duties effectively.

#### Audit Committee

The Audit Committee's role is to assist the Board with the discharge of its responsibilities in relation to internal and external financial reporting, audits and controls, including reviewing the Company's annual and halfyearly financial statements, reviewing and monitoring the scope of the annual audit and the extent of the non-audit work undertaken by external auditors, advising on the appointment of external auditors and the tendering process and reviewing the effectiveness of the Company's corporate governance, internal audit and controls, insurance and risk management, whistle-blowing and fraud-prevention systems. The ultimate responsibility for reviewing and approving the Company's annual report and accounts and its half-year reports remains with the Board.

The Audit Committee is chaired by Richard Cotton and its other member is Gerry Beaney. The Board has satisfied itself that Richard Cotton has recent and relevant financial experience, having previously been Chief Financial Officer of FTSE250 listed Dechra Pharmaceuticals plc, and that the committee has competence relevant to the sector in which the Company operates. The Audit Committee will normally meet no fewer than three times in each financial year and at such other times as the chair of the committee requires. It has unrestricted access to the Company's auditors.

Audit Committee Meeting Attendance during 2021:

Audit Committee Member	Times held/attendance
Richard Cotton	5/5
Gerry Beaney	5/5

continued

#### **Renumeration Committee**

The Remuneration Committee has delegated responsibility for all elements of the remuneration of the Chair of the Board, the executive Director of the Company and such other senior executives of the Company as it is designated to consider. It must ensure that the remuneration policy and practices of the Company are designed to support strategy, purpose and values that are linked to the Company's long-term success. The Remuneration Committee will also make recommendations to the Board on proposals for the granting of share options and other equity incentives under any share option scheme or equity incentive scheme in operation from time to time. In exercising this role, the Directors will have regard to the recommendations in the QCA Code. The remuneration of non-executive Directors will be a matter for the executive Director and Chairman. No Director may be involved in any decision as to their own remuneration.

The Remuneration Committee is chaired by Gerry Beaney. The other member of the committee is Richard Cotton. The Board has satisfied itself that Gerry Beaney has recent and relevant experience, having previously held senior positions at London-based institutional stockbrokers and AIM advisory firms, and that the committee has competence relevant to the sector in which the Company operates. The Remuneration Committee will normally meet not less than twice in each financial year and as otherwise required by its chair.

Renumeration Committee Meeting Attendance during 2021:

Renumeration Committee Member	Times held/attendance
Gerry Beaney	2/2
Richard Cotton	2/2

During the period from admission to AIM on 22 June 2021 to 6 May 2022 there were two meetings of the remuneration committee. Further, at two full board meetings, the directors approved bonuses and/or option awards to the CEO and certain senior employees as recommended by the remuneration committee.

#### **Nomination Committee**

The Nomination Committee leads the process for appointments, ensures plans are in place for orderly succession to both the Board and senior management positions and oversees the development of a diverse pipeline for succession. It is also responsible for periodically reviewing the Board's structure and identifying potential candidates to be appointed as Directors, as the need may arise.

The Nomination Committee is chaired by Dr. Cynthia Cai. The other members of the committee are Martin Mellish and Wensheng Fan. The committee's remit will extend to senior management and the Advisory Board to ensure candidates possess the attributes required for the role. Director candidates will also be assessed to ensure appropriateness to act as a director of a London AIM Market company. The Nomination Committee will meet once during each 12-month period and at such other times as the chair of the committee requires. The Nomination Committee did not meet in 2021.

### Principle Ten: Shareholder Communication

The Board is committed to maintaining good communication and having constructive dialogue with its shareholders. The Investors section of the Company's website provides all required regulatory information as well as additional information shareholders may find helpful including: information on Board members, advisors and significant shareholdings, a historical list of the Company's Announcements, its corporate governance information, the Company's publications including historic annual reports and notices of annual general meetings or special meetings, together with share price information.

#### continued

The Company also takes a proactive approach to investor relations initiatives with ongoing support from Walbrook PR Limited, the Company's Financial PR and IR Advisers. These investor relations initiatives include (but are not limited to):

- responsive IR enquiry service for all investors to ask questions and provide feedback via phone or email
- shareholder events in London and elsewhere
- access to virtual investor presentations and Q&A sessions
- the use of social media, in accordance with the Company's social media policy
- and access to media commentary or video interviews providing a summary of Company strategy and around other key developments.

Institutional shareholders and analysts will have the opportunity to discuss issues and provide feedback at meetings with the Company. The Board have engaged Walbrook PR to provide investor relations services allowing all investors to have the opportunity to ask questions and provide feedback through Walbrook PR – either by phone or email, details below.

Shareholders may contact the company as follows:

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

Through Walbrook the Board will also allow all investors to attend Company investor presentations (held physically or virtually) and to submit questions to the management. In addition, all shareholders are encouraged to attend the Company's Annual General Meeting or any other Special Meetings that will be held throughout the year.

Results of shareholder meetings and details of votes cast will be publicly announced through a regulatory information system and displayed on the Company's website with suitable explanations of any actions undertaken as a result of any significant votes against resolutions.

#### Share dealings

The Company has adopted a dealing code for Directors, senior managers and employees in relation to securities dealings which is appropriate for a company with securities traded on AIM ("Share Dealing Code").

The Share Dealing Code imposes restrictions beyond those that are imposed by law (including by FSMA and MAR and other relevant legislation) and its purpose is to ensure that persons discharging managerial responsibility and persons connected with them do not abuse, and do not place themselves under suspicion of abusing, price-sensitive information that they may have or be thought to have, especially in periods leading up to an announcement of financial results. The Share Dealing Code sets out a notification procedure which is required to be followed prior to any dealing in the Company's securities. The Company intends to take proper steps to ensure compliance with the dealing code by Directors, senior managers and employees.

The Corporate Governance Statement was approved by the Board on 06 May 2022 and signed on its behalf by:

Vincent Capone Company Secretary

## Director's Remuneration Report

For the Period Ended 31 December 2021

#### Dear shareholder,

As the Chair of the Remuneration Committee (the "Committee"), I am pleased to present, on behalf of the board of directors (the "Board") of Spectral MD Holdings, Ltd. (the "Company" or "Spectral MD"), the Directors' remuneration report for the year ended 31 December 2021 (the "Directors' Remuneration Report").

The Company's Annual Report and Accounts, along with the Directors' Remuneration Report, will be subject to an advisory vote at the forthcoming Annual General Meeting in the second half of 2022 (the "AGM") and the proposed Long Term Incentive Plan will be subject to a binding vote at the AGM.

#### Introduction

During the period covered by this Directors' Remuneration Report, we maintained the remuneration programs and policies that the Committee established during the financial year 2021 and implemented strategic compensation initiatives designed to incentivize and retain key employees in the Company.

Details of the Company's remuneration programs and policies are set out on the following pages.

As we move into 2022 and beyond, the Committee's role will be to ensure that Directors and senior executives at Spectral MD are appropriately compensated and incentivized to deliver growth to shareholders in a long-term and sustainable manner. The Committee seeks to accomplish this by establishing remuneration programs that are grounded in market practice, are effective at driving proper management behaviors, clearly link pay and performance and are cost efficient overall.

#### Corporate Governance Standards

As a company incorporated in Delaware whose common stock is admitted to trading on the AIM market of the London Stock Exchange, we are subject to corporate governance standards and regulations applicable in the US and the United Kingdom.

#### The Global Marketplace for Talent

Spectral MD is an international company with operations in US and the Europe. The Company plans to expand its operations in both geographic regions in line with the growth of its clinical and manufacturing activities and its plans to commercialize its products in these geographies. Given that the market for experienced directors and appropriately qualified executive management talent, particularly in the US, is extremely competitive, the Committee references the US market as the leading indicator for remuneration levels and practices. This will help attract and retain directors and motivate the superior executive management talent needed to successfully manage the Company's complex global operations. Being consistent in this market view of the US as the primary benchmark for remuneration practices for directors and executive management (including CEO and CFO) is key for the Company as it builds its global operations in a manner designed to deliver sustainable long-term growth and shareholder value.

Committee decisions have been taken considering the extensive benchmarking for director and executive director compensation conducted in 2021, which included a review of compensation practices of comparable companies to Spectral MD in the US and Europe. In taking any actions, the Committee is mindful of the general UK compensation framework, including investor bodies' guidance, and the UK Corporate Governance Code, and has incorporated these into its remuneration programs, policies, and decisions where it believes they best serve the long-term interests of shareholders.

continued

### **Pay and Performance**

The directors have sought to align executive directors' and senior managements' interests with those of our shareholders by having an element of their compensation in the form of performance-related pay, including equity. The Company's existing equity incentive plans have limited capacity to issue further shares or options. The Board will establish a new Long Term Incentive Plan for approval by shareholders at the forthcoming AGM.

### Conclusion

The Committee believes the proposals put forth in this report will properly motivate our directors and our CEO to deliver sustainable growth and shareholder value over the long term and do so in a responsible and cost-efficient manner. I hope that you find the information in this report helpful, and look forward to the AGM, where we hope to have your support.

### Gerry Beaney

Chair of the Renumeration Committee

continued

### DIRECTORS' REMUNERATION POLICY

Remuneration of Directors is split into three categories:

- Basic salaries and benefits in kind: Basic salaries are recommended to the Board by the Remuneration Committee, considering the requirements of the role and the rates for similar positions in comparable companies. Certain benefits in kind are available to certain senior staff and executive directors.
- Bonus Scheme: The Company has a discretionary bonus scheme for staff and executive directors which
  is specific to each individual and the role performed by that individual within the Company. Bonuses
  will be linked to the achievement of a range of key performance indicators (financial and non-financial).
- Long-term incentive plan (LTIP): The Company operates an LTIP for Executive Directors and other employees to attract, retain and reward those individuals through equity participation in the Company's stock. The LTIP includes share options, restricted shares, and restricted share units. Options can also be granted to non-employees (including consultants and non-independent NEDs) through a sub-plan. Exercise of share options under the plans are subject to specified exercise periods and compliance with the AIM Rules. The LTIP and option plan are overseen by the Remuneration Committee which recommends to the Board all grants of equity and share options to directors and employees based on the Remuneration Committee's assessment of personal performance and specifying the terms under which eligible individuals may be invited to participate.

### EXECUTIVE DIRECTORS' SERVICE CONTRACTS

Wensheng Fan is employed as Chief Executive Officer under a service agreement that provides for an annual salary. He is eligible to participate in the Company's discretionary annual bonus scheme in an amount to be determined by the remuneration committee. Mr. Fan also receives private medical and dental care provided by the Company as well as a contribution to such benefits for his immediate family members. The Company matches a proportion of Mr. Fan's contributions to the Company's 401(k) defined contribution plan.

### NON-EXECUTIVE DIRECTORS' TERMS OF ENGAGEMENT

Each non-executive director has entered into a letter of appointment with the Company for the provision of his or her services.

Mr. Mellish receives a fee of £75,000 per annum for acting as chairman.

Mr. Spangenberg is paid a salary of £40,000 per annum.

Dr. Cai, Mr. Beaney and Mr. Cotton each receive an annual base fee of £40,000 plus an additional £25,000 per annum for acting as Chair of the Nomination, Remuneration and Audit Committees respectively.

### REMUNERATION COMMITTEE (THE "COMMITTEE")

#### Governance

In its decision-making process, the Committee takes account of information from both internal and independent sources.

No Executive Director or employee can participate in any discussion relating to their own personal conditions of service or remuneration.

No conflicts of interest have arisen during the year and none of the members of the Committee has any personal financial interest in the matters discussed, other than as shareholders. The fees of the Non-Executive Directors are approved by the Board on the joint recommendation of the Committee and the Chief Executive Officer.

continued

### Discretions retained by the Committee

The Committee operates under the powers it has been delegated by the Board. In addition, it complies with rules that require certain matters to be put to either shareholder or Board approval. These rules provide the Committee with certain discretions which serve to ensure that the implementation of the Remuneration Policy is fair, both to the individual director and to the shareholders. The Committee operates the Company's remuneration plans in accordance with their rules from time to time. To maintain an efficient administrative process, the Committee retains the following discretions to apply its judgement in setting remuneration:

- the eligibility to participate in the plans
- the timing of grant of awards and any payments
- the size of awards and payments (subject to any maximum limits set out in the policy table above and the respective plan rules)
- the determination of whether the performance conditions have been met
- determining a good or bad leaver under the terms of the plan and the treatment of such leaver's cash and equity remuneration
- dealing with a change of control or restructuring of the Company
- adjustments required in certain capital events such as rights issues, corporate restructuring, events and special dividends and certain other out-of-the-ordinary events
- the annual review of performance and other vesting conditions for the annual bonus plan and equity awards

In certain circumstances, such as a material acquisition/divestment of a Company business, which mean the original performance conditions are no longer appropriate, the Committee may adjust the targets, alter weightings, or set different measures as necessary, to ensure the conditions achieve their original purpose and are not materially less difficult to satisfy.

The Committee may make minor amendments to the Remuneration Policy (for regulatory, exchange control, tax, or administrative purposes or to take account of a change in legislation) without obtaining shareholder approval for that amendment.

### ANNUAL REPORT ON REMUNERATION

This section of the remuneration report provides details of how our remuneration policy was implemented during the financial year ended 31 December 2021, and how it will be implemented during the year ending 31 December 2022.

This report splits certain information into that for Executive Directors and that for Non-Executive Directors.

#### Directors' Remuneration – financial year ended 31 December 2021

The total remuneration of the individual Directors who served during the period is shown below. Total remuneration is the sum of emoluments for the period in service as a director plus Company pension contributions, and the value of long-term incentive awards vesting by reference to performance in the twelve months to 30 June 2021.

### continued

Name	Year	Base Salary	Benefits	Bonus	LTIP	401k Match	Total Renumeration	Total Fixed Renumeration	Total Variable Renumeration
Executive Directors									
Wensheng Fan	2021	US\$ 462,021	US\$ 11,741	US\$ 285,000	US\$ 577,604	US\$ 25,198	US\$ 1,361,564	US\$ 498,960	US\$ 862,604
	2020	US\$ 446,433	US\$ 13,255	US\$ -	US\$ 364,500	US\$ 24,258	US\$ 848,446	US\$ 483,946	US\$ 364,500
Key Management									
Nils Windler, CFO	2021	US\$ 31,818	US\$ 1,579	US\$ -	US\$ 4,091	US\$ -	US\$ 37,488	US\$ 33,397	US\$ 4,091
	2020	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -
Wan Lung Eng,	2021	US\$ 225,000	US\$ 21,947	US\$ -	US\$ 86,086	US\$ 6,750	US\$ 339,783	US\$ 253,697	US\$ 86,086
CFO	2020	US\$ 62,708	US\$ 5,321	US\$ 25,000	US\$ 30,375	US\$ 269	US\$ 123,673	US\$ 68,298	US\$ 55,375
Non-Executive Di	rectors								
Martin Mellish	2021	US\$ 50,664	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 50,664	US\$ 50,664	US\$ -
	2020	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -
Cynthia Cai	2021	US\$ 43,909	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 43,909	US\$ 43,909	US\$ -
	2020	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -
Gerald Beaney	2021	US\$ 43,909	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 43,909	US\$ 43,909	US\$ -
	2020	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -
Richard Cotton	2021	US\$ 43,909	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 43,909	US\$ 43,909	US\$ -
	2020	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -
Erich	2021	US\$ 37,021	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 37,021	US\$ 37,021	US\$ -
Spangenberg	2020	US\$ 55,000	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 55,000	US\$ 55,000	US\$ -
John Stevens	2021	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -	US\$ -
	2020	US\$ 31,557	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 31,557	US\$ 31,557	US\$ -
Howard Goodman	2021	US\$ 10,000	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 10,000	US\$ 10,000	US\$ -
	2020	US\$ 30,000	US\$ -	US\$ -	US\$ -	US\$ -	US\$ 30,000	US\$ 30,000	US\$ -

### ANNUAL PERFORMANCE BONUS – 2020/2021 FINANCIAL YEAR

In respect of the year ended 31 December 2021, Mr. Fan was awarded cash bonuses amounting to US\$285,000 as a result of achieving milestones set out at the time of the Company's admission to AIM.

These milestones included:

- securing non-dilutive funding of US\$40.5 million from various government agencies in order to further the development of the Company's DeepView burn technology, device miniaturization and other initiatives. The remuneration committee noted that US\$18.8 million of such funding was received six months earlier than originally anticipated
- the Company's successful IPO on the London AIM market in June 2021 raising US\$15.6 million to provide funding for the development of the DFU product, create a European presence and build a US distribution capability
- enrollment of 150 patients into the DFU training study; and
- recruitment of senior employees as the Company enters the next phase of its development

### DIRECTORS' EQUITY AWARDS

During the year ended 31 December 2021, Mr. Fan was awarded 100,000 share options in recognition of securing US\$18.8 million of BARDA funding as set out above. The options have an exercise price of 39 pence and vest over three years. Additionally, a grant of 800,000 options was made to Mr. Fan following the year end in respect of achieving the milestones as set out above. The options have an exercise price of 35.5 pence and vest over three years.

Director	Total shares owned outright plus vested options	Shares owned outright	Percentage of issued share capital	Vested but not exercised	Unvested but subject to performance	Unvested and not subjected to performance
Wensheng Fan	9,300,000	1,500,000	1.10%	7,800,000	0	8,428,000
Erich Spangenberg	54,929,513	54,929,513	40.36%	0	0	300,000
Richard Cotton	338,984	338,984	0.25%	0	0	0
Cynthia Cai	0	0	0	0	0	0
Gerry Beaney	16,950	16,950	0.01%	0	0	0

### Directors' interests in shares at 31 December 2021

### **Base salary**

The base salary of the CEO for 2022 has been adjusted to reflect the increase in his responsibilities resulting from the change in the Company's status from private to public, international activities as well as the management of enlarged headcount the number of employees increased from 42 on 1 January 2021 to 55 on 31 December 2021. Further recruitment has continued into 2022. Consequently, Mr. Fan's base salary has been increased to US\$ 500,000.

The Chairman and non-executive directors will continue to be paid their current level of fees.

### Pension and benefits

There has been no change in pension and benefits arrangements.

### Annual performance bonus

Specific targets are commercially sensitive and therefore are not disclosed in advance. However, full details of the targets and performance against them will be disclosed when they are no longer considered commercially sensitive. Bonuses and equity awards payable to Mr. Fan and other senior executives will continue to be linked to the achievement of milestones as set out in the Company's annual budget as approved by the Board.

### Payments to past Directors (audited information)

There were no payments to past directors in 2020/2021.

### **Gerry Beaney**

Chair of the Renumeration Committee

# **Directors Audit Committee Report**

For the Period Ended 31 December 2021

### Dear shareholder,

As the Chair of the Audit Committee (the "Committee"), I am pleased to present, on behalf of the board of directors (the "Board") of Spectral MD Holdings, Ltd. (the "Company" or "Spectral MD"), the Directors' Audit Committee report for the year ended 31 December 2021 (the "Directors' Audit Report").

### Membership, Meetings and Attendance

Members of the Audit Committee are Gerry Beaney and Richard Cotton (Chair): both are considered independent. The General Counsel attends to take the minutes. The Committee met five times during the period and both members attended all five meetings. In addition, the committee invites the CEO, CFO, Financial Controller and External Auditors to attend. At the end of each meeting, the Committee members meet in private with the External Auditors.

### **Roles and Responsibilities**

The roles and responsibilities of the Audit Committee are laid out in the Corporate Governance Statement above.

Meeting Agenda Topics Meeting Date	Topics discussed
8 July 2021	Engagement of External Auditor
3 September 2021	H1 Interim Report External Auditor's report Risk Assurance Internal Audit Delegated authority
8 December 2021	Full year Audit planning Delegation of Authority Internal Audit Anti-Corruption procedures Whistleblowing arrangements 401K Pension arrangements R&D Budget preparation
16 March 2022	Insurance coverage / renewal Full year Preliminary Report External Auditor's report External Auditor Independence Risk Assurance Internal Audit Internal Controls Delegated Authority Representation letter to External Auditors Annual report 401K Pension arrangements Insurance renewal
3 May 2022	Annual report Fair Balanced and Understandable assessment of Annual Report

### Annual Report and Accounts 2021 41

### **Going Concern**

The Committee reviewed the Group's going concern statement set out in the Directors' report. In reviewing the statement, the Committee considered the Budget and forecast for 2022 and 2023, including embedded risks and opportunities.

The external auditor reviewed the management's assessment and discussed this review with the Committee. They concurred with the Committee's assessment that the Company was a Going Concern – See Independent Auditor's report.

### Fair Balanced and Understandable Assessment of Annual Report

At the request of the Board, the Committee considered whether the 2021 Annual Report was fair, balanced and understandable and whether it provided the necessary information for shareholders to assess the Group's performance, business model and strategy.

The external auditor confirmed that in their opinion the Annual Report 2021 was fair, balanced and understandable, which can be found in the Independent Auditor's Report.

This assessment was carried out by the Committee on 3 May 2022, following which the Committee reported to the Board that it was satisfied that, taken as a whole, the Annual Report 2021 is fair, balanced and understandable.

### **Internal Controls and Risk Management**

Following the finalization of the Financial Position, Prospects and Procedures memorandum (FPPP) for the IPO in June 2021, the Committee and management remain focused on ensuring that these procedures – many of which are new to the Company – are fully embedded in the Company. The recent appointees Nils Windler (CFO) and David Bronson (Financial Controller) will be leading this process.

On risk management, the company completed an assessment of key risks and their mitigation at the time of the IPO. This review has been maintained by management and the Committee at the two reporting periods since IPO. Following the appointment of the new CFO, the risk assessment process is being progressively embedded in the company via the senior management team.

### **Internal Audit**

Given that the Company is pre-commercial, it does not have a dedicated in-house Internal Audit resource. Instead, the Company has contracted external Internal Audit services during the year and intends to continue to do so in the forthcoming 12 months.

The Committee has reviewed a draft Internal program with management for the forthcoming 12 months which is in the course of commissioning.

# **Directors Audit Committee Report**

continued

### **External Auditor**

Following the IPO, the Committee sought tenders to provide External Audit services to the Company.

The Committee reviewed the proposals submitted, including a review of service scope, Audit capacity, sectoral knowledge relevant to the Company, provider independence, and costs.

The Committee appointed KPMG at its meeting on 8 July 2021, when it also discussed the scope of the Interim review. At the meeting of 3 September 2021, the Committee reviewed the External Auditors' report on the Interim result, and at its meeting on 8 December, KPMG presented to the Committee a draft Full Year Audit scope for discussion and agreement. At the meeting of 16 March 2022, KPMG presented their report and opinion to the Committee for review.

The Committee regularly reviews the ongoing independence of the External Auditor and is satisfied that KPMG remains independent of the Company. As part of ensuring this independence, the Company does not engage KPMG in activities besides the provision of External Auditor services.

### **Richard Cotton**

Chair of the Audit Committee

### OPINION

We have audited the consolidated financial statements of Spectral MD Holdings, Ltd and its subsidiaries (the Company), which comprise the consolidated balance sheets as of December 31, 2021 and 2020, and the related consolidated statements of operations, comprehensive (loss) income, changes in temporary equity and stockholders' equity (deficit), and cash flows for the years then ended, and the related notes to the consolidated financial statements.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in accordance with US. generally accepted accounting principles.

### **BASIS FOR OPINION**

We conducted our audits in accordance with auditing standards generally accepted in the US (GAAS). Our responsibilities under those standards are further described in the Auditors' Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

# RESPONSIBILITIES OF MANAGEMENT FOR THE CONSOLIDATED FINANCIAL STATEMENTS

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with US. generally accepted accounting principles, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year after the date that the consolidated financial statements are issued.

## AUDITORS' RESPONSIBILITIES FOR THE AUDIT OF THE CONSOLIDATED FINANCIAL STATEMENTS

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the consolidated financial statements.

In performing an audit in accordance with GAAS, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements.

# Independent Auditor's Report to the Board of Directors Spectral MD Holdings, Ltd.

#### continued

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the consolidated financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that
  raise substantial doubt about the Company's ability to continue as a going concern for a reasonable
  period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

PMG LLP

Dallas, Texas March 18, 2022

# Consolidated Income Statement

For the year ended 31 December 2021

	2021 US\$	2020 US\$
Research and development revenue	15,167,827	17,300,884
Cost of revenue	(8,186,698)	(9,314,427)
Gross profit	6,981,129	7,986,457
Operating costs and expenses:		
General and administrative	11,326,513	6,537,687
Total operating costs and expenses	11,326,513	6,537,687
Operating income (loss)	(4,345,384)	1,448,770
Other income (expense):		
Interest expense	(17,342)	(39,839)
Change in fair value of warrant liability	297,779	-
Foreign exchange transaction loss	(187,582)	-
Other income	-	426
Total other income (expense)	92,855	(39,413)
(Loss) income before income taxes	(4,252,529)	1,409,357
Benefit (provision) for income taxes	97,525	(174,626)
Net (loss) income	(4,155,004)	1,234,731
Dividend on Series A preferred stock	(1,258,959)	_
Net (loss) income applicable to common stockholders Other comprehensive loss	(5,413,963)	1,234,731
Foreign currency translation adjustment	(7)	_
Total comprehensive (loss) income applicable to common stockholders	(5,413,970)	1,234,731
Net (loss) income per share of common stock	(0.05)	0.00
Basic	(0.05)	0.02
Diluted	(0.05)	0.00
Weighted average common shares outstanding Basic	100,291,815	57,897,520
Diluted	100,291,815	132,856,898

# Consolidated Balance Sheet

For the year ended 31 December 2021

	2021 US\$	2020 US\$
Assets	035	
Current assets:		
Cash and cash equivalents	16,120,779	5,124,639
Accounts receivable, net	1,434,954	2,690,911
Prepaid expenses and other current assets	857,666	92,868
Total current assets	18,413,399	7,908,418
Non-current assets:		
Property and equipment, net	31,593	-
Other noncurrent assets	39,695	31,046
Total Assets	18,484,687	7,939,464
Liabilities, temporary equity and stockholders' equity		
Current liabilities:		
Accounts payable	1,740,217	3,799,208
Accrued expenses	2,390,687	1,122,129
Notes payable	582,698	-
Warrant liability	185,724	-
Total current liabilities	4,899,326	4,921,337
Non-current liabilities:		
Notes payable	-	768,575
Total non-current liabilities	-	768,575
Total Liabilities	4,899,326	5,689,912
Series A preferred stock (US\$0.001 par value); no shares authorized, issued or outstanding as of December 31, 2021; 10,000,000 shares authorized and 4,324,330 shares issued and outstanding as of December 31, 2020	-	1,113,987
Stockholders' Equity		
Common stock (US\$0.001 par value); 400,000,000 shares authorized;		
135,034,564 shares and 61,347,000 shares issued and outstanding as of		
December 31, 2021 and 2020, respectively	135,035	61,347
Additional paid-in capital	22,639,625	6,096,178
Accumulated deficit	(9,189,292)	(5,021,960)
Accumulated other comprehensive loss	(7)	_
Total Stockholders' equity	13,585,361	1,135,565
Total Liabilities, Temporary Equity and Stockholders' Equity	18,484,687	7,939,464

The notes on pages 50-63 are an integral part of these financial statements.

The financial statements were approved and authorized for issue by the Board on 06 May 2022 and signed on its behalf by:

**Martin Mellish** 

Chairman

Wensheng Fan Chief Executive Officer

Company number:4348471 (Delaware Companies Registry)

# Consolidated Statement of Cashflows

For the year ended 31 December 2021

	2021 US\$	2020 US\$
Cash flows from operating activities:		
Net (loss) income	(4,155,004)	1,234,731
Adjustments to reconcile net (loss) income to net cash (used in) provided by		
operating activities:		
Depreciation expense	723	-
Stock based compensation	1,364,064	2,215,959
Change in fair value of warrant liability	(297,779)	-
Changes in operating assets and liabilities:		
Accounts receivable	1,255,957	(1,913,451)
Prepaid expenses and other current assets	(275,228)	8,580
Other assets	(8,649)	-
Accounts payable	(2,071,319)	2,574,387
Accrued expenses	1,268,558	(300,634)
Net cash (used in) provided by operating activities	(2,918,677)	3,819,572
Cash flows from investing activity:		
Purchases of property and equipment	(7,216)	-
Net cash used in investing activity	(7,216)	-
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrant, net of issuance costs	14,618,161	-
Proceeds from PPP loan	-	768,575
Proceeds from stock option exercise	4,426	46,200
Payments for notes payable	(700,547)	-
Payments for notes payable to related parties	-	(280,000)
Net cash provided by financing activities	13,922,040	534,775
Effect of foreign exchange rates on cash	(7)	4 254 247
Net increase in cash and cash equivalents	10,996,140	4,354,347
Cash and cash equivalents, beginning of period	5,124,639	770,292
Cash and cash equivalents, end of period	16,120,779	5,124,639
Supplemental cash flow information:		
Cash paid for interest	12,220	18,500
Cash paid for income taxes	254,963	12,989
	_01,000	.2,505
Noncash financing activities disclosure:		
Cumulative dividend on Series A preferred stock	1,258,959	-
Conversion of preferred stock to common stock	2,372,946	-
Prepaid asset acquired for debt	473,913	-
Software and prepaid software maintenance acquired for debt	40,757	-
Issuance of common stock to convert notes payable and accrued		
interest to related parties	-	359,732

# Consolidated Statement of Changes in Equity

For the year ended 31 December 2021

	Preferred	Stock	Common	Stock	Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount USS	Shares	Amount USS	Capital US\$	Deficit US\$	Loss US\$	(Deficit) US\$
Balance at December 31, 2019	4,324,330	1,113,987	53,809,092	53,809	3,481,825	(6,256,691)		(2,721,057)
Issuance of common stock to convert notes payable and accrued interest to related								
parties	-	-	1,754,790	1,755	357,977	-	-	359,732
Stock option exercised for cash	-	-	1,980,000	1,980	44,220	-	-	46,200
Stock compensation	-	-	3,803,118	3,803	2,212,156	-	-	2,215,959
Net income	-	-	-	-	-	1,234,731	-	1,234,731
Balance at December 31, 2020	4,324,330	1,113,987	61,347,000	61,347	6,096,178	(5,021,960)	-	1,135,565
Issuance of common stock								
for cash	-	-	19,067,797	19,068	15,594,808	-	-	15,613,876
Issuance cost, net of								
US\$0.5 million warrant liability	-	-	-	-	(1,479,218)	-	-	(1,479,218)
Cumulative dividend on								
Series A preferred stock	-	1,258,959	-	-	(1,258,959)	-	-	(1,258,959)
Conversion of preferred stock								
to common stock	(4,324,330)	(2,372,946)	53,889,765	53,890	2,319,056	-	-	2,372,946
Stock option exercised for cash	-	-	42,500	43	4,383	-	-	4,426
Stock compensation	-	-	687,502	687	1,363,377	-	-	1,364,064
Foreign currency translation								
adjustment	-	-	-	-	-	-	(7)	(7)
Prior period adjustment	-	-	-	-	-	(12,328)		(12,328)
Net loss	-	-	-	-	-	(4,155,004)	-	(4,155,004)
Balance at December 31, 2021	-	-	135,034,564	135,035	22,639,625	(9,189,292)	(7)	13,585,361

### 1. ORGANIZATION, NATURE OF BUSINESS AND LIQUIDITY

Spectral MD, Inc., headquartered in Dallas, Texas, was incorporated in Delaware on March 9, 2009.

On December 23, 2020, the Company formed its wholly owned subsidiary in Delaware, Spectral MD Holdings, Ltd. (the "Company"). The subsidiary had no activity through December 31, 2020.

On June 21, 2021, Spectral MD Merger Sub, Inc. ("Merger Sub"), a Delaware corporation and wholly owned subsidiary of Spectral MD Holdings, Ltd., merged with and into Spectral MD, Inc. Following the merger, the separate corporate existence of Merger Sub ceased and Spectral MD, Inc. continued as the surviving corporation and through the merger became a wholly owned subsidiary of the Company. In connection with the merger, each share of the Spectral MD, Inc.'s common stock and the Spectral MD, Inc.'s preferred stock issued and outstanding immediately prior to the effective date were converted into one share of Common Stock. All of the stockholders of the Spectral MD, Inc. prior to the merger became stockholders of the Company immediately following the merger. All existing Common Stock of the Company held by the Spectral MD, Inc. were cancelled at the effective date of the merger.

On June 22, 2021, the Company was listed and started trading on the AIM market of the London Stock Exchange (the "AIM").

Effective June 21, 2021, all shares of the Company's common stock issued and outstanding were combined and reclassified on a six for one basis. The effect of this stock split has been retroactively applied to all periods presented.

On July 22, 2021, the Company formed its wholly owned subsidiary in the UK, Spectral MD UK Ltd., ("Spectral MD UK") in order to prepare for and initiate the regulatory approval process in the E.U. and U.K.

The Company is devoting substantially all of its efforts towards research and development of its DeepView<sup>®</sup> Wound Imaging System. The Company has not generated any product revenue to date. The Company currently generates revenue from contract development and research services by providing such services to governmental agencies, primarily to the Biomedical Advanced Research and Development Authority ("BARDA"). The Company operates in one segment.

### Liquidity

As of December 31, 2021 and 2020, the Company had approximately US\$ 16.1 million and US\$5.1 million, respectively in cash, and an accumulated deficit of US\$ 8.9 million and US\$ 5.0 million, respectively. The Company has historically funded its operations through the issuance of notes and the sale of preferred stock and common stock. In July 2021, the Company received net proceeds of approximately US\$ 14.6 million from its initial public offering ("IPO") on the AIM on June 22, 2021 (see Note 3). Additionally, during 2021, the Company finalized its execution of Options 1A and 1B of the contract with BARDA, which may provide the Company with an additional US\$ 39.4 million to execute the clinical training study of DeepView<sup>®</sup> Wound Imaging System for burn wound healing assessment. This contract option funding of US\$ 39.4 million follows the US\$ 27.3 million contract received from BARDA in July 2019 in the original award. In total, the contract has a potential funding of up to US\$ 88.7 million if all future options are executed.

The Company evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the release date of the consolidated financial statements. Based on such evaluation and the Company's current plans as described above, management believes that the Company's existing working capital as of December 31, 2021, will be sufficient to satisfy its operating cash needs within one year beyond the release date of the consolidated financial statements.

During the early months of 2020, COVID-19 emerged and has subsequently spread world-wide. The World Health Organization has declared COVID-19 a pandemic resulting in federal, state, and local governments and private entities mandating various restrictions, including travel restrictions, restrictions on public gatherings, stay at home orders and advisories, and quarantining people who may have been exposed to the virus. Management has determined that there has been no significant impact to the Company's operations, however management continues to monitor the situation.

continued

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### **Basis of Presentation**

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the US ("GAAP") as determined by the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC").

### **Basis of Consolidation**

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Spectral MD, Inc. and Spectral MD UK. Significant inter-company transactions and balances have been eliminated in consolidation.

### **Use of Estimates**

The preparation of these consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, revenue recognition, warrant liability, stock-based compensation expense, and income tax valuation allowances. Actual results could differ from these estimates.

### Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash and cash equivalents are held in US financial institutions.

### **Accounts Receivable**

Accounts receivable represent amounts due from US. government agencies pursuant to research and development contracts associated with the Company's DeepView<sup>®</sup> Wound Imaging System. Accounts receivable amounted to approximately US\$1.4 million and US\$ 2.7 million as of December 31, 2021 and 2020, respectively.

The Company evaluates the collectability of its receivables based on a variety of factors, including the length of time the receivables are past due, the financial health of its customers and historical experience. Based upon the review of these factors, the Company recorded no allowance for doubtful accounts as of December 31, 2021 and 2020.

### **Concentrations of Credit Risk**

Financial instruments which potentially subject the Company to credit risk consist principally of cash and cash equivalents and accounts receivable. All cash and cash equivalents are held in US financial institutions which, at times, exceed federally insured limits. The Company has not recognized any losses from credit risks on such accounts. The Company believes it is not exposed to significant credit risk on cash and cash equivalents.

Additional credit risk is related to the Company's concentration of receivables. As of December 31, 2021 and 2020, receivables were concentrated from one customer (which is a US. government agency) representing 94% and 99% of total net receivables, respectively. No allowance for doubtful accounts were recorded as of December 31, 2021 and 2020.

One customer (which is a US. government agency) accounted for 98% of the recognized research and development revenue for each of the years ended December 31, 2021 and 2020.

### Fair Value

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 Unadjusted quoted prices in active markets that are assessable at the measurement date for identical, unrestricted assets or liabilities.
- Level 2 Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3 Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

#### Fair Value of Financial Instruments

Financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments.

### Foreign Currency

The reporting currency for the consolidated financial statements of the Company is the US. dollar. The functional currency of Spectral MD Holdings, Ltd. is the US. dollar. The functional currency of the Company's subsidiaries is the local currency of the subsidiaries. The assets and liabilities of this subsidiary is translated into US. dollars at exchange rates in effect at the end of each reporting period. Revenues and expenses for these subsidiaries are translated at average exchange rates in effect during the applicable period. Translation adjustments are included in accumulated other comprehensive income as a component of stockholders' equity.

Monetary assets and liabilities denominated in currencies other than the functional currency are translated at exchange rates in effect at the balance sheet date. Resulting unrealized gains and losses are included in other income, net in the consolidated statements of operations. For the year ended December 31, 2021, the Company recorded a US\$ 160,782 foreign exchange transaction loss, primarily related to the Company's bank account denominated in British Pounds, included in foreign exchange transaction loss on the consolidated statement of operations and comprehensive (loss) income. The Company did not have any foreign exchange transaction gains or losses for the year ended December 31, 2020.

#### **Derivative Liabilities**

The Company does not generally use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. During the year ended December 31, 2021, the Company entered into one derivative instrument, to set a foreign currency exchange rate, that settled during the year. The accounting for changes in fair value of derivatives depends on the intended use of the derivative and resulting designation. The Company did not designate its derivative instrument as a hedge for accounting purposes and, as a result, marked its derivative instrument to fair value and recognized a change in fair value of US\$ 26,800 included in foreign exchange transaction loss in the consolidated statement of operations and comprehensive (loss) income.

The Company evaluates all of its financial instruments, including issued stock purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC 480 and FASB ASC Topic 815, "Derivatives and Hedging" ("ASC 815"). The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. The Company accounts for its warrants issued to SP Angel, who acts as nominated adviser and broker to the Company for the purposes of the AIM Rules as derivative liabilities in accordance with ASC 815. Accordingly, the Company recognizes the instruments as liabilities at fair value, determined using the Black-Scholes option-pricing model, and adjusts the instruments to fair value at the

#### continued

end of each reporting period. The liabilities are subject to re-measurement at each consolidated balance sheet date until exercised, and any change in fair value is recognized in the Company's consolidated statements of operations.

### **Research and Development Revenue**

The Company recognizes revenue when the Company's customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services by analyzing the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation. In order to transfer control to the customer for contract development and manufacturing services, the Company must have a present right to payment, legal title must have passed to the customer, and the customer must have the significant risks and rewards of ownership. Research and development revenue contracts are generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with transferring control of the good or service over time.

The Company generates research and development revenue primarily from cost-plus-fee contracts associated with development of certain product candidates. Revenues from reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. The Company uses this input method to measure progress as the customer has the benefit of access to the development research under these projects and therefore benefits from the Company's performance incrementally as research and development activities occur under each project. We consider fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. Revenue for long-term development contracts is considered variable consideration because the deliverable is dependent on the successful completion of development and is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with satisfying the performance obligation over time. The Company was awarded multiyear contracts in 2019 and 2021 by BARDA for the development of the Company's DeepView® Wound Imaging Solution. BARDA may award contracts that are less than 12 months depending on the scope of work and deliverables.

Payments from customers are generally received within 30 days of when the invoice is sent.

Because the Company's contracts have an expected duration of one year or less, the Company has elected the practical expedient in ASC 606-10-50-14(a) to not disclose information about its remaining performance obligations.

### Research and Development

The Company expenses research and development costs as operating expenses as incurred. These expenses include salaries for research and development personnel, consulting fees, product development, pre-clinical studies, clinical trial costs, and other fees and costs related to the development of the technology.

### Stock-Based Compensation

The Company accounts for all stock-based payments to employees and non-employees, including grants of stock options, restricted stock awards ("RSAs") and stock options with non-market performance conditions ("PSOs") to be recognized in the consolidated financial statements, based on their respective grant date fair values. The Company estimates the fair value of stock option grants and PSOs using the Black-Scholes option pricing model. The RSAs are valued based on the fair value of the Company's common stock on the date of grant. The assumptions used in calculating the fair value of the Company's stock and stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company expenses stock-based compensation related to stock options and RSAs over the requisite service period. As the PSOs have performance conditions, compensation expense is recognized for each award if and when the Company's management deems it probable that the performance conditions will be satisfied. Forfeitures are recorded as they occur. Compensation previously recorded for unvested equity awards that are forfeited is reversed upon forfeiture. The Company expenses stock-based compensation to employees over the requisite service period, on a straight-line basis, based on the estimated grant-date fair value of the awards.

continued

#### Income Taxes

Income taxes are recorded in accordance with ASC 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company has no uncertain tax positions as of December 31, 2021 and 2020 that qualify for either recognition or disclosure in the consolidated financial statements under this guidance.

The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the consolidated statements of operations. There were no amounts accrued for interest or penalties for the years ended December 31, 2021 and 2020.

### Net (Loss) Income per Share of Common Stock

Basic net (loss) income per share of common stock is computed by dividing the net (loss) income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted (loss) income per share of common stock adjusts basic earnings per share for the potentially dilutive impact of unvested restricted stock, stock options, warrants and preferred stock. Dilutive securities having an anti-dilutive effect on diluted net earnings per share are excluded from the calculation. The dilutive effect of the unvested restricted stock and stock options is calculated using the treasury stock method. For warrants that are liability-classified, during periods when the impact is dilutive, the Company assumes share settlement of the instruments as of the beginning of the reporting period and adjusts the numerator to remove the change in fair value of the warrant liability and adjusts the denominator to include the dilutive shares calculated using the treasury stock method. The Company applies the if-converted method to compute the potentially dilutive effect of the Series A preferred stock.

### **Recently Adopted Accounting Standards**

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The Company adoption of this standard on January 1, 2021 did not have an effect on its consolidated financial statements as it did not change the way collaborative development services and the related costs of these services are reflected in the Company's consolidated financial statements.

### **Recently Issued Accounting Standards**

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The Company will adopt ASU 2016-02 on January 1, 2022. The Company does not expect ASU 2016-02 to have a material impact on the Company's consolidated financial statements.

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In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses, which was subsequently amended by ASU 2018-19 and ASU 2019-10. This standard requires the measurement of expected credit losses for financial instruments carried at amortized cost held at the reporting date based on historical experience, current conditions and reasonable forecasts. The updated guidance also amends the current other-than-temporary impairment model for available-for-sale debt securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security's amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. With the issuance of ASU 2019-10 in November 2019, the standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2022. The Company will continue to assess the possible impact of this standard, but currently does not expect the adoption of this standard will have a significant impact on its consolidated financial statements, given its limited history of bad debt expense relating to trade accounts receivable.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. The ASU is effective for the Company on January 1, 2024. Early adoption is permitted, but no earlier than January 1, 2021. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

### 3. INITIAL PUBLIC OFFERING

The Company completed its initial public offering on AIM on June 22, 2021. The Company issued 19,067,797 shares of common stock for net proceeds of approximately US\$ 14.6 million after deducting offering expenses of approximately US\$1.0 million incurred by the Company (the "Offering"). The Company also issued 762,712 warrants to SP Angel, who acts as nominated adviser and broker to the Company for the purposes of the AIM Rules at the Placing Price. The initial fair value of warrants was approximately US\$ 0.5 million (see Note 4). The proceeds of the Offering will be primarily used for Diabetic Foot Ulcer ("DFU") clinical trials in the US (US.) and Europe, and FDA clearance in the US. and CE Mark application and approval in Europe to use DeepView for DFU application.

### 4. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial liabilities that are measured at fair value on a recurring basis as of December 31, 2021, by level within the fair value hierarchy:

	Fair value measured at December 31, 2021						
	Fair value at	Fair value at Quoted prices Significant					
	December 31,	in active	other observable	unobservable			
	2021	markets (Level 1)	inputs (Level 2)	inputs (Level 3)			
	US\$	US\$	US\$	US\$			
Warrant Liability	US\$185,724	US\$-	US\$-	US\$185,724			

There were no transfers between Level 1, 2 or 3 during the year ended December 31, 2021. There was no warrant liability in 2020.

continued

The following table presents changes in Level 3 liabilities measured at fair value for the year ended December 31, 2021 (in US\$).

Balance - December 31, 2021	US\$185,724
Change in fair value	(297,779)
Issuance of warrants	483,503
Balance - January 1, 2021	US\$-

Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs.

The following table provides quantitative information regarding Level 3 fair value measurements inputs at their measurement:

	December 31, 2021	June 16, 2021
Strike price (per share in US\$)	US\$0.80	US\$0.89
Contractual term (years)	5.5	6.0
Volatility (annual)	67.6%	85.0%
Risk-free rate	1.3%	0.9%
Dividend yield (per share)	0.0%	0.0%

### 5. RESEARCH AND DEVELOPMENT REVENUE

For the years ended December 31, 2021 and 2020, the Company's revenues disaggregated by the major sources was as follows:

	2021 US\$	2020 US\$
BARDA	14,897,161	17,037,784
Other US governmental authorities	270,666	263,100
Total revenue	15,167,827	17,300,884

### 6. ACCRUED EXPENSES

Accrued expenses consist of the following as of December 31, 2021 and 2020:

	2021 US\$	2020 US\$
Salary and wages	896,200	619,510
Provision operating expenses	700,224	-
Benefits	469,518	302,540
Franchise tax	291,425	-
Deferred rent	22,623	32,867
Accrued interest	10,697	5,575
Income tax	-	161,637
Total accrued expenses	2,390,687	1,122,129

### continued

### 7. NOTES PAYABLE AND NOTES PAYABLE TO RELATED PARTIES

### **Notes Payable**

### PPP Loan

On April 13, 2020, the Company entered into a promissory note with JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program ("PPP") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") for US\$ 768,575 (the "PPP Loan"). The PPP Loan, which matures on April 13, 2022 and bears interest at 1% per annum, can be prepaid at any time prior to maturity with no prepayment penalties. The Company could defer interest and principal payments until September 13, 2021. Beginning on September 13, 2021, the Company was required to make equal monthly payments of principal and interest until the loan maturity on April 13, 2022. The PPP Loan is subject to customary terms for payment defaults and breaches of representations and warranties. The Company did not request the PPP Loan. As of December 31, 2021, the Company repaid US\$ 355,270 of principal and interest for the PPP Loan. As of December 31, 2021 and 2020, the remaining principal is US\$ 415,500 and US\$ 768,575, respectively, and accrued interest is US\$ 10,586 and US\$ 5,554, respectively, for the PPP Loan.

### Insurance Note

On June 21, 2021, the Company entered into a financing agreement for a portion of its insurance premium for US\$ 473,913 ("Insurance Note"). The Insurance Note bears interest at 5.7% per annum and is payable in nine equal monthly payments of principal and interest beginning on July 21, 2021. As of December 31, 2021, the remaining principal is US\$ 160,405.

### Software Note

On February 28, 2021, the Company entered into a note for the purchase of software of US\$ 40,757 ("Software Note") which is due in six equal payments beginning September 1, 2021. The imputed interest for the Software Note is immaterial. As of December 31, 2021, the remaining principal is US\$ 6,793.

### **Notes Payable to Related Parties**

#### 2019 Notes Payable to Related Parties

On August 7, 2019, the Company entered into two promissory notes (the "Notes") with Granicus IP, LLC, an entity owned by the Company's then Chairman of the Board, and John H and Marcia Kirk Stevens Family Trust, an entity owned by the Company's then board member, each for US\$ 100,000. The Notes bore interest at 10% per annum and were due on demand. During 2020, the Company repaid the Notes for US\$ 218,500, including principal and accrued interest.

### 2013 Notes Payable to Related Parties

During 2013, the Company entered into two demand notes (the "2013 Notes") with Erich Spangenberg, a shareholder of the Company, and LSC Holding, LLC, an entity affiliated with a shareholder of the Company, for US\$ 136,220 and US\$ 150,000, respectively, that bore interest at 7% per annum and 8% per annum, respectively.

During 2020, the Company issued 1,754,790 shares of its common stock to related parties to extinguish outstanding principal and accrued interest of US\$ 359,732 and paid cash of US\$ 80,000 for the remaining balance of the 2013 Notes.

The following table summarizes interest expense included in the consolidated statements of operations and comprehensive (loss) income for the years ended December 31, 2021 and 2020:

	2021 US\$	2020 US\$
PPP loan	7,317	5,575
Insurance premium financing	10,025	-
2019 Notes payable to related parties	-	11,833
2013 Notes payable to related parties	-	19,461
Interest charge on credit card	-	2,970
Total interest expense	17,342	39,839

### 8. COMMITMENTS

### Legal Matters

The Company is not currently subject to any material legal proceedings; however, the Company may from time to time become a party to various legal proceedings arising in the ordinary course of the Company's business.

### Leases

In August 2017, the Company assumed a lease for its principal office in Dallas, Texas, which expires on March 1, 2023. Base rent in connection with the lease is US\$ 47,645 per month, as of December 31, 2021. During 2021, the Company also entered into a short-term lease agreement for office space and property in the United Kingdom.

The Company recorded rent expense of US\$ 779,812 and US\$ 663,746 for the years ended December 31, 2021 and 2020, respectively.

Future minimum payments under the Company's lease agreement, as of December 31, 2021 is as follows:

	2021 US\$
2022	579,189
2023	96,780
Total	675,969

### 9. PREFERRED STOCK

Effective June 21, 2021, the Company increased its authorized shares for preferred stock to 10,000,000 shares.

The preferred stock had the following key terms:

Liquidation: In the event of certain voluntary or involuntary acquisition or sale transactions or upon the liquidation, dissolution or winding up of the Company (each, a "Distribution Event"), the holders of Series A preferred stock were entitled to receive out of the proceeds or assets of the Company legally available for distribution to its shareholders (the "Proceeds"), prior and in preference to any distribution of the Proceeds of such Distribution Event to the holders of common shares by reason of their ownership thereof, an amount per share equal to the Liquidation Value per share, plus a cumulative preference of 8% per annum, compounded annually from the date of issuance of the Series A preferred stock (collectively, the "Distribution in full of the Distribution Preference Amount"). In the event that the Proceeds shall be insufficient to enable the distribution in full of the Distribution Preference Amount to the holders of the Series A preferred stock for all of the preferred shares held by them, all of the Proceeds shall be distributed among the holders of Series A preferred stock on a pro rata, as-converted basis. Upon completion of the distribution to shareholders shall be distributed among the holders of series A preferred stock on a pro rata, as-converted basis. Upon completion of the number of common shares shall be distributed among the holders of series and preferred stock on a pro rata based on the number of common shares held by each such holder.

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The aggregate liquidative value of the Series A preferred stock was US\$ 2,283,845 as of December 31, 2020.

Conversion: At any time after issuance, the Series A preferred stock was convertible, in whole or in part, into shares of the Company's common stock at the option of the Holder. Each Series A preferred share was automatically converted into common stock of the Company upon the closing a firmly underwritten public offering netting proceeds of at least US\$ 25 million at an offering price calculated based on a Company valuation of at least US\$ 150 million, and approved by holders of the Series A preferred stock. The number of shares of common stock to be converted by the Liquidation Value, (ii) adding to the result a cumulative preference of 8% per annum, compounded annually from the date of issuance of the Series A preferred stock, and then (iii) dividing the result by the conversion price in effect immediately prior to such conversion. The conversion price of the Series A preferred stock is US\$ 0.2642 per share, subject to adjustment for stock dividends, reclassifications, recapitalizations and combinations.

Immediately prior to the Offering, all outstanding shares of Series A preferred stock and unpaid cumulative dividend were converted into 53,889,765 shares of common stock.

Voting: Holders of Series A preferred stock voted on as-converted basis and have full voting rights and powers equal to the voting rights and powers of the holders of common shares, voting as a single class. Holders representing a Series A preferred majority, exclusively and as a separate class, were entitled to elect two (2) directors of the Company.

As of December 31, 2021, there were no outstanding preferred stock.

### 10. STOCKHOLDERS' EQUITY

The Company was authorized to issue 400,000,000 and 25,000,000 shares of common stock, par value US\$ 0.001 per share, as of December 31, 2021 and 2020, respectively. The Company had 135,034,564 and 61,347,000 shares of common stock issued and outstanding as of December 31, 2021, and 2020, respectively.

During the year ended December 31, 2021, the Company issued 19,067,797 shares of common stock for net proceeds of approximately US\$ 14.6 million after deducting offering expenses of approximately US\$ 1.0 million incurred by the Company. During the year ended December 31, 2021, the Company issued 42,500 shares of common stock for aggregate proceeds of US\$ 4,426 from stock option exercises. During the year ended December 31, 2020, the Company issued 1,980,000 shares of common stock for aggregate proceeds of US\$ 46,200 from stock option exercises.

During the year ended December 31, 2020, the Company issued 1,754,790 shares of its common stock to related parties to extinguish outstanding principal and accrued interest of US\$ 359,732 of loans to related parties.

### 11. STOCK-BASED COMPENSATION

### 2018 Long Term Incentive Plan

On July 24, 2018, the Company's' Board adopted the 2018 Long Term Incentive Plan (the "2018 Plan") which permits granting of incentive stock options (they must meet all statutory requirements), non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, and other cash-based or stock-based awards. Pursuant to the 2018 Plan, stock options must expire within 10 years and must be granted with exercise prices of no less than the fair value of the common stock on the grant date, as determined by the Board of Directors.

### **Restricted Stock**

The RSAs generally vest over four years. A summary of RSA activities for the year ended December 31, 2021 and 2020 are presented below.

	Number of Shares	Weighted Average Grant Date Fair Value per Share US\$
Nonvested at January 1, 2020	27,925,002	US\$0.10
Restricted stock forfeited	(22,371,876)	
Vested	(3,803,124)	US\$0.10
Nonvested at December 31, 2020	1,750,002	US\$0.10
Vested	(687,500)	US\$0.10
Nonvested at December 31, 2021	1,062,502	US\$0.10

### **Stock Options**

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company's common stock became publicly traded on July 22, 2021 and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options for employees has been determined utilizing the "simplified" method for awards. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the US. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

In applying the Black Scholes option pricing model, the Company used the following assumptions for stock options granted in 2021 and 2020:

	2021	2020
Exercise price (per share in US\$)	US\$0.26	US\$0.16
Expected term (years)	5.3	5.0
Volatility (annual)	82%	85%
Risk-free rate	0.4%	0.2%
Dividend yield (per share)	0%	0%

A summary of stock options activity for the years ended December 31, 2021 and 2020 is presented below:

	Stock Options	Weighted Average Exercise Price US\$	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value US\$
Outstanding at January 1, 2020	24,894,000	US\$0.10	8.8	US\$-
Options granted	11,940,000	US\$0.21	10.0	
Options exercised for cash	(1,980,000)	US\$0.02		
Options forfeited/expired	(7,249,500)	US\$0.11		
Outstanding at December 31, 2020	27,604,500	US\$0.15	8.8	US\$1,604,758
Options granted	7,208,000	US\$0.26	8.9	
Options exercised for cash	(42,500)	US\$0.15		
Options forfeited/expired	(801,000)	US\$0.20		
Outstanding at December 31, 2021	33,969,000	US\$0.17	8.1	US\$10,963,319
Options vested and exercisable at December 31, 2021	25,746,426	US\$0.14	7.7	US\$5,558,828

#### continued

During 2021 and 2020, the Company granted 180,000 and 1,320,000 stock options, respectively, to certain employees with certain performance conditions, including achieving a qualified financing or clinical milestones. For the year ended December 31, 2021, all of the performance conditions were achieved and the Company recorded US\$ 200,948 of stock-based compensation expense for these awards based on the grant date fair value of each award in the consolidated statement of operations and comprehensive (loss) income. For the year ended December 31, 2020, management did not deem that it was probable that the performance conditions would be satisfied so expense was not recorded for these awards.

In November 2020, the Company modified the stock option awards to change the awards from vesting over four years to vesting over three years. Subsequent to November 2020, stock option awards generally vest over three years.

For the years ended December 31, 2021 and 2020, the Company recorded stock-based compensation of US\$ 1,364,064 and US\$ 2,215,959, respectively, in general and administrative expenses in the consolidated statements of operations and comprehensive (loss) income.

As of December 31, 2021, there was US\$ 1,706,590 of unrecognized stock-based compensation related to stock option grants that will be amortized over a weighted average period of 0.9 years.

As of December 31, 2021, there was US\$ 103,334 of unrecognized stock-based compensation related to restricted stock option grants that will be amortized over a weighted average period of 0.9 years.

During the year ended December 31, 2018, the Company issued 983,022 shares of common stock and 1,673,321 stock options (the "Investor Options") for an aggregate proceeds of US\$ 973,192. The Investor Options have a two-year term and are exercisable at a price of US US\$1.20 per share. The Investor Options expired on December 31, 2020.

### Warrants

On June 22, 2021, in conjunction with the closing of the Company's IPO, the Company issued 762,712 warrants, with strike price of US\$ 0.89 and a ten-year life, to SP Angel, who acts as nominated adviser and broker to the Company for the purposes of the AIM Rules. As of December 31, 2021, there are 762,712 warrants outstanding with an exercise price of US\$ 0.80.

### 12. INCOME TAXES

As of December 31, 2021 and 2020, the Company had available federal net operating loss carryforwards ("NOLs") of US\$ 3,042,616 and US\$ 0, respectively, which are available to offset future federal taxable income. Under the Tax Cuts and Jobs Act, all NOLs incurred after December 31, 2017 are carried forward indefinitely for federal tax purposes. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") signed in to law on March 27, 2020, provided that NOLs generated in a taxable year beginning in 2020, 2019, or 2018, may now be carried back five years and forward indefinitely. In addition, the limitation of NOL utilization up to 80% of taxable income limitation is temporarily (for 2020, 2019 and 2018) removed, allowing NOLs to fully offset taxable income. Federal tax returns for the years 2018, 2019 and 2020 remain subject to audit.

The tax effects of temporary differences that give rise to significant portions of the deferred tax asset is presented below:

	2021 US\$	2020 US\$
Deferred income tax assets:		
Net operating loss carryforwards	638,949	-
Stock-based compensation	250,431	370,822
Other	195,975	165,552
Total deferred income tax assets	1,085,355	536,374
Deferred income tax liabilities:		
Fixed assets	759	-
Total deferred income tax liabilities	759	-
Net deferred income tax assets	1,084,596	536,374
Valuation allowance	(1,084,596)	(536,374)
Deferred income tax assets, net of valuation allowance	-	-

ASC 740, "Income Taxes" requires that a valuation allowance be established when it is "more likely than not" that all, or a portion of, deferred tax assets will not be realized. A review of all available positive and negative evidence needs to be considered, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. After consideration of all the information available, management believes that uncertainty exists with respect to future realization of its deferred tax assets and has, therefore, established a full valuation allowance as of December 31, 2021, and 2020. The net change in valuation allowance for the years ended December 31, 2021 and 2020 was an increase of US\$ 548,222 and a decrease of US\$ 279,423, respectively.

The income tax provision consists of the following as of December 31:

	2021 US\$	2020 US\$
Current:		
US Federal	(159,341)	161,637
US State	61,816	12,989
Total current provision	(97,525)	174,626
Deferred:		
US Federal	-	-
US State	-	-
Total deferred provision	-	-
Total provision for income taxes	(97,525)	174,626

A reconciliation of the US. Statutory income tax rate to the Company's effective tax rate is as follows:

	2021 US\$	2020 US\$
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal	(1.1%)	0.7%
Stock-based compensation	(6.1%)	10.2%
Other	1.4%	0.3%
Change in valuation allowance	(12.9%)	(19.8%)
Provision for income taxes	2.3%	12.4%

### continued

### 13. RELATED PARTY TRANSACTIONS

There are no related party transactions or balances, other than as disclosed in Note 7, above.

## 14. NET (LOSS) INCOME PER COMMON SHARE

The reconciliations between basic and diluted net (loss) income per common share for the years ended December 31, 2021 and 2020 are as follows:

	2021 US\$	2020 US\$
Numerator		
Net (loss) income	US\$ (4,155,004)	US\$ 1,234,731
Dividend on Series A preferred stock	(1,258,959)	-
Net (loss) income applicable to common stockholders		
(numerator for net (loss) income per common share - basic)	US\$ (5,413,963)	US\$ 1,234,731
Less: preferred dividends upon conversion of Series A preferred stock	-	(1,145,859)
Numerator for net (loss) income per common share - diluted	US\$ (5,413,963)	US\$ 88,872
Denominator		
Weighted-average common shares outstanding - basic	100,291,815	57,897,520
Weighted-average dilutive shares issuable - unvested restricted stock	-	10,369,593
Weighted-average dilutive shares issuable - stock options	-	12,621,203
Weighted-average dilutive shares issuable - Series A preferred stock	-	51,968,582
Weighted-average common shares outstanding - diluted	100,291,815	132,856,898
Net (loss) income per common share		
Basic	US\$ (0.05)	US\$0.02
Diluted	US\$ (0.05)	US\$0.00

The table below summarizes potentially dilutive securities that were not considered in the computation of diluted net (loss) income per common share because the effect would be anti-dilutive.

	2021	2020
Shares issuable upon vesting of restricted stock	1,062,502	-
Shares issuable upon exercise of stock options	33,969,000	11,820,000
Shares issuable upon exercise of warrants	762,712	-
Total anti-dilutive shares	35,794,214	11,820,000

### **15. SUBSEQUENT EVENTS**

In February 2022, the Company granted approximately 2,175,000 stock options to various employees of the Company, including Wensheng Fan, CEO of the Company. All options are granted under the 2018 Long Term Incentive Plan.

In February 2022, the Company paid aggregate bonuses of US\$ 265,000 to Mr. Fan, CEO of the Company, including a bonus of US\$ 225,000 that was included in accrued expenses on the consolidated balance sheet as of December 31, 2021, and a discretionary bonus of US\$ 40,000.

