27 February 2023

Spectral MD Holdings, Ltd
("Spectral MD" or the "Company")

Final Results
Strong foundations laid ahead of planned regulatory submissions in 2023

LONDON, U.K. AND DALLAS, TX, U.S. – Spectral MD Holdings, Ltd. (AIM: SMD), a predictive analytics company with proprietary AI algorithms and optical technology for faster and more accurate treatment decisions in wound care, announces its audited results for the year ended 31 December 2022.

Operational Highlights:

US Burn Indication supported by BARDA (Biomedical Advanced Research and Development Authority)

- Awarded US$ 8.2 million contract expansion to accelerate the commercialization pathway for DeepView™
- Burn Image Assessment Study ("BIAS") findings reinforce DeepView™'s value proposition and clinical need:
    - In 31% of healing wounds Emergency Department ("ED") physicians incorrectly selected immediate referral to a burn center or surgery
    - In 74% of non-healing wounds ED physicians failed to select immediate referral or surgery
- Adult enrollment in Burn AI training study completed

Diabetic Foot Ulcer ("DFU") Indication

- Clinical Study is on track to complete enrollment by end of Q2 2023 to support DeepView™ AI-DFU FDA regulatory submission in 2023

Commercial readiness

- Strengthened senior leadership team with four key appointments: Niko Pagoulatos, Chief Operating Officer; Christine Marks, VP Marketing & Commercialization; Vince Capone, General Counsel & Company Secretary; and Mary Regan, VP of Clinical Affairs
- Won Best Technology Award at the European Mediscience Awards in June 2022

Financial Highlights:

- R&D revenue up 67% to US$ 25.4 million (2021: US$ 15.2 million) funding Burn indication development as well as the development of handheld prototype DeepView SnapShot® M
- Strong cash position with cash on hand of US$ 14.2 million (2021: US$ 16.1 million)

Post-Period Highlights:

US Burn Indication

- Pediatric enrollment in Burn AI training study has been completed in February 2023.
- Federal contract opportunity initiated for Health and Human Services Burn Wound Imaging technology. Company responded with proposal and will be evaluated for contract fulfillment.
- DeepView™ AI-3D developed to capture millimetric level wound size measurement accuracy with single image acquisition without requiring external reference markers for seamless integration into the clinical workflow.

DFU Indication

- Successful interim results reported showing AI diagnostic accuracy improvement from 81% to 86%.
- US clinical study is on track with additional sites being incorporated in Q1 2023, providing data to support FDA and UKCA regulatory submissions.

- Initiated EU clinical study with the Royal College of Surgeons in Ireland ("RCSI") conducted at Connolly Hospital in Dublin, Ireland.

Wensheng Fan, Chief Executive Officer of Spectral MD, said: *"We are pleased with the rate of progress and development made in 2022 and have delivered strong operational results for both our Burn and DFU indications. Spectral MD also exceeded financial expectations during the period through effective cost management. Importantly, this will allow the Company to increase investment in 2023 to drive forwards our commercialization strategy for DFU.*

"Our immediate strategy remains focused on commercialization planning activities. We are in regular communication with BARDA to further develop our infrastructure readiness for a federal level commercial contract and look forward to building upon our strong momentum, whilst continuing to collaborate with BARDA and our clinical partners to scale and advance our transformative technology."

Market Abuse Regulation (MAR) Disclosure

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014 as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018 ('MAR'). Upon the publication of this announcement via Regulatory Information Service ('RIS'), this inside information is now considered to be in the public domain.

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

Using its DeepView™ Wound Imaging Solution, an internally developed AI technology and multispectral imaging system which has received FDA Breakthrough Designation for the burn indication, Spectral MD is able to distinguish between non-healing and healing human tissue invisible to the naked eye. Spectral MD currently is able to provide 'Day One' healing assessments for burn wounds and diabetic foot ulcers (DFU), with other applications being explored.

Spectral MD has to date received substantial support from the US government with contracts from institutions such as Biomedical Advanced Research and Development Authority (BARDA), National Science Foundation (NSF), National Institute of Health (NIH) and Defense Health Agency (DHA) in support of the burn application for its DeepView™ solution.

Spectral MD started trading on the AIM market of the London Stock Exchange on June 22nd, 2021, after raising US $16 million through an oversubscribed initial public offering. The Company has two principal trading subsidiaries, Spectral MD, Inc. and Spectral MD UK Limited.

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™ technology and operations. Spectral MD continues to make significant advances in the development of the DeepView™ 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™ 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™ Wound Imaging System. The award expanded the current clinical training study for burn wounds by adding clinical sites, further increases DeepView™'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®'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™ in Emergency Rooms across the US.

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™'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™'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™ 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™ 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.

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 AI® -DFU algorithm and support the 2023 Company's regulatory submissions for UKCA, US FDA, and EU CE Mark.

Technology Miniaturization (DeepView SnapShot® 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®M, a fully handheld prototype and wireless version of the cart-based Deep View™ 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®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, Vince 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® 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.

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™, 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™ 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™'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.

Financial Review

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™ AI-Burn indication and the handheld prototype DeepView SnapShot®M.

The cost of sales in 2022 was US$ 14.5 million (2021: US$ 8.2 million) and gross profit was US$ 10.9 million (2021: US$ 7.0 million). This 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-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 permanent 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 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.

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™ 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
27 February 2023

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® 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.
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

SUPPLEMENTARY INFORMATION- DEFINITIONS AND RECONCILIATIONS OF NON-GAAP MEASURES

Non-GAAP measures as defined by the Company

The Company uses adjusted EBITDA as a non-GAAP metric when measuring performance, including when measuring current period results against prior periods adjusted EBITDA.

Because of their non-standardized definitions, non-GAAP measures (unlike GAAP measures) may not be comparable to the calculation of similar measures of other companies. Supplemental non-GAAP measures are presented solely to permit investors to more fully understand how Spectral MD management assesses underlying performance. Supplemental non-GAAP measures are not, and should not be viewed as, a substitute for GAAP measures.

Adjusted EBITDA

The Company defines adjusted earnings before interest, tax, depreciation and amortization ("adjusted EBITDA") as net income/(loss) excluding income taxes, depreciation of property, plant and equipment (including any related impairment charges), amortization of intangible assets (including any related impairment charges), interest expense, stock compensation, any non-operating financial income and expense.

The following table presents the Company's Adjusted EBITDA as of December 31, 2022 and December 31, 2021:

	2022	2021
	US$	US$
Net loss	(2,912)	(3,988)
Adjust:		
Depreciation Expense	11	1
Provision for Income Taxes	106	(98)
Interest Expense	12	17
EBITDA	**(2,783)**	**(4,068)**
Additional Adjustments:		
Stock based Compensation	1,155	1,365
Change in fair value of warrant liability	(57)	(298)
Foreign exchange transaction loss	253	188
Other income	(49)	-
Adjusted EBITDA	**(1,481)**	**(2,813)**

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.

KPMG 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

See accompanying notes to the consolidated financial statements

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
Operating costs and expenses:		
General and administrative	13,484	11,231
Total operating costs and expenses	13,484	11,231
Operating income (loss)	(2,647)	(4,179)
Other income (expense):		
Interest expense	(12)	(17)
Change in fair value of warrant liability	57	298
Foreign exchange transaction loss	(253)	(188)
Other income	49	-
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

See accompanying notes to the consolidated financial statements

Consolidated Statements of Changes in Equity

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount US$	Shares	Amount US$	US$	US$	US$
Balance at December 31, 2020	4,324,330	1,114	61,347,000	61	6,096	(5,034)	1,123
Issuance of common stock for cash	—		19,067,797	19	15,595	—	15,614
Issuance cost, net of $0.5 million warrant liability	—		—	—	(1,479)	—	(1,479)
Cumulative dividend on Series A preferred stock	—		—	—	(1,259)	—	(1,259)
		1,259					
Conversion of preferred stock to 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	—	—	375,000	—	1,155	—	1,155
Net loss	—	—	—	—	—	(2,912)	(2,912)
Balance at December 31, 2022	—	—	135,409,564	135	23,795	(11,934)	11,996

See accompanying notes to the consolidated financial statements

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

See accompanying notes to the consolidated financial statements

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® 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.

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® 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.

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 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 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® Wound Imaging Solution. BARDA may award contracts that are less than 12 months depending on the scope of work and deliverables.

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

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

Research and Development

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

Stock-Based Compensation

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

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.

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, 2021	Adjustments	As Adjusted December 31, 2021
	US$	US$	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

	As Previously Reported 2021	Adjustments	As Adjusted 2021
	US$	US$	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):

	Fair value measured at December 31, 2022			
Warrant Liability	Fair Value at December 31, 2022 US$	Quoted prices to active markets (Level 1) US$	Significant observable inputs (Level 2) US$	Significant unobservable inputs (Level 3) US$
	$ 129	$ -	$ -	$ 129

	Fair value measured at December 31, 2021			
Warrant Liability	Fair Value at December 31, 2021 US$	Quoted prices to active markets (Level 1) US$	Significant observable inputs (Level 2) US$	Significant unobservable inputs (Level 3) US$
	$ 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):

	US$	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

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
Operating cash flows from operating leases (in US$)	$	594
Right-of-use assets obtained in exchange for new operating lease liabilities (in US$)	$	632
Right-of-use assets obtained in exchange for new operating liabilities upon lease extension (in US$)	$	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):

		2022 US$
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 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	Waited 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.

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%

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.