

# Annual Report and Accounts

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for the year ended 31 December 2022

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# To the Members of Spectral MD

I am pleased to present the Company's Annual Report and Accounts for the year ended 31 December 2022, a year of great progress for both our Burn and Diabetic Foot Ulcer ("DFU") indications. We are nearing the final phase of our preparation for commercialization of the Company's DeepView<sup>®</sup> Wound Imaging System ("DeepView<sup>®</sup>"). With a cash position at year end of US\$ 14.2 million (2021: US\$ 16.1 million), we are well placed to drive this forward.

# Operations - DeepView® Wound Imaging System

Throughout 2022 we have continued to work closely with US Government partners for the Company's Burn indication, principally, the Biomedical Advanced Research and Development Authority ("BARDA") and the Defense Health Agency of the Department of Defense, who have awarded Spectral MD a total funding commitment of US\$123 million since 2013. BARDA continued its support for Spectral MD and in August 2022 awarded an US\$8.2 million contract to accelerate the commercialization of DeepView<sup>®</sup> by expanding the number of sites for the clinical training study for burn wounds, increasing DeepView<sup>®</sup>'s interoperability with electronic health records, and further accelerating the Company's manufacturing readiness.

Substantial progress has also been made with the Company's DFU indication. Following initiation of the DFU Validation Study in June 2022, Spectral announced positive interim results in January 2023. The DeepView AI-DFU<sup>®</sup> diagnostic accuracy, being the prediction of a 50% DFU size reduction by week four, improved five-percentage points to 86% on day one healing assessment. The Validation Study is on track to complete enrollment by end of Q2 2023, and data from the study will support improvements to the DeepView AI-DFU<sup>®</sup> algorithm that will strengthen the Company's planned 2023 US Food and Drug Administration ("FDA") regulatory submission. Post year end, we have initiated the EU Clinical study for DFU with the Royal College of Surgeons in Ireland ("RCSI") at the Connolly Hospital in Dublin. We believe the industry-academic partnership of distinguished clinicians and clinical researchers involved in the study is a significant endorsement for the DeepView<sup>®</sup> technology and its potential to address a significant unmet need.

Since the Company's IPO in June 2021, we have become more widely recognized and were very proud to receive the Best Technology Award at the European Mediscience Awards in June 2022, an accolade that compliments the hard work and diligence of the Spectral MD team.

2022 also saw further advancement of the DeepView SnapShot<sup>®</sup>M, a fully handheld prototype and wireless version of the DeepView<sup>®</sup> solution with similar performance to the Company's cart-based system which we will continue to develop in 2023. The miniaturization of DeepView<sup>®</sup> is fundamental to our future strategic goals for the technology and its plurality of use cases, as it opens up new indications such as use in medical clinics, primary care, plastic surgery, primary responders, dermatology and at-home-use. The Company expects to receive further grant funding in 2023 to continue the development of DeepView SnapShot<sup>®</sup>M.

### Financial

The Company continued its excellent cost management in 2022 with two positive trading updates reflecting cost controls related to the Company's Burn and DFU clinical studies. We have increased our investment in DeepView® technology, and this has been aided by continued support from BARDA, with R&D revenue up 67% to US\$ 25.4 million (2021: US\$ 15.2 million), which includes funding our Burn indication development as well as the development of DeepView SnapShot®M. As a result, we ended the year with a strong cash position of US\$ 14.2 million (2021: US\$ 16.1 million), and the Board is confident this will support our clinical and regulatory goals in 2023 and beyond as the Company increases investment as it nears commercialization.

# Chairman's Statement

continued

### People

In 2022, we increased our headcount from 55 to 71 full time employees across the US and UK to enable the Company to realize its technology, IP, clinical, regulatory, and commercial goals in 2022 and 2023. Our senior hires include the appointment of Dr. Niko Pagoulatos as Chief Operating Officer; Christine Marks, VP Marketing & Commercialization; Vincent Capone, General Counsel & Company Secretary; and Mary Regan, VP of Clinical Affairs.

I would like to thank all of our hardworking employees at Spectral MD for their contributions over the last 12 months. Since Spectral MD's IPO in June 2021, the Company has realized several of its key operational milestones on or ahead of schedule. This would not have been possible without the dedication and efforts of our team.

## Outlook

It has been a successful year for Spectral MD which we expect to replicate in FY23. Our immediate focus remains on commercialization. We will continue to update shareholders as we progress towards this goal. Through excellent cost management we have ensured that the Company is in a strong position to support our clinical and regulatory goals in 2023 and beyond.

Our objective for DeepView's AI engine is to make world-leading diagnostic expertise accessible to every provider, in every country. In supporting burn injury evaluation and treatment decisions on day one, Spectral can help shorten hospital stays and reduce the extended patient discomfort associated with the traditional wait-and-see approach to burn tissue triage. For the DFU patient, DeepView provides critical support to the clinician in ensuring that these painful, chronic wounds are set on a pathway to treatment, and healing. We hold these to be worthy goals, and we are grateful for your support as we progress towards them.

Martin Mellish Chairman

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## CHIEF EXECUTIVE'S REVIEW

I am pleased to present the audited results for the twelve months ended 31 December 2022 for Spectral MD, Holdings, Ltd. 2022 was a year focused on sizable expansion, and development of our DeepView<sup>®</sup> technology and operations. Spectral MD continues to make significant advances in the development of the DeepView<sup>®</sup> Wound Imaging Technology for both Burn and DFU indications, as the Company continues to work towards commercialization.

The development of each AI application involves an initial study for training the AI algorithm followed by a separate clinical validation study, subsequently followed by regulatory submission. Below is an update and outlook on each application, and on other key strategic elements.

### **BURN INDICATION (BARDA)**

### Update

Spectral MD has received substantial support from the US Government, with contracts from institutions such as the BARDA, National Science Foundation ("NSF"), National Institute of Health ("NIH") and Defense Health Agency ("DHA") in support of the Burn indication for its DeepView<sup>®</sup> platform. Total grant funding awarded to date from these organizations is over US\$ 125 million, including the recently awarded US\$ 8.2 million BARDA contract expansion. The Company is in regular communication with BARDA to further develop its infrastructure readiness for a federal level commercial contract.

This US\$ 8.2 million contract expansion from BARDA awarded in August 2022 helps the Company further accelerate the commercialization pathway for the Company's DeepView<sup>®</sup> Wound Imaging System. The award expanded the current clinical training study for burn wounds by adding clinical sites, further increases DeepView<sup>®</sup>'s interoperability with health systems' electronic health records ("EHR") and boosts the Company's manufacturing capacity readiness.

In 2022, the Company made substantial progress in the Burn AI Training study, completing adult enrollment, and getting close to the enrollment goal for pediatrics. As of 31 December 2022, the Company's proprietary, and clinically validated database for burns, is comprised of 6.7 terabytes and 263 billion pixels. This database presents both a significant barrier to entry to would-be competitors in wound care healing assessment, and a potential additional commercial opportunity for the Company to develop further in the future.

### **Emergency Department Update**

The unpredictability of severe burn injuries is a complex critical care problem. As training in burn injuries is no longer required during medical training residency, the appropriate determination of burn depths is extremely low. In published literature, non-burn care providers are accurate 50% of the time in predicting early healing potential in burn injuries using visual clinical judgment. Due to the lack of lab tests and diagnostic tools, some Emergency Department ("ED") physicians often adopt the "wait and see" approach for wound progression for 3-7 days, thereby occupying valuable bed space, additional costs, longer hospital stays and over-excision of viable skin. Some physicians prefer to directly transfer the patient to a specialty burn center. This practice is confirmed by the published Journal of Burn Care Research that found 41% of patients with Total Body Surface Area ("TBSA") less than 10% were unnecessarily transferred to burn centers for specialized treatment and discharged within 24 hours.

In alignment with BARDA's emergency preparedness mission, the US\$ 8.2 million contract expansion awarded in August 2022 provides funding to expand the current Burn AI dataset to include ED patient enrollment. The addition of EDs will facilitate establishing a clinical benchmark for DeepView<sup>®</sup>'s ED burn healing assessment, which the Company anticipates will have a major impact in the delivery of care for burns in that setting.

In February 2022, the Company and the FDA conducted a pre-submission meeting for alignment on the Company's ED strategy. The FDA's feedback confirmed the Company's ED approach and stated that they see utility of DeepView<sup>®</sup> in Emergency Rooms across the US.

# CEO Statement

continued

### Burn Image Assessment Study (BIAS) Update

The goal of the Institutional Review Board ("IRB") approved Burn Image Assessment Study ("BIAS") was to quantify the current US clinical visual judgment of burn wound healing assessment from ED and Burn healthcare professionals to determine clinicians' accuracy of burn wound healing assessment from still images.

In 2022, the BIAS study was conducted at four national conferences, American Burn Association ("ABA"), Southern Region Burn Conference ("SRBC"), American Academy of Emergency Medicine ("AAEM"), and American College of Emergency Physicians ("ACEP"). The Company invited Emergency Medicine and Burn clinicians from across the country to participate in the BIAS study at its exhibit booth.

The BIAS study demonstrated that ED physicians incorrectly selected immediate referral to a burn center or surgery in 31% of healing wounds and failed to select immediate referral or surgery in 74% of non-healing wounds. This reinforces DeepView<sup>®</sup>'s value proposition that ED physicians need clinical decision support in assessing healing potential of burn wounds.

### Outlook

In February 2023, Spectral MD completed the enrollment for pediatrics in the Burn AI Training Study. Following completion of enrollment for pediatrics, the Company plans to complete its pre-submission to the FDA to achieve alignment on the Burn Validation Study protocol. The Company also plans to initiate its Burn AI Validation Study in 2023, with data collected supporting its FDA submission for DeepView<sup>®</sup>'s Burn indication.

The Company continues to be in regular communication with BARDA to further develop its infrastructure readiness for a potential federal level commercial contract award. A federal contract opportunity for Health and Human Services Burn Wound Imaging technology has been initiated and the Company responded with its proposal. Spectral MD will be evaluated for contract fulfillment. The Company is fully committed to upscaling its operations and infrastructure in the near term to ramp up commercial readiness by the end of 2024 and into 2025 for deployment of DeepView<sup>®</sup> technology into health systems across the US.

While our commercial priority for the Burn indication continues to be BARDA, the Company is also optimistic about the opportunity to gain regulatory approval in the UK following amendments to the UK regulatory regime post Brexit. The Company is evaluating an accelerated UK regulatory submission pathway for 2023.

# DFU INDICATION

### Update

The Company made substantial progress in its US DFU Clinical Validation Study (the "US DFU Clinical Study") in 2022 and is on track with additional sites being incorporated in Q1 2023. The endpoint of the clinical study is to predict on "Day One" if the DFU wound will reduce in size by 50% by week four. The Company performed an interim analysis showing improvement of the AI diagnostic accuracy by five percentage points to 86%.

The data collected from the clinical study will be used to augment the Company's existing proprietary and clinically validated database of DFU data and healthcare matrix information; and to validate the DeepView<sup>®</sup> DFU AI algorithm as the Company prepares for US regulatory submission in 2023.

### Outlook

In H1 2023, the Company will continue to enroll subjects in the US DFU Clinical Study to finalize its admission goal. Following effective cost management mainly related to the US DFU Clinical Study, the Company expects to increase investment in its DFU indication in 2023 to drive its commercialization strategy. Post period end, the Company continued to enroll subjects in the US DFU clinical study, and we look forward to the enrollment progress which is expected to conclude by mid-2023. In preparation of submitting for regulatory approval, Spectral MD plans to conduct a pre-submission meeting with the FDA to ensure alignment for its future final regulatory submission. In H2 2023, the Company will submit for FDA and UKCA regulatory evaluations. Regulatory approvals are expected to be granted by end of 2023 for UKCA and in H1 2024 for FDA.

# **CEO** Statement

continued

In February 2023, the Company also initiated a clinical study in the EU with the Royal College of Surgeons in Ireland conducted at Connolly Hospital in Dublin, Ireland. The EU clinical study will collect data from DFU patients monitored up to 12 weeks. The intention of the clinical study is to further develop DeepView Al<sup>®</sup> algorithm and support the 2023 Company's regulatory submissions for UKCA, US FDA, and EU CE Mark.

# TECHNOLOGY MINIATURIZATION (DEEPVIEW SNAPSHOT<sup>®</sup> M)

### Update

The Company has previously been awarded STTR Phase I (US\$ 150k), Phase II (US\$ 624k), and Sequential Phase II (US\$ 1.1 million) amounting to US\$ 1.8 million. This funding enabled the Company to improve upon key optical and computing capabilities, which led to the DeepView SnapShot<sup>®</sup>M, a fully handheld prototype and wireless version of the cart-based Deep View<sup>™</sup> solution with similar performance to the Company's cart-based system.

### Outlook

The Company is committed to the development and clinical research of the DeepView SnapShot<sup>®</sup>M technology and is working towards advancing the current prototype.

# PEOPLE AND ORGANIZATION

### Update

With the Company accelerating towards commercialization, much focus has been given to the development, hiring, and retention of highly skilled individuals with proven commercial track records. In 2022, the Company saw a headcount growth of +29% with the addition of 16 full-time employees. The Company currently has 71 full-time employees in the US and UK. Spectral MD hired three additional personnel in the UK to accelerate regulatory and commercialization goals. The Company continues to prioritize recruitment in the areas of operations, production, regulatory, marketing, government contracts, and product development, which it believes will enable it to meet technology, IP, clinical, regulatory and commercialization readiness goals in 2023 and 2024.

In November 2022, the Company successfully strengthened the leadership team by appointing Dr. Niko Pagoulatos as Chief Operating Officer of Spectral MD. As Chief Operating Officer of Spectral MD, reporting to CEO Wensheng Fan, Dr. Pagoulatos will accelerate growth and operational performance of the Company with specific focus on scientific research, engineering, product development leading to global portfolio launch and clinical adoption. In addition to Dr. Pagoulatos' appointment, in 2022 the Company also added Christine Marks, VP of Marketing and Commercialization, Vincent Capone, General Counsel and Company Secretary, and promoted Mary Regan, VP of Clinical Affairs, to the leadership team.

### Outlook

The Company expects to strengthen its professional team to meet the demand for commercial sales contracts, including the potential federal level commercial contract. The Company will dedicate funding support toward human and infrastructure readiness to execute its go-to marketing strategy. Additional personnel to include sales, clinical research staff, clinical educators, field service technicians and product management as Spectral MD advances toward regulatory and commercial milestones.

### INTELLECTUAL PROPERTY (IP) DEVELOPMENT

Developing and protecting Spectral MD's intellectual property is one of the Company's key priorities. In 2022, the Company filed a total of nine new patent applications, including two US continuation/divisional applications, five foreign applications, one international Patent Cooperation Treaty application (high-precision, single-aperture, MSI snapshot imaging with multiplexed illumination), and one new provisional application (topological characterization and assessment of tissue).

Five new patents were approved, including a Japanese patent in the Snapshot<sup>®</sup> family and US patents in the DFU family, the Snapshot family, the MSI amputation site analysis/tissue classification family, and the original MSI Photoplethysmography (PPG) tissue classification family.

# CEO Statement

continued

Furthermore, during the period Spectral MD has completed validation of trademark registrations across all future major commercial markets.

### **R&D PIPELINE STRATEGY**

During 2022, the Company has begun to further assess other disease indications for DeepView<sup>®</sup>, leveraging its AI data pipeline infrastructure developed for the Burn and DFU clinical indications. Spectral MD's AI data pipeline infrastructure is one of the key company assets developed and refined over 10+ years of AI development, and it enables the Company to develop AI for additional clinical indications faster and more cost-efficiently than the original two Burn and DFU clinical indications; it is designed for large scale, i.e., large data volumes from a plurality of clinical sites, and seamless integration of DeepView<sup>®</sup> imaging data with corresponding patient clinical data to drive AI training.

Additional analysis will result in an expanded and prioritized roadmap of future commercial opportunities building on the universal imaging platform to include innovative technologies such as AI-3D Wound Measurement, AI-Venous Leg Ulcer ("VLU") indication, AI-Critical Limb Ischemia ("CLI") indication, AI-Digital Health, AI-Guided Therapy, and AI-Cosmetics. More specifically, DeepView<sup>®</sup>'s 3D Wound Measurement patent-pending technology will offer physicians millimetric level wound size measurement accuracy with single image acquisition and without requiring external reference markers for seamless integration into the clinical workflow. Plurality of indications is an important criterion in BARDA's evaluation of potential commercial contracts. The Company will continue to evaluate and investigate its data commercialization strategy, further expand its database of proprietary and clinically validated wound data points and continue to work towards assessing additional monetary value of this dataset.

# **CLOSING STATEMENTS**

We continue to demonstrate that Spectral MD's technology has the potential to be of tremendous benefit to patients and a powerful new tool for clinicians in distinguishing between damaged and healthy human tissue invisible to the naked eye, providing 'Day One' healing assessments for burn wounds and DFU. We believe DeepView<sup>®</sup> is a market leading technology, supported by the largest known burn wound database in the US, and has the potential to disrupt current treatment pathways, improving the standard of care for many patients across multiple geographical markets and applications. We remain confident in our strategic approach and that our transformative technology is well positioned ahead of regulatory submissions planned in 2023.

Wensheng Fan

Chief Executive Officer

Spectral MD 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 SnapShot<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 86 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.

The DeepView<sup>®</sup> product solution will have two revenue streams, a SaMD (software as a medical device) and an imaging device component. The SaMD model will feature a software licensing fee that includes maintenance, image hosting, and access to algorithm updates. The proprietary imaging device accesses the artificial intelligence algorithms and is a universal platform to house multiple clinical applications. Pricing for these components will be evaluated and strategically set per country and site-of-service for heightened customer adoption.

### Go-To-Market Strategy:

The first to market applications of DeepView<sup>®</sup>, Burn and DFU, deliver a paradigm shift from how the current standard of care treatment is provided. Like any disruptive technology it will require a coordinated and well executed plan to have a successful DeepView<sup>®</sup> product launch. There are four critical milestones that need harmonious alignment: regulatory approval, clinical evidence, reimbursement, and adoption. These four milestones may have different timelines per country or clinical indication; however, all are required for a seamless execution.

### Regulatory:

Due to the regulatory changes implemented post Brexit, the organization is optimistic about the potential to submit and receive its UKCA mark in H1 2023 for both the DeepView<sup>®</sup> Imaging Solution and its Burn application since both are classified as a class 1 device in the United Kingdom. For the majority of developed countries, the AI is a medical device classified as class 2 and comes with a deeper evaluation and timeline of a minimum of six months for regulatory review. In the US, the DeepView<sup>®</sup> Imaging Solution will be under a DeNovo application due to previously awarded Breakthrough designation. The DFU application will be submitted to the FDA H2 2023. The new Medical Device Readiness (MDR) requirements to obtain a CE mark are extensive; there, it will be submitted H2 2024.

### Clinical Evidence:

Although the DeepView<sup>®</sup> system will have its performance claims assessed as part of the regulatory approval mechanism, each country with a national reimbursement payer system will want additional clinical evidence with their population and processes to show the patient outcomes utilizing this new technology and the health economic impact. This clinical evidence, post-market, will commence post regulatory approval and is an important step towards developing key opinion leaders and establishing reimbursement.

# Product Overview and Strategy

continued

### Reimbursement:

The Company also expects to utilize its post-market clinical evidence and health economic impact analysis to submit the NHS for reimbursement for its Burn indication in the United Kingdom. Upon more market penetration, the organization will apply for NICE certification. In the United States, the Company's product will be used in both inpatient and outpatient sites of service. The process of reimbursement varies greatly between the two. The DeepView<sup>®</sup> Burn indication will be used inpatient both in Emergency Departments and Burn Centers. It will be reimbursed as an expense under the existing nationwide DRG codes for burn. The Company will 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 will be tied to burn diagnosis codes and allow additional payment to the site of service that diagnoses the patient. This will be a positive impact for the burn application in the Emergency Department setting. The DeepView<sup>®</sup> DFU indication will utilize existing CPT codes while gaining the clinical evidence to apply for a unique CPT. The reimbursement for the DFU indication could vary regionally and from CMS to private payers.

### Adoption:

DeepView<sup>®</sup> technology is disruptive by nature and there will be those who will want to "wait and see". This emphasizes the importance of having the right strategic partnerships, institutions, and physician key opinion leaders as early adopters. The Company plans to engage in relationships that can act as key opinion leaders to share their experience on why they adopted the DeepView<sup>®</sup> technology. The adoption will be supported by a team of field clinical educators and digital marketing campaigns.

The results presented cover FY22. The presentational currency for SpectralMD Holdings, Ltd. and its subsidiaries (together, the "Company") is the US Dollar.

Revenue of US\$ 25.4 million represents research and development revenue in 2022. This is the result of the realization of non-dilutive research and development contracts with BARDA and DHA (2021: US\$ 15.2 million). This 67% increase versus 2021 arises from the increase in research and development activities for the DeepView Al<sup>®</sup> -Burn indication and the handheld prototype DeepView SnapShot<sup>®</sup>M.

The cost of sales in 2022 was US\$ 14.5 million (2021: US\$ 8.2 million) and gross profit was US\$ 10.8 million (2021: US\$ 7.1 million). This cost is entirely associated with BARDA research and development contract activities, invoiced to BARDA monthly.

During 2022, operating expenses increased US\$ 2.2 million year over year to US\$ 13.5 million (2021: US\$ 11.3 million). This is predominantly driven by the DeepView AI<sup>®</sup> -DFU indication development, and by scaling up the organizational infrastructure to support near term commercialization.

During 2022, the operating loss was US\$ (2.6) million (2021: loss of US\$ (4.2) million). During 2022, adjusted EBITDA was a loss of US\$ (1.5) million (2021: loss of US\$ (2.8) million).

Cash and cash equivalents totaled US\$ 14.2 million at the end of 2022 (2021: US\$ 16.1 million). The 2022 cash figure represents a strong working capital performance, as management has made improvements in the accounts receivable cycle.

Notes Payable totaled US\$ 0.2 million at the end of 2022 (2021: US\$ 0.6 million). During 2022, the Company repaid the remaining balance of a promissory note entered in 2020 with JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program ("PPP") of the US federal government COVID-19 small business stimulus.

In conjunction with the closing of Company's initial public offering on the AIM market in 2021, the Company issued 762,712 warrants, with a strike price of US\$ 0.89 and a five-year life, to SP Angel, who acts as nominated advisor and joint broker to the Company. As of 31 December 2022, the strike price was US\$ 0.71. The change in the strike price is due to the change in exchange rates as the warrants will settle in shares denominated in British Pounds. The fair value was calculated to be US\$ 0.1 million at the end of 2022 (2021: US\$ 0.2 million).

Effective 1 January 2022, the Company accounts for its leases under Accounting Standards Codification ("ASC") 842, Leases. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded in the condensed consolidated balance sheets as both a right of use asset and a lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. See additional discussion regarding lease accounting in the Consolidated Financial Statements and Footnotes.

Following the first anniversary of the Company's admission to the AIM market, the 'Regulation S' market trading restrictions were removed from the shares of common stock, saved for those held by certain controlling shareholder thus enabling wider market access to acquire and sell stock via multiple trading platforms. Additionally, the removal of the charter restriction on the Spangenberg entities' acquisition of certain further shares announced on 7 July 2022 provides further sources of potential market liquidity.

# **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 – BARDA awarded an expansion of Option 1B in August 2022. Federal contract opportunity initiated for Health and Human Services Burn Wound Imaging technology. Company responded with proposal and will be evaluated for contract fulfillment.	
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 – BARDA awarded an expansion of Option 1B in August 2022. Federal contract opportunity initiated for Health and Human Services Burn Wound Imaging technology. Company responded with proposal and will be evaluated for contract fulfillment.	
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 – Increased marketing team by two product managers (US & UK). Outlined evidence needed in US & UK to support claims post regulatory approval and securing physicians to run case studies.	

# Risk Management

# continued

Risk	Description	Risk Status	Mitigation	Mitigation Effectiveness	
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 16 new employees with world leading capabilities in 2022	
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	
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.	
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 2022	

# **Board of Directors**



### Martin Mellish

#### Independent Non-Executive Chairman (Aged 65)

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 54)

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.



### **Richard Cotton**

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

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. Richard also serves as Financial Advisor to Novumgen Ltd., a specialty pharmaceuticals company, amongst other NED / advisory roles.

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.

# **Board of Directors**

continued



# Cynthia Cai

### Independent Non-Executive Director (Aged 59)

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, Basking Biosciences, 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.

### **Gerry Beaney**

### Independent Non-Executive Director (Aged 63)

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 2022. The Corporate Governance Statement set out on pages 19-28 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 25-27.

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 2022 the Company has available cash resources of US\$ 14.2 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 7.

continued

### FINANCIAL RESULTS

Financial results are detailed in the Financial Statements and accompanying notes beginning on page 40.

### **EMPLOYEE POLICIES**

Employee policies are discussed in the Strategic Report on page 6.

# 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 2022 (FY21: nil).

# DIRECTORS' INTERESTS

The interests in the share capital of the Company of those Directors serving on 31 December 2022 and as at the date of signing of these financial statements, all of which are beneficial, were as follows:

Director	On 31 December 2022 Ordinary Shares of 0.01p each	On 31 December 2021 Ordinary Shares of 0.01p each
Wensheng Fan	1,500,000	1,500,000
Richard Cotton	338,984	338,984
Gerry Beaney	30,283	16,950

## SUBSTANTIAL SHAREHOLDERS

As of 31 December 2022, 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	10,347,282	7.60%
Link Mar (Nominees) Limited	9,145,615	6.72%
Jose Melendez	8,325,000	6.12%
Laurence Hirsch	7,821,010	5.75%
Erich Spangenberg*	5,954,790	4.38%

\* Ownership by Spangenberg Entities

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 25-27. 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 28 March 2023 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 2022. 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 86 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. This contract is valued at US\$ 96.9 million, including the recent expansion of US\$ 8.2 million awarded in the third quarter of 2022. The Company has completed the BARDA Burn II Base phase in 2021 and Option 1A in 2022, valued at US\$ 27.3 million and US\$ 20.6 million, respectively and is currently executing Option 1B valued at US\$ 27 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<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 2024 for the DFU application and 2025 for burns, although the burns application is expected to continue to attract considerable government funding through BARDA, having recently extending Option 1B through September, 2023.

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 holds 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. In 2022, the Company held its Annual General Meeting on 27 September 2022. 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 (www.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 of its manufacturing through a contract manufacturing service, Cobalt Production Solutions ("Cobalt") based in Plano, Texas. Cobalt is involved with manufacturing the DeepView<sup>®</sup> 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.

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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 extends 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 of 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<sup>®</sup> 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.

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

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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<sup>®</sup> 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<sup>®</sup> 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 three other Non-Executive Directors ("NED"): Gerry Beaney, Dr. Cynthia Cai and Richard Cotton. In 2022, Erich Spangenberg, the largest shareholder of the Company, was a member of the Board from 1 January 2022 through 31 October 2022. All current NEDs 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 any 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 five 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. The Board will undertake this 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, including strict compliance with its 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. In 2022, Richard Cotton was appointed the Senior independent non-executive director.

During 2022, the Company held fourteen meetings which were attended by at least a majority of all of the then Directors. The attendance record of the Directors during that period of office is as follows:

Director	Times held/attendance
Gerry Beaney	14/13
Cynthia Cai	14/14
Richard Cotton	14/14
Wensheng Fan	14/14
Martin Mellish	14/14
Erich Spangenberg*	12/8

\* Mr. Spangenberg was a Director from 1 January 2022 through 30 October 2022.

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 half-yearly 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 2022:

Audit Committee Member	Times held/attendance
Richard Cotton	6/6
Gerry Beaney	6/6

### 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

continued

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 Dr. Cynthia Cai. The other member of the committee is Richard Cotton. The Board has satisfied itself that Dr. Cai has recent and relevant experience, having previously held senior leadership positions at multinational organizations, 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 2022:

Renumeration Committee Member	Times held/attendance
Dr. Cynthia Cai	3/3
Richard Cotton	3/3

In 2022, there were three meetings of the remuneration committee. Further, at three 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 Gerry Beaney. 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.

Nomination Committee Meeting Attendance during 2022:

Renumeration Committee Member	Times held/attendance
Gerry Beaney	1/1
Wensheng Fan	1/1
Martin Mellish	1/1

### **Special Committees**

The Company also avails itself of special committees comprised of members of the Board. These committees are used for discrete and timely matters generally relating to the Company's audit and/or financial or other transactions that require the timely review of such matters. The Company had two meetings of its special committee during 2022 relating to the final approval of the Company's Annual Report and potential discrete financing transactions.

Special Committee Meeting Attendance during 2022:

Special Committee Member	Times held/attendance
Richard Cotton	2/2
Martin Mellish	2/2
Wensheng Fan	2/2

### 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

continued

governance information, the Company's publications including historic annual reports and notices of annual general meetings or special meetings, together with share price information.

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 / Louis Ashe-Jepson/ Alice Woodings	/ Mob: +44 (0)7980 541 893 +44 (0)7747 515 393 / +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 28 March 2023 and signed on its behalf by:

Vincent Capone Company Secretary

For the Period Ended 31 December 2022

#### 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 2022 (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 (the "AGM")

### Introduction

During the period covered by this Directors' Remuneration Report, the Committee retained an independent consulting firm, Aon's Human Capital Solutions ("Aon"), in April 2022 to assess Spectral MD's remuneration practices and recommended a course of action. The overall objectives of the Remuneration Committee brief are to attract, retain and motivate superior talents. This includes the provision of incentives that reward the achievement of performance goals that directly correlate to the enhancement of the shareholder value; the facilitation of executive and high potential individuals' retention; and the alignment of employee interests with those of the Company's shareholders' through long-term incentives linked to specific performance.

The process included the development of a public peer group, reflecting specific peers focused on artificial intelligence, in the software/technology and healthcare equipment industries with similar financial profiles. In addition, the project used the survey data from the Radford Global Compensation database for broader size-appropriate companies in related industries as the secondary market.

The project included the remuneration assessment for the following three groups

- Executive Compensation: benchmarked all elements of pay (base salary, target bonus long-term incentives, benefits in kind, total direct pay) against the defined marketplace. Reviewed peer/market practices with respect to contractual severance and change-in-control protection provided to executive officers.
- Board of Directors Compensation: reviewed the cash compensation policy for board membership, committee membership, and board leadership roles; established an equity compensation policy for non-executive directors.
- Non-executive employee Equity and Bonus Guidelines: established grant level and target bonuses based on a blend of market value and the percentage of company ownership data for each non-executive employee level/salary band.

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

As we move into 2023 and beyond, the Committee's role will continue to ensure that Directors and senior executives, as well as employees at Spectral MD are appropriately compensated and incentivized to deliver growth to shareholders in a long-term and sustainable manner. The Committee is also going to focus on enhancing the performance, goal setting and review processes throughout the company.

### **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 continued

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 is key for the Company as it builds its global operations in a manner designed to deliver sustainable long-term growth and shareholder value.

### **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.

### 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.

### Xiaojia Cynthia Cai

Chair of the Remuneration Committee

continued

### DIRECTORS' REMUNERATION POLICY

The 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 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. Restricted Stock Units can be granted to employees as well as non-employees (including independent NEDs). Exercise of share options under the plans are subject to specified exercise periods and compliance with appropriate regulations. 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 £90,000 per annum for acting as Chairman.

Mr. Cotton receives a fee of £85,000 per annum for acting as the Senior Independent Director and Audit Committee Chairman

Dr. Cai, Mr. Beaney each receive an annual base fee of £68,250 per annum for acting as Chair of the Remuneration, and Nomination Committees respectively.

# REMUNERATION COMMITTEE (THE "COMMITTEE")

### Governance

In its decision-making process, the Committee takes into account 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 judgment in setting remuneration:

- the eligibility to participate in the plans
- the timing of the grant of awards and any payments
- the size of awards and payments
- 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 means 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 2022, and how it will be implemented during the year ending 31 December 2023.

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

### Directors' Remuneration – financial year ended 31 December 2022

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 Remuneration	Total Fixed Remuneration	Total Variable Remuneration
Executive Directo	rs								
Wensheng Fan	2022	\$500,000	\$18,516	\$425,000	\$421,171	\$25,896	\$1,390,583	\$544,412	\$846,171
	2021	\$462,021	\$11,741	\$285,000	\$577,604	\$25,198	\$1,361,564	\$498,960	\$862,604
Key Management									
Nils Windler, CFO	2022	\$350,000	\$19,814	\$110,000	\$103,982	\$ -	\$583,796	\$369,814	\$213,982
	2021	\$31,818	\$1,579	\$ -	\$4,091	\$ -	\$37,488	\$33,397	\$4,091
Wan Lung Eng,	2022	\$42,708	\$ -	\$ -	Ş -	\$1,281	\$43,989	\$43,989	\$ -
CFO	2021	\$225,000	\$21,947	\$ -	\$86,086	\$6,750	\$339,783	\$253,697	\$86,086
Niko Pagoulatos,									
CO0	2022	\$38,447	\$1,647	\$20,000	\$11,806	\$ -	\$71,900	\$40,094	\$31,806
Non-Executive Di	rectors								
Martin Mellish	2022	\$92,098	\$ -	\$ -	\$ -	\$ -	\$92,098	\$92,098	\$ -
	2021	\$50,664	\$ -	\$ -	\$ -	\$ -	\$50,664	\$50,664	\$ -
Cynthia Cai	2022	\$79,816	\$ -	\$ -	\$ -	\$ -	\$79,816	\$79,816	\$ -
	2021	\$43,909	\$ -	\$ -	Ş -	\$ -	\$43,909	\$43,909	\$ -
Gerry Beaney	2022	\$79,816	\$ -	\$ -	Ş -	\$ -	\$79,816	\$79,816	\$ -
	2021	\$43,909	\$ -	\$ -	Ş -	\$ -	\$43,909	\$43,909	\$ -
Richard Cotton	2022	\$79,816	\$ -	\$ -	Ş -	\$ -	\$79,816	\$79,816	\$ -
	2021	\$43,909	Ş -	Ş -	\$ -	\$ -	\$43,909	\$43,909	Ş -
Erich	2022	\$40,930	\$ -	\$ -	Ş -	\$ -	\$40,930	\$40,930	\$ -
Spangenberg	2021	\$37,021	\$ -	\$ -	Ş -	\$ -	\$37,021	\$37,021	\$ -
Howard Goodman	2022	\$ -	\$ -	\$ -	Ş -	\$ -	\$ -	\$ -	\$ -
	2021	\$10,000	\$ -	\$ -	\$ -	\$ -	\$10,000	\$10,000	\$ -

### ANNUAL PERFORMANCE BONUS - 2022 FINANCIAL YEAR

In respect of the year ended 31 December 2022, Mr. Fan was awarded cash bonuses amounting to \$385,000 as a result of achieving specific performance milestones within each of the elements below:

I. Burn Indication Development, and Federal Contract readiness: (60%)

- II. DFU Indication Development: (20%)
- III. Organizational Development: (10%)

IV. Investor Relations: (10%)

# DIRECTORS' EQUITY AWARDS

### Directors' interests in shares at 31 December 2022

o Director	Total shares wned 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	15,943,905	1,500,000	1.10%	14,443,905	0	2,942,667
Erich Spangenberg*	55,488,085	54,929,513	40.36%	1,992,860	0	100,000
Richard Cotton	338,984	338,984	0.25%	0	0	0
Cynthia Cai	0	0	0.00%	0	0	0
Gerry Beaney	30,283	30,283	0.02%	0	0	0
Martin Mellish	0	0	0.00%	0	0	0

\* Mr. Spangenberg was a Director from 1 January 2022 through 30 October 2022.

continued

### Base salary

The base salary of Wensheng Fan has been increased from \$500,000 to \$525,000 as an adjustment for inflation.

Cynthia Cai and Gerry Beaney's fees have also been adjusted for inflation by 5% from £65,000 to £68,250.

Martin Mellish's fee was adjusted from £70,000 to £90,000 per annum based on an independent consulting firm, Aon's market assessment.

Richard Cotton's fee was adjusted from £65,000 to £85,000 per annum for increased responsibility acting as the Senior Independent Director in addition to Chair of Audit Committee.

#### 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 award 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 and operating plan as approved by the Board.

### Payments to past Directors (audited information)

There were no payments to past directors in 2022.

#### Xiaojia Cynthia Cai

Chair of the Remuneration Committee

## **Directors Nomination Committee Report**

#### Dear Shareholder,

As Chair of the Nomination Committee, I am pleased to present the report of the Nomination Committee for the year ended 31 December 2022.

#### Introduction

During 2022, the board decided that the membership of the Nomination and Remuneration Committees should change to ensure that the profile of the Company compares favorably with similar entities at the main board and advisory board levels taking account of governance, operational, strategic, clinical and technical elements. Equally, detailed knowledge and experience of the highly competitive US compensation market in which the Company operates is essential to the recruitment and compensation discussions and decisions of the board. With these factors in mind, Dr Cynthia Cai agreed to chair the remuneration committee.

The other members of the Nomination committee are Martin Mellish and Wensheng Fan.

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. Director candidates will also be assessed to ensure appropriateness to act as a director of a listed company. The Committee's remit will extend to the Advisory Board to ensure candidates possess the attributes required for the role.

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 met once in 2022 although the senior management appointments noted below were approved by the board as a whole.

#### **Director changes**

On October 24, the Company announced the resignation of Erich Spangenberg as a non-executive director of the Company, effective as of 31 October 2022. Mr. Spangenberg through his family interests is the largest shareholder in the Company. He had served on the board for more than ten years and now wishes to focus on his other business interests. The board is initiating a selection process for a replacement Non-Executive Director that possesses the appropriate skill set and profile as the Company progresses to the next stage of its development.

#### Senior management changes

During the year the following senior management appointments were made:

Christine Marks appointed as VP Marketing and Commercialization;

Dr. Niko Pagoulatos appointed as Chief Operating Officer; and

Vincent Capone confirmed as General Counsel.

External advisers were used to assist the directors in the recruitment of these individuals.

#### Advisory board

There were no changes to the Advisory Board during 2022.

#### Gerry Beaney

Chair of the Nomination Committee

For the Period Ended 31 December 2022

#### 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 2022 (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 six times during the period and both members attended all six 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
16 March 2022	2021 Full Year Financial Performance 2021 KPMG Audit Risk Assurance Insurance
3 May 2022	2021 Annual Report Pensions
24 June 2022	Engagement of Auditors 2022 Interim Review Planning Pensions Management Accounts Format
13 September 2022	Risk Assurance Internal Controls 2022 First Half Financial Performance KPMG Interim Review
7 December and 14 December 2022	Risk Assurance Internal Controls Treasury Committee Taxation Insurance Annual review of Anti Bribery and Corruption Procedures Annual review of Anti Bribery and Corruption Procedures Annual Review of Audit Committee Terms of Reference Annual Review of Audit Committee Performance

## **Directors Audit Committee Report**

continued

#### **Financial Reporting**

The Company has made significant advances in the quality of its monthly financial reporting and forecasting in the last 12 months, in both content and timeliness. This has been achieved through the strengthening of the financial control personnel and systems in particular.

Similarly, the semi-annual process for the preparation and publication of statutory financial reports and accompanying narrative has materially improved in process and timeliness. The Committee oversees the preparation process and the integrity of the financial statements.

#### 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 for 2023 and forecast for 2024, including embedded risks and opportunities.

The external auditor reviewed 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 2022 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 2022 was fair, balanced and understandable, which can be found in the Independent Auditor's Report.

This assessment was carried out by the Committee on 27 March 2023, following which the Committee reported to the Board that it was satisfied that, taken as a whole, the Annual Report 2022 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 agreed an Internal program with management for the forthcoming 2023 financial year which is in progress.

#### **External Auditor**

KPMG were retained to provide Audit Services to the company on 8 July 2021, following a tender process.

At the meeting of 16 March 2022, KPMG presented their full year 2021 report and opinion to the Committee for review.

The Committee reviewed and agreed KPMG's Audit Services proposal for the 2022 Financial Period at its meeting on 24 June 2022, when it also discussed the scope of the 2022 Interim review.

At the meeting of 13 September 2022, the Committee reviewed the External Auditors' report on the 2022 Interim results.

KPMG presented to the Committee a draft Full Year Audit scope for discussion and agreement at its meeting of 7 December 2022. At the meeting of 22 February 2023, 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

## Independent Auditors Report

To the Stockholders and Board of Directors Spectral MD Holdings, Ltd:

### OPINION ON THE CONSOLIDATED FINANCIAL STATEMENTS

We have audited the accompanying consolidated balance sheets of Spectral MD Holdings, Ltd and its subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, changes in equity, and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

### CHANGE IN ACCOUNTING PRINCIPLE

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leasing transactions as of January 1, 2022 due to the adoption of Accounting Standards Codification 842, Leases.

### **BASIS FOR OPINION**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

PMG LLP

We have served as the Company's auditor since 2021.

Dallas, Texas February 24, 2023

# Consolidated Balance Sheets

For the year ended 31 December 2022, and 2021 (in thousands, except share and per share data)

	2022 US\$	2021 US\$
Assets		
Current assets:		
Cash and cash equivalents	14,174	16,121
Accounts receivable, net	2,294	1,435
Unbilled revenue	618	71
Prepaid expenses and other current assets	601	840
Total current assets	17,687	18,467
Non-current assets:		
Property and equipment, net	21	32
Right-of-use assets	1,008	-
Other noncurrent assets	-	40
Total Assets	18,716	18,539
Liabilities and stockholders' equity Current liabilities:		
Accounts payable	2,759	1,414
Accrued expenses	2,631	2,603
Lease liabilities, short-term	680	-
Notes payable	175	583
Warrant liability	129	186
Total current liabilities	6,374	4,786
Lease liabilities, long-term	346	-
Total Liabilities	6,720	4,786
Commitments and contingencies (Note 8)		
Stockholders' Equity		
Common stock (US\$0.001 par value); 400,000,000 shares authorized;		
135,409,564 and 135,034,564 shares issued and outstanding as of		
December 31, 2022 and 2021, respectively	135	135
Additional paid-in capital	23,795	22,640
Accumulated deficit	(11,934)	(9,022)
Total Stockholders' equity	11,996	13,753
Total Liabilities and Stockholders' Equity	18,716	18,539

# Consolidated Statement of Operations

For the year ended 31 December 2022, and 2021 (in thousands, except share and per share data)

	2022 US\$	2021 US\$
Research and development revenue	25,368	15,239
Cost of revenue	(14,531)	(8,187)
Gross profit	10,837	7,052
<b>Operating costs and expenses</b> : General and administrative	13,484	11,231
Total operating costs and expenses	13,484	11,231
Operating income (loss)	(2,647)	(4,179)
<b>Other income (expense)</b> : Interest expense Change in fair value of warrant liability Foreign exchange transaction loss Other income	(12) 57 (253) 49	(17) 298 (188) –
Total other income (expense)	(159)	93
(Loss) income before income taxes	(2,806)	(4,086)
Benefit (provision) for income taxes	(106)	98
Net (loss) income	(2,912)	(3,988)
Dividend on Series A preferred stock	-	(1,259)
Net loss attributable to common stockholders	(2,912)	(5,247)
Net (loss) income per share of common stock Basic and Diluted	(0.02)	(0.05)
Weighted average common shares outstanding Basic and Diluted	135,442,441	100,291,815

# Consolidated Statements of Changes in Equity

# For the year ended 31 December 2022, and 2021 (In thousands, except share data)

Balance at December 31, 2020	Prefe Shares 4,324,330	Amount US\$ 1,114	Commo Shares 61,347,000	n Stock Amount US\$ 61	Additional Paid-in Capital US\$ 6,096	Accumulated Deficit US\$ (5,034)	Equity US\$
Issuance of common stock for ca			19,067,797	19	15,595	-	15,614
Issuance cost, net of \$0.5 millior warrant liability Cumulative dividend on Series A	-		-	-	(1,479)	-	(1,479)
preferred stock Conversion of preferred stock to	-	1,259	-	-	(1,259)	-	(1,259)
common cash	(4,324,330)	(2,373)	53,889,765	54	2,319	-	2,373
Stock options exercised for cash	-	-	42,500	-	4	-	4
Stock-based compensation			687,502	1	1,364	-	1,365
Net loss	-	-	-	-	-	(3,988)	(3,988)
Balance at December 31, 2021	-	-	135,034,564	135	22,640	(9,022)	13,753
Stock-based compensation Net loss	-	- -	375,000	-	1,155 -	_ (2,912)	1,155 (2,912)
Balance at December 31, 2022	-	-	135,409,564	135	23,795	(11,934)	11,996

# Consolidated Statements of Cash flows

For the year ended 31 December 2022, and 2021 (in thousands)

	2022 US\$	2021 US\$
Cash flows from operating activities:		
Net (loss) income	(2,912)	(3,988)
Adjustments to reconcile net (loss) income to net cash (used in) provided by		
operating activities:		
Depreciation expense	11	1
Stock based compensation	1,155	1,365
Amortization of right-of-use assets	557	-
Change in fair value of warrant liability	(57)	(298)
Changes in operating assets and liabilities:		
Accounts receivable	(859)	1,256
Unbilled revenue	(547)	(71)
Prepaid expenses and other current assets	615	(257)
Other assets	40	(9)
Accounts payable	1,345	(2,398)
Accrued expenses	51	1,481)
Lease liabilities	(561)	-
Net cash (used in) provided by operating activities	(1,162)	(2,918)
Cash flows from investing activity:		
Purchases of property and equipment	-	(7)
Net cash (used in) provided by investing activity	-	(7)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrant, net of issuance costs	-	14,618
Proceeds from stock option exercise	-	4
Payments for notes payable	(785)	(701)
Net cash (used in) provided by financing activities	(785)	13,921
Net increase (decrease) in cash and cash equivalents	(1,947)	10,996
Cash and cash equivalents, beginning of period	16,121	5,125
Cash and cash equivalents, end of period	14,174	16,121
Supplemental cash flow information:		
Cash paid for interest	23	12
Cash paid for income taxes	-	255
Noncash operating and financing activities disclosure:		
Cumulative dividend on Series A preferred stock	-	1,259
Conversion of preferred stock to common stock	-	2,373
Prepaid asset acquired for debt	376	474
Software and prepaid software maintenance acquired for debt	-	41

## 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, 2022 and 2021, the Company had approximately US\$14.2 million and US\$16.1 million, respectively in cash, and an accumulated deficit of US\$11.9 million and US\$ 9.0 million, respectively. The Company has historically funded its operations through the issuance of notes and the sale of preferred stock and common stock. During 2022, the Company was awarded additional funding of \$8.2 million associated with option 1B of the contract with BARDA. During 2021, the Company executed Options 1A and 1B of the contract with BARDA for funding of US\$39.4 million and during 2022 was awarded additional funding of \$8.2 million associated with option 1B, resulting in aggregated funding for Options 1A and 1B of US\$ 47.6 million, of which US\$ 13.6 million is remaining as of December 31, 2022. The BARDA contract funding is to execute the clinical training study of DeepView® Wound Imaging System for burn wound healing assessment. See Research and Development Revenue below. With the Company's closing on its initial public offering (the "Offering") during 2021 (see Note 4) and the remaining funding under the BARDA contract, the Company believes it will have sufficient working capital to fund operations for at least one year beyond the release date of the consolidated financial statements. Additionally, the contract with BARDA has a potential funding of up to US\$ 96.9 million, in aggregate for Option 1A, 1B and 2, if all future options are executed.

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## 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").

Also see Note 3 - Previously Reported Financial Statements relating to the immaterial correction of an error in the consolidated balance sheet as of December 31, 2021, consolidated statement of operations, consolidated statement of changes in equity, and consolidated statement of cash flows for the year ended December 31, 2021.

#### **Principles 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, Net and Unbilled Revenue

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\$ 2.3 million and US\$ 1.4 million as of December 31, 2022 and 2021, 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, 2022 and 2021.

The Company records unbilled revenue when revenue is recognized prior to billing customers. Unbilled revenue amounted to approximately US\$ 0.6 million and US\$ 0.1 million as of December 31, 2022 and 2021, respectively.

#### **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.

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Additional credit risk is related to the Company's concentration of receivables. As of December 31, 2022 and 2021, receivables were concentrated from one customer (which is a US. government agency) representing 96% and 94% of total net receivables, respectively. No allowance for doubtful accounts were recorded as of December 31, 2022 and 2021.

One customer (which is a U.S. government agency) accounted for 98% of the recognized research and development revenue for both the years ended December 31, 2022 and 2021.

#### 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. As of December 31, 2022 and December 31, 2021, the Company's translation adjustments are not material.

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, 2022 and December 31, 2021 the Company recorded US\$ 0.3 million and US\$ 0.2 million foreign exchange transaction loss, respectively, primarily related to the Company's bank account denominated in British Pounds and accounts payable denominated in British Pounds, included in foreign exchange transaction loss in the consolidated statements of operations.

#### Leases

Effective January 1, 2022, the Company accounts for its leases under Accounting Standards Codification ("ASC") 842, Leases. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded in the consolidated balance sheets as both a right of use asset and a lease liability, calculated by discounting fixed lease payments at the rate implicit in the lease or the Company's incremental borrowing rate factoring the term of the lease. The incremental borrowing rate used by the Company is an estimate of the interest rate the Company would incur to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease. Because the Company does not generally borrow

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on a collateralized basis, it uses the interest rate it pays on its noncollateralized borrowings as an input to deriving an appropriate incremental borrowing rate, adjusted for the amount of lease payments, the lease term and the effect on that rate of designating specific collateral with a value equal to the unpaid lease payments for that lease. Lease liabilities are increased by interest and reduced by payments each period, and the right of use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right of use asset results in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred. For the period ending December 31, 2022 and December 31, 2021, the Company did not have any finance leases.

The Company adopted ASC 842 using the modified retrospective transition approach. The Company did not have a cumulative effect of adoption as of January 1, 2022. The Company elected a package of practical expedients, under which the Company does not need to reassess (a) whether any expired or existing contracts are or contain leases, (b) the lease classification for any expired or existing leases, or (c) initial direct costs for any existing leases. In calculating the right of use assets and lease liabilities, the Company elects to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election.

The Company accounted for leases prior to January 1, 2022 under ASC 840, Leases. For the year ended December 31, 2022, the Company recognized rent payments in the Company's operating leases on a straight-line basis over the lease term.

#### **Derivative Liabilities**

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

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 in July 2021. 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. As of December 31, 2021, the change in fair value of the derivative instrument was immaterial when the Company marked its derivative instrument to fair value. For the year ended December 31, 2022, the Company did not have any derivative instruments, other than the stock purchase warrants, discussed above.

#### **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

continued

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 (modified for additional funding in 2022) by BARDA for the development of the Company's DeepView<sup>®</sup> 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 grant-date fair value of the awards.

#### 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, 2022 and 2021 that qualify for either recognition or disclosure in the consolidated financial statements under this guidance.

#### continued

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, 2022 and 2021.

#### **Comprehensive Loss**

Comprehensive loss is equal to net loss as presented in the consolidated statements of operations, as the Company did not have any material other comprehensive income or loss for the periods presented.

#### Net Loss per Share of Common Stock

Basic net loss share of common stock is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss 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 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 adopted ASU 2016-02 on January 1, 2022. The Company recorded a right-of-use asset and lease liabilities each of approximately US\$ 0.6 million upon the adoption of ASU 2016-02. See Note 9.

#### **Recently Issued Accounting Standards**

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.

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic 820 "Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions". The FASB is issuing this Update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. The Company is still evaluating the impact of this pronouncement on the consolidated financial statements.

### 3. IMMATERIAL CORRECTIONS

SEC Staff Accounting Bulletin No. 99, "Materiality," and FASB, Statement of Financial Accounting Concepts No. 2 "Qualitative Characteristics of Accounting Information" indicate that quantifying and aggregating errors is only the beginning of an analysis of materiality and that both quantitative and qualitative factors must be considered in determining whether individual errors are material. The Company evaluated the corrections related to incorrectly recording certain revenues and operating expenses for the year ended December 31, 2021. As a result, adjustments for the immaterial correction of the error were applied for comparative purposes, as shown below.

The consolidated balance sheet as of December 31, 2021, consolidated statement of operations, consolidated statement of changes in equity, and consolidated statement of cash flows for the year ended December 31, 2021 have been adjusted as presented in the following tables (in thousands):

	As Previously Reported December 31,		As Adjusted December 31,
	2021 US\$	Adjustments US\$	2021 US\$
Assets			
Current assets:			
Unbilled revenue	-	71	71
Prepaid expenses and other current assets	858	(18)	840
Total current assets	18,414	53	18,467
Total Assets	18,486	53	18,539
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	1,740	(326)	1,414
Accrued expenses	2,391	212	2,603
Total current liabilities	4,900	(114)	4,786
Total Liabilities	4,900	(114)	4,786
Stockholders' Equity			
Accumulated deficit	(9,189)	167	(9,022)
Total stockholders' equity	13,586	167	13,753
Total Liabilities and Stockholders' Equity	18,486	53	18,539

continued

	As Previously Reported 2021 US\$	Adjustments US\$	As Adjusted 2021 US\$
Research and development revenue	15,168	71	15,239
Gross profit	6,981	71	7,052
Operating costs and expenses:			
General and administrative	11,327	(96)	11,231
Total operating costs and expenses	11,327	(96)	11,231
Operating loss	(4,346)	167	(4,179)
Loss before income taxes	(4,253)	167	(4,086)
Net loss	(4,155)	167	(3,988)
Net loss attributable to common stockholders	(5,414)	167	(5,247)

	As Previously Reported 2021 US\$	Adjustments US\$	As Adjusted 2021 US\$
Cash flows from operating activities:			
Net loss	(4,155)	167	(3,988)
Changes in operating assets and liabilities:			
Unbilled revenue	-	(71)	(71)
Prepaid expenses and other current assets	(275)	18	(257)
Accounts payable	(2,072)	(326)	(2,398)
Accrued expenses	1,269	212	1,481

## 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, 2022 and December 31, 2021, by level within the fair value hierarchy (in thousands):

	I	Fair value measured	at December 31, 2	022
	Fair value at December 31, 2022 US\$	to active	Significant observable inputs (Level 2) US\$	Significant unobservable inputs (Level 3) US\$
Warrant Liability	\$129	\$-	\$-	\$129
		Fair value measured	at December 31, 2	021
	Fair value at December 31, 2021 US\$	to active	Significant observable inputs (Level 2) US\$	Significant unobservable inputs (Level 3) US\$
Warrant Liability	\$186	\$-	\$-	\$186

There were no transfers between Level 1, 2 or 3 during the year ended December 31, 2022 and December 31, 2021.

The following table presents changes in Level 3 liabilities measured at fair value for the year ended December 31, 2022 and 2021 (in thousands).

	US\$-
Balance – January 1, 2021	\$-
Issuance of warrants	484
Change in fair value	(298)
Balance – December 31, 2021	186
Change in fair value	(57)
Balance – December 31, 2022	\$129

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:

	2022	2021
Strike price (per share in US\$)	US\$0.71	US\$0.80
Contractual term (years)	4.5	5.5
Volatility (annual)	72.6%	67.6%
Risk-free rate	4.0%	1.3%
Dividend yield (per share)	0.0%	0.0%

## 5. RESEARCH AND DEVELOPMENT REVENUE

For the years ended December 31, 2022 and 2021, the Company's revenues disaggregated by the major sources was as follows (in thousands):

	2022 US\$	2021 US\$
BARDA	24,827	14,968
Other US governmental authorities	541	271
Total revenue	25,368	15,239

## 6. ACCRUED EXPENSES

Accrued expenses consist of the following as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022 US\$	December 31, 2021 US\$
Salary and wages	1,135	896
Provision operating expenses	736	957
Benefits	650	470
Franchise tax	110	246
Income Taxes	-	-
Deferred rent	-	23
Accrued interest	-	11
Total accrued expenses	2,631	2,603

continued

### 7. NOTES PAYABLE

#### **Insurance Note**

In June 2022 and 2021, the Company entered into a financing agreements for a portion of its insurance premium for approximately US\$ 0.4 million (the "2022 Insurance Note") and US\$ 0.5 million (the "2021 Insurance Note"), respectively. The 2022 Insurance Note and 2021 Insurance Note bear interest at 6.7% per annum and 5.7% per annum, respectively, and are each payable in equal monthly payments of principal and interest maturing in May 2023 and February 2022, respectively. The Company determined that the carrying amounts of the 2022 Insurance Note and 2021 Insurance Note approximate fair value due to the short-term nature of borrowings and current market rates interest rates.

During the year ended December 31, 2022, the Company repaid approximately, US \$0.2 million of principal and interest for the 2022 Insurance Note. As of December 31, 2022, the Company had an outstanding balance of \$0.2 million for the 2022 Insurance Note.

During the year ended December 31, 2022 and 2021, the Company repaid approximately US \$0.2 million and US \$0.3 million, respectively, of principal and interest for the 2021 Insurance Note. There was no outstanding balance for the 2021 Insurance Note as of December 31, 2022.

#### 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 matured 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 to be forgiven. During each of the years ended December 31, 2022 and 2021, the Company repaid US\$ 0.4 million of principal and interest for the PPP Loan. There was no outstanding balance for the PPP Loan as of December 31, 2022.

### 8. COMMITMENTS AND CONTINGENCIES

#### Legal Matters

In the ordinary course of business, the Company may be subject to various pending or threatened legal actions. In 2022, the Company was incorrectly named as a defendant in a lawsuit. On January 13, 2023, the Company was properly removed as a defendant in the above-mentioned matter. The Company is not currently subject to any material legal proceedings.

### 9. LEASES

The Company leases office space for its principal office in Dallas, Texas, which was extended during 2022 to expire in May 2024. During 2022, the Company entered into a lease for office space in the United Kingdom under a lease that expires in May 2023.

The following table summarizes quantitative information about the Company's operating leases for the year ended December 31, 2022 (US dollars in thousands):

	2022 US\$
Operating cash flows from operating leases (in US\$)	\$594
Right-of-use assets obtained in exchange for new operating lease liabilities (in US\$)	\$594
Right-of-use assets obtained in exchange for new operating liabilities upon lease extension (in US\$)	\$052 \$955
Weighted average remaining lease term – operating leases (in years)	1.4
Weighted average discount rate – operating leases	8.46%

The following table provides the components of the Company's lease cost included in general and administrative expense in the consolidated statement of operations (in thousands):

2	022
	USŚ

Operating leases	
Operating lease cost	\$590
Variable lease cost	126
Total rent expense	\$716

Variable lease cost is primarily attributable to amounts paid to lessors for utility charges and property taxes under an office space lease.

As of December 31, 2022, future minimum payments under the non-cancelable operating leases under ASC 842 were as follows (in thousands):

	US\$
Year ending December 31, 2023	\$744
Year ending December 31, 2024	354
Total	1,098
Less: imputed interest	(72)
Operating lease liabilities	\$1,026

For the year ended December 31, 2021, the Company recorded rent expense of approximately US\$ 0.8 million included in general and administrative expenses in the consolidated statement of operations in accordance with ASC 840. The future minimum lease minimum payments under the Company's lease agreement as of December 31, 2021 are as follows (in thousands):

	US\$
Year ending December 31, 2022	\$579
Year ending December 31, 2023	97
Year ending December 31, 2024	-
Total	\$676

### 10. PREFERRED STOCK

As of December 31, 2022 and December 31, 2021, there were no authorized or outstanding shares of preferred stock. Immediately prior to the Offering, all outstanding shares of Series A preferred stock and unpaid cumulative dividends were converted into 53,889,765 shares of common stock.

### 11. STOCKHOLDERS' EQUITY

The Company was authorized to issue 400,000,000 shares of common stock, par value US\$0.001 per share, as of December 31, 2022 and December 31, 2021, respectively. The Company had 135,409,564 and 135,034,564 shares of common stock issued and outstanding as of December 31, 2022 and December 31, 2021, respectively. As of December 31, 2022, the Company was in the process of completing the issuance of an additional 370,000 shares of stock through the exercise of certain stock options by former Company employees.

## 12. 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. In June 2021, in connection with the

#### continued

IPO, the 2018 Plan was amended so that stock issued pursuant to the 2018 Plan would be the common stock of the Company. 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. As of December 31, 2022, 38,354,118 shares of common stock were authorized for issuance under the 2018 Plan, of which 2,187,618 remain available for issuance.

#### 2022 Long Term Incentive Plan

On September 27, 2022, the Company's stockholders approved the adoption of the 2022 Long Term Incentive Plan (the "2022 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 2022 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. As of December 31, 2022, 20,000,000 shares of common stock were authorized for issuance under the 2022 Plan, of which all remain available for issuance.

#### **Restricted Stock**

The RSAs generally vest over four years. A summary of RSA activities for the twelve months ended December 31, 2022 are presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share US\$
Nonvested at January 1, 2021	1,750,002	US\$0.10
Vested	(687,500)	US\$0.10
Nonvested at December 31, 2021	1,062,502	US\$0.10
Vested	(750,000)	US\$0.10
Nonvested at December 31, 2022	312,502	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 2022 and 2021, respectively:

	2022	2021
Exercise price (per share in US\$)	US\$ 0.44	US\$ 0.26
Expected term (years)	5.9	5.3
Volatility (annual)	68%	82%
Risk-free rate	2.7%	0.4%
Dividend yield (per share)	0%	0%

A summary of stock options activity for the years ended December 31, 2022 and 2021 is presented below:

	Stock Options	Weighted Average Exercise Price US\$	Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value US\$
Outstanding at January 1, 2021	27,604,500	US\$0.15	8.8	US\$1,605
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
Options granted	4,285,000	US\$0.44	9.2	
Options exercised for cash	-	-		
Options forfeited/expired	(2,130,000)	US\$0.23		
Outstanding at December 31, 2022	36,124,000	US\$0.20	7.3	US\$6,831
Options vested and exercisable				
at December 31, 2022	25,429,771	US\$0.15	6.8	US\$5,842

For the year ended December 31, 2022 and 2021, the Company recorded stock-based compensation expense of approximately US\$ 1.2 million and US\$ 1.4 million, respectively, in general and administrative expenses in the consolidated statements of operations.

As of December 31, 2022, there was approximately US\$ 1.6 million of unrecognized stock-based compensation related to stock option grants that will be amortized over a weighted average period of 1.1 years.

As of December 31, 2022, there was approximately US\$ 26,000 of unrecognized stock-based compensation related to restricted stock grants that will be amortized over a weighted average period of 0.3 years.

During the year ended December 31, 2018, the Company granted of 10,039,926 stock options to investors (the "Investor Options") that were approved by the Board of Directors outside of the 2018 Plan. During the year ended December 31, 2022, 358,572 Investor Options expire and the remaining 9,681,354 Investor Options will expire in November 2023. The Investor Options have an exercise price of US\$1.20 per share. As of December 31, 2022, there is no unrecognized stock-based compensation expense related to the Investor Options.

#### 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 five-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, 2022, there are 762,712 warrants outstanding with an exercise price of US\$ 0.71.

### **13. INCOME TAXES**

As of December 31, 2022 and 2021, the Company had available federal net operating loss carryforwards ("NOLs") of US\$ 2.2 million and US\$ 3.0 million, 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.

#### continued

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

	2022 US\$	2021 US\$
Deferred income tax assets:		
Net operating loss carryforwards	429	601
Capitalized research expenses	420	-
Stock-based compensation	262	251
Lease liabilities	216	-
Other	279	196
Total deferred income tax assets	1,606	1,048
Deferred income tax liabilities:		
Right-of-use assets	212	-
Other	6	1
Total deferred income tax liabilities	218	1
Net deferred income tax assets	1,388	1,047
Valuation allowance	(1,388)	(1,047)
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, 2022, and 2021. The net change in valuation allowance for the years ended December 31, 2022 and 2021 was an increase of \$US 0.3 million and US\$ 0.5 million, respectively.

The income tax provision consists of the following as of December 31 (in thousands):

	2022 US\$	2021 US\$
Current:		
US Federal	5	(159)
US State	101	61
Total current provision	106	(98)
Deferred:		
US Federal	-	-
US State	-	-
Total deferred provision	-	-
Total provision for income taxes	106	(98)

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

	2022 US\$	2021 US\$
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal	(2.8%)	(1.1%)
Stock-based compensation	(7.6%)	(6.1%)
Other	(2.2%)	1.4%
Change in valuation allowance	(12.2%)	(12.9%)
Provision for income taxes	(3.8%)	2.3%

continued

### 14. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share attributable to common stockholders are the same for the year ended December 31, 2022 and 2021, since the inclusion of all potential shares of common stock outstanding would have been anti-dilutive due to the Company's net loss.

The table below summarizes potentially dilutive securities that were excluded from the computation of net loss per common share as of the periods presented because including them would be anti-dilutive.

	2022	2021
Common stock options	45,805,354	33,969,000
Common stock warrants	762,712	762,712
Unvested restricted stock	312,500	1,062,502
Potentially dilutive securities	46,880,566	35,794,214

## **15. RELATED PARTY TRANSACTIONS**

For the years ended December 31, 2022 and 2021, the Company did not have any transactions with related parties.

## **16. SUBSEQUENT EVENTS**

In February 2023, the Company paid aggregate bonuses of US\$755,000 to various employees of the Company, including US\$385,000 to Mr. Fan. These amounts were included in accrued expenses on the consolidated balance sheet as of December 31, 2022.

