PROSPECTUS SUPPLEMENT
To Prospectus dated January 2, 2024

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-275218

Primary Offering of
Up to 8,433,231 Shares of Common Stock Issuable upon Exercise of Warrants

Secondary Offering of
Up to 10,069,748 Shares of Common Stock

This prospectus supplement updates and supplements the information contained in the prospectus dated January 2, 2024 (as may be supplemented or amended from time to time, the "Prospectus"), which forms part of our registration statement on Form S-1 (File No. 333-275218) with the information contained in Spectral AI, Inc.'s (the "Company") Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on March 29, 2024 (the "Annual Report"). Accordingly, we have attached the Annual Report to this prospectus supplement.

The Prospectus and this prospectus supplement relate to the issuance by the Company of up to 8,433,231 shares of our common stock, par value $0.0001 per share (the "Common Stock") that are issuable upon the exercise of 8,433,231 warrants (the "Warrants"), which were originally issued in Rosecliff Acquisition Corp I's ("RCLF") initial public offering (the "RCLF IPO") as part of RCLF's units at a price of $10.00 per unit (the "Units"), with each unit consisting of one share of Common Stock and one third of one Warrant, by the holders thereof. Each Warrant entitles the holder thereof to purchase one share of our Common Stock at a price of $11.50 per share.

This prospectus also relates to the offer and resale from time to time by the selling stockholders (including their transferees, donees, pledgees and other successors-in-interest) named in this prospectus (the "selling stockholders") of (i) up to 10,069,748 shares of Common Stock, which consists of (a) up to 8,623,081 shares of Common Stock issued in connection with closing of the Business Combination (as defined in the Prospectus) (the "Closing") at an equity consideration value of $10.00 per share by certain of the selling stockholders named in this prospectus, (b) up to 880,000 shares of Common Stock that were originally issued to the Initial Holders (as defined in the Prospectus) in the form of founder shares prior to the RCLF IPO at a price of approximately $0.004 per share, and (c) up to 566,667 shares of Common Stock that were issued to certain service providers of the Company in connection with the Closing at an equity consideration value of $7.50 per share.

You should read this prospectus supplement in conjunction with the Prospectus. This prospectus supplement is qualified by reference to the Prospectus except to the extent that the information in this prospectus supplement supersedes the information contained in the Prospectus. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement. Terms used in this prospectus supplement but not defined herein shall have the meanings given to such terms in the Prospectus.

Our common stock is currently listed on The Nasdaq Global Market ("Nasdaq") under the symbol "MDAI". On April 22, 2024, the closing price of our common stock was $1.81.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 8 of the Prospectus and in the other documents that are incorporated by reference in the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities to be issued under the Prospectus or determined if the Prospectus or this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is April 23, 2024.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

Or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

To

Commission File No. 001-40058

SPECTRAL AI, INC.

(Exact name of registrant as specified in its charter)

Delaware	**85-3987148**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2515 McKinney Avenue, Suite 1000 Dallas, Texas	75201
(Address of Principal Executive Offices)	(Zip Code)

(972) 499-4934
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	MDAI	The Nasdaq Stock Market LLC
Redeemable warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of $11.50	MDAIW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

The aggregate market value of the Registrant's Common Stock outstanding held by non-affiliates of the Registrant, computed as of September 12, 2023 (the date of completion of the registrant's Business Combination (as defined below)) was approximately $81,000,000.

As of March 25, 2024, there were 17,466,871 shares of Common Stock, $0.0001 par value per share, issued and outstanding.

SPECTRAL AI, INC.
FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2023
TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTOR SUMMARY

This Annual Report on Form 10-K contains statements that are forward-looking and as such are not historical facts. This includes, without limitation, statements under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" regarding our financial position, business strategy and the plans and objectives of management for future operations. These statements constitute projections, forecasts and forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this Annual Report on Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the following risks, uncertainties and other factors:

- We have incurred significant losses since inception and may not be able to achieve significant revenues or profitability.
- We are devoting substantially all of our efforts towards research and development of our DeepView System.
- We depend on government funding, which if lost or reduced, could have a material adverse effect on our research and development activities and our ability to commercialize our DeepView technology. Our largest contract is with Biomedical Advanced Research and Development Authority ("BARDA") and is the largest single source of revenue for us. Our BARDA contract is not guaranteed to be completed or extended.
- The regulatory review process is expensive, time-consuming, and uncertain and we may be unable to obtain clearance, approval, De Novo classification, or certification for our DeepView technology.
- We may experience significant delays in completing clinical trials, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.
- New legislation and regulations and legislative and regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance, approval, De Novo classification, or certification of our DeepView System, or to manufacture, market and distribute our device after clearance, approval, or classification is obtained.
- Disruptions at the FDA and foreign regulatory agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.
- The ongoing labor shortage may limit our ability or the investigators' ability to find and retain medical staff that are needed to conduct the clinical studies.
- Modifications to our DeepView System may require new clearances, approvals, De Novo classifications, certifications, or new or amended certifications, and may require us to cease marketing or to recall the modified device until clearances, approvals, De Novo classifications, or the relevant certifications are obtained.
- Quality problems and product liability claims could lead to recalls or safety alerts, reputational harm, adverse verdicts or costly settlements, and could have a material adverse effect on our business, results of operations, financial condition, and cash flows.
- We must comply with anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations.
- If our manufacturers fail to comply with the regulatory quality system regulations or any applicable equivalent regulations, our proposed operations could be interrupted, and our operating results would suffer.
- Actual or perceived failure to comply with data protection, privacy and security laws, regulations, standards and other requirements could negatively affect our business, financial condition or results of operations.
- As the regulatory framework for AI technology evolves, our business, financial condition and results of operation may be adversely affected.
- If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our DeepView System, if approved.
- We may not be able to achieve or maintain satisfactory pricing and margins for our DeepView technology.

- We will depend upon third-party suppliers, including contract manufacturers and single and sole source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- We are highly dependent on our senior management, directors and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.
- The use of artificial intelligence, including machine learning, in our analytics platforms may result in reputational harm or liability.
- Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our DeepView System. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.
- The success of our algorithms depends on our significant repository of proprietary DFU and burn data.
- Changes in patent law or its interpretation could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.
- Our patent rights and other intellectual property may be subject to priority, ownership or inventorship disputes, interferences, and similar proceedings and we may not be able to enforce our intellectual property rights throughout the world.
- Nasdaq may delist our securities from trading on its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.
- As a newly listed Nasdaq company, we will incur increased costs as a result of operating as a public company, and the Company's management will be required to devote substantial time to new compliance and investor relations initiatives.
- The price of our Common Stock and Warrants may be volatile.
- Changes in laws, regulations or rules, or a failure to comply with any laws, regulations or rules, may adversely affect our business, investments and results of operations.
- If we fail to maintain proper and effective internal controls over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our Common Stock may decline.
- Certain existing stockholders purchased, or may purchase, securities in the Company at a price below the current trading price of such securities and may experience a positive rate of return based on the current trading price. Future investors in the Company may not experience a similar rate of return.
- Warrants may become exercisable for Common Stock, which would increase the number of shares eligible for resale in the public market and result in dilution to our stockholders.
- The other risk and uncertainties discussed in "Item 1A. Risk Factors," elsewhere in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission (the "SEC").

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

PART I.

References in this Annual Report on Form 10-K (this "Annual Report") to "we," "us," "our" or the "Company" are to Spectral AI, Inc., a Delaware corporation. References to our "management" or our "management team" refer to our officers and directors.

Item 1. Business. **Overview**

We are an AI company focused on predictive medical diagnostics. Our DeepView System uses proprietary AI algorithms to distinguish between fully damaged, partially damaged and healthy human tissue characters invisible to the naked eye, at the initial time point of wound presentation. The DeepView System delivers a binary prediction on the wounds capacity to heal or not-heal by a specified time point in the future. Our DeepView System's output is specifically engineered to assist the physician in making a more accurate, timely and informed decision regarding the treatment of the patient's wounds. Our focus from 2013 through 2021 was on the burn indication. In 2022, we expanded our focus to include the DFU indication.

We were notified that our DeepView System, comprised of the multispectral imaging ("MSI") component integrated with the predictive AI-Burn® software component received United Kingdom Conformity Assessed (UKCA) marking for use in the United Kingdom for burn indications on February 22, 2024. The UKCA marking registration was fully completed on March 7, 2024. We anticipate that our full DeepView System may achieve Class II medical device designation in the with the United States Food and Drug Administration (FDA) via a De Novo application. Subject to our receipt of additional necessary market authorization, our business will have two revenue streams, a SaaS model component predicated on utilizing the regulatory method, SaMD (software as a medical device), and the imaging device component. The SaaS component will feature a software licensing fee that includes maintenance, image hosting, and access to algorithm updates. The proprietary imaging device acquires the images for the AI algorithms and is a universal platform to house multiple clinical applications including burn and DFU. Pricing for these components will be evaluated and strategically set per country and site-of-service for heightened customer adoption.

The MSI imaging technology, which comprises one part of the DeepView System, consists of patented proprietary multi-spectral optics and sensors, capturing injured tissue images ranging from near UV lights, through the human visible wavelengths, all the way into the near infrared range (NIR). The broad wavelength ranges go beyond what the human eyes can see and capture what medical professionals cannot observe with their naked eyes. This wide range of wavelength images contains wound tissue physiology and captures the viability of various biomarkers within the skin and from the injured tissue spectral signatures. The imaging technology extracts appropriate clinical data, processes the image data to provide the injured tissue spectral signatures to the AI model and algorithms. The AI algorithm classifies various severities of the injuries as (i) full damaged (non-healing), (ii) partially damaged or (iii) healthy tissue (healing) and displays a comparison of the original image next to an image with a color overlay of the non-healing portions of the wound. The image acquisition takes 0.2 seconds, and all image processing and AI model classification takes approximately 20 to 25 seconds. Our DeepView System's proprietary optics can extract millions of pixels of data or AI model features from each group of raw images. This information is then used to build and continually improve the AI model, which is trained and tested against a proprietary and clinically validated database of approximately 340 billion pixels of DFU and burn data as of December 31, 2023. The DeepView-AI Burns® software is used with the DeepView SnapShot® imaging device, and it is intended to be used as an adjunctive tool to aid health care providers in the assessment of burn wound healing potential by differentiating non-healing from healing burned tissue within an image.

Below at Figure 1 is an example of the DeepView System technological process.

Figure 1 — DeepView Imaging technology

To our knowledge, there are no digital wound healing assessment in predictive medical diagnostic products that provide clinicians with an objective and immediate assessment of a wound's future healing potential and that benefit from the application of AI. Currently, healthcare professionals rely on their experience and subjective assessments to determine if wounds, such as burn injuries and DFUs, will heal under routine care after a period of time, typically several weeks, or are in need of advanced wound care products and procedures including surgical interventions. Our DeepView System allows health care professionals to make a "Day One" assessment of a wound's healing potential over time.

We have received substantial support from the U.S. government for our DeepView System's application for burn wounds, including from agencies such as BARDA, which is part of the HHS Office of the Assistant Secretary for Preparedness and Response ("ASPR") in the United States, established to aid in securing the United States from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases. We have also received funding from the National Science Foundation ("NSF"), National Institute of Health ("NIH") and the DHA an agency within the Department of Defense ("DoD"). Since 2013, we have been awarded approximately $279.6 million in funding from government contracts, substantially all of which is from BARDA, which accounts for $272.9 million. This has allowed us to develop our technology and further our clinical trials. On September 27, 2023, the Company executed a new contract with BARDA, providing the Company with additional funding of up to $150.0 million, including an initial award of approximately $54.9 million to support the clinical validation and application for FDA De Novo status of our DeepView AI – Burn software. This will include the distribution of up to 30 DeepView Systems in various emergency rooms and burn centers to support the clinical validation study. The contract also includes options, similar to our prior BARDA contracts, with an additional total value of approximately $95.1 million which can be exercised for additional product development, procurement and the expanded deployment of DeepView Systems at emergency rooms, trauma and burn centers. These deployments will enable the Company to conduct health economic and outcome research to support the broader clinical adoption of the DeepView System. This grant funding is non-dilutive to our stockholders, and we believe it validates the important nature of our mission and technology.

Subject to our receipt of the necessary regulatory market authorizations, we intend to initially sell the DeepView System throughout the United States and the UK for its burn and its DFU indication. Given our receipt of the UKCA authorization for our burn indication we anticipate initial sales in UK in the second half of 2024. The sales channel for these two indications are different. We expect that our burn indication will be supported by existing and future governmental contracts, primarily from agencies such as BARDA and the DHA, while the DFU indication will be an add-on to the burn indication sales channel and will have its own separate sales channel to penetrate the podiatric and wound care clinics. In the United States, there are approximately 100 burn centers, 700 trauma centers and 5,400 federal and community hospitals with Emergency Rooms where the burn patients are most likely to visit upon injuries. The DeepView System provides a quick clinical decision tool to the emergency rooms, so it can be decided quickly whether patients need routine care or should be transferred to trauma centers or burn centers for advanced care, and for quick and accurate surgical planning. In the burn centers, the DeepView System provides an advanced guidance on the non-healing areas of a burns, Therefore, we plan to target our sales efforts to these facilities through our highly-trained technical sales support staff that we plan to hire given the nature of DeepView as a truly disruptive AI driven predictive assistance tool. For the DeepView System's burn application and following receipt of any future contract awards, we plan to partner with the U.S. governmental agency sponsors to implement the distribution of our DeepView System throughout the United States into key regions to support the United Stats' mass casualty countermeasure directives, with the goal of making our country better prepared for mass casualty events and saving scarce healthcare resources.

Subject to our receipt of the necessary market authorizations, we plan to begin our commercial sales efforts of the DeepView System's DFU application in the UK through key clinical sites and related networks. We expect to engage contract sales organizations to distribute our DeepView System throughout the UK as well as eventually in the Netherlands, Germany, Italy and Spain ("EU4"). Preliminary discussions with distributors occurred during 2023 to determine which organizations possess the key relationships and insights for selling diagnostic systems within their respective countries. We intend to focus our commercial strategy initially in the UK, which we are targeting for mid-2024, with the EU4 to follow in 2026, subject to CE mark approval for our technologies. Similar to the United States, the primary customer base for the DFU application in Europe will be outpatient wound centers and secondary sites of care that have a high-volume of DFU patients. We also expect to engage internal and/or third party resources to help us navigate the various regional tender and contracting entities within each country. In the United States, subject to our receipt of the necessary regulatory market authorization, we anticipate initially distributing the DeepView Systems using our DFU indication in hospitals' emergency rooms and trauma centers. We will then build in additional indications, given that we can run multiple indications on the same imaging devices. In addition, wound care centers are typically the first line of specialty care for DFUs in the United States. Vascular and cardiology companies and outpatient podiatry practices also treat wounds. We will need to grow our distribution network to support the expanded sales efforts for the DFU indication to these facilities by initially focusing on management companies that have multiple podiatric and/or wound care centers under their management. In this way, we believe we can build a mature sales model, pricing structure, and customer instructions, to enable us to further grow our distribution networks with third-parties and other sales channel sources.

As noted above, subject to our receipt of the necessary regulatory market authorizations, our business is expected to have two revenue streams, a SaaS model component predicated on utilizing the regulatory method, SaMD (software as a medical device), and an imaging device component. The SaaS component will feature a software licensing fee that includes maintenance, image hosting, and access to algorithm updates. The capital sale component will be competitively priced for acceptance into independent practices and clinics.

In 2018, the FDA designated our earlier version of the DeepView System with BDD status for its burn indication. The FDA's designation as a Breakthrough Device ("BDD") allows for prioritized reviews and a dedicated line of communication with reviewing members of the FDA. In the first quarter of 2021, the Health Products Regulatory Authority of Ireland (HPRA) provided a medical device classification recommendation of IIa for our DeepView System. We have enrolled subjects in our DFU studies in clinical and academic sites across the United States and Ireland. In 2022, we completed our first DFU clinical training study with 100 adult subjects in the United States at five well-known medical facilities. In the third quarter of 2022, we extended the AI training study with an additional 100 adult subjects. We completed this study in January 2023, providing us with a much-improved DFU AI prediction performance at 86%. In April 2023, we commenced our validation study with an additional 200 adult subjects at 10 well-known medical facilities. This study is expected to be completed in 2024. We have also signed with international partners, including well-respected institutions in the field and have partnered with leading wound care physicians. We believe that we will be able to leverage these relationships to access other institutions and individuals, which should increase awareness and early adoption of our technology in the United States, the UK and the EU. U.S. adoption will also benefit from the potential future BARDA funding of technology placement for burns applications. Our focus will be on the continued development of the DFU AI model as we progress through the validation study.

We expect to complete the validation studies for the DFU regulatory application in the United States in 2024, while targeting for the FDA's grant of our De Novo petition in early 2025.

Subject to our receipt of the necessary regulatory market authorization, we would expect to leverage results from the U.S. study for a simultaneous conformity assessment procedure in the EU to obtain the CE marking of conformity ("CE Mark"), and we would expect to commence post-market studies in the UK and Germany. Subject to our receipt of the necessary regulatory market authorization, we would expect to initiate commercialization in the United States during 2025 and intend to submit for FDA review of the burn application in 2025 in accordance with the projected timeline for our BARDA contract.

Burn Indication

We began conducting our validation study for burn in the early 2024, where we plan to enroll an additional 240 adult and pediatric subjects at up to 20 clinical sites.

In adult participants, the DeepView GEN3 System has shown 92% accuracy, with cross-validation from the AI model for identification of non-healing burn regions. This represents a significant improvement above the diagnostic accuracy of burn physicians assessing the same adult burn patients, and above 50% to 75% accuracy, according to industry literature. In addition, in head-to-head clinical trial evaluations, our DeepView System provided higher accuracy on "Day One" to "ground truth" determined on day 21 on burn wound analysis than the accuracy of burn specialists, reporting at 70 – 80% accuracy, and non-burn specialist physicians, reporting at 50 – 60% accuracy. We have conducted three large clinical studies with multiple sites across the United States, enrolling 413 patients, including 329 adult burn patients and 84 pediatric patients. Through these studies we were able to determine burn assessment accuracy in both healing and non-healing wounds.

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

As of December 31, 2023, our proprietary and clinically validated database for burns is comprised of approximately 340 billion pixels of DFU and burn data. 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 us to develop further in the future.

DFU Indication

We made substantial progress in our U.S. DFU Clinical Validation Study (the "US DFU Clinical Study") in 2023. The endpoint that we are pursuing in the clinical study is to predict on "Day One" whether the DFU wound will reduce in size by 50% by week four. Our DeepView System showed improvement of the AI diagnostic accuracy to 86%.

The data collected from the US DFU Clinical Study will be used to augment our existing proprietary and clinically validated database of DFU data and healthcare matrix information; and to validate the DeepView DFU AI algorithm as we prepare for U.S. regulatory submission in 2024.

In the first half of 2023, we continued to enroll subjects in the US DFU Clinical Study to finalize our admission goal. Additionally, we increased investment in the DFU indication in 2023 to drive our commercialization strategy. We intend to submit for U.K. Conformity Assessment ("UKCA") regulatory evaluations in mid-2024. We are currently targeting to receive the required UKCA certificates in 2024, and to receive FDA marketing authorization in 2025, although these authorizations cannot be guaranteed, and may take longer than expected.

In February 2023, we 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 for up to 12 weeks. The intention of the clinical study is to further develop the DeepView AI algorithm to support our regulatory submissions for UKCA, FDA, and EU CE Mark. The imaging system that makes up our DeepView System recently received United Kingdom Conformity Assessed (UKCA) marking for use in the United Kingdom and has Class I medical device classification with the United States Food and Drug Administration (FDA), while we anticipate that the DeepView System as a whole, including the AI component, may achieve Class II classification in the US via a De Novo application.

Other DeepView Programs in Development

Funding from the U.S. government has also allowed us to develop additional "Horizon" indication uses of our DeepView System, including DeepView Snapshot M, DeepView AI 3-D wound measurement technology, and other indications. We believe that our DeepView System's use in emergency rooms, trauma and burn centers and other would care facilities should be expanded to provide greater utility of the DeepView System in such settings.

DeepView SnapShot M

In addition to our DeepView System, our primary additional technology is the DeepView SnapShot® M, a fully handheld, portable, wireless diagnostic tool based on the DeepView System's AI platform. The DeepView SnapShot M provides a potential enhanced and expanded use for the U.S. government and emergency care, first responders and potentially home health care professionals. On June 23, 2021, we were awarded a two-year, $1.1 million, Sequential Phase II STTR contract by the DHA within the U.S. Department of Defense. This funding enables us to research and develop the DeepView SnapShot M product primarily for military and combat settings. In April 2023, we were awarded a $4.0 million grant from the Medical Technology Enterprise Consortium ("MTEC"), a 501I(3) biomedical technology consortium working in partnership with the Department of Defense, to develop our DeepView SnapShot M device in a Phase III feasibility and commercialization study. This grant was increased by over $500,000 on March 12, 2024. These grants, along with prior awards from DHA, bring our funding total for our DeepView SnapShot® M to over $6.0 million. The funding will be used to support military battlefield burn evaluation using DeepView SnapShot M.

3-D Wound Measurement Technology

We are also currently developing 3-D software-based wound measurement technology for our DeepView System. This technology will produce rapid, accurate and easy-to-use wound size measurement images to produce an accurate 3-D tissue representation from a single image snapshot enabling distance, area and volume measurements with sub-millimetric accuracy without reference to any attendant markers or manually placed stickers or multiple images. We believe this is a significant improvement over current wound size measurement technologies which are limited in their ability to measure all three wound dimensions (distance, area and volume) or are otherwise cumbersome, requiring reference markers/stickers or multiple images to determine would size measurements. Our 3D wound measurement technology calculates the total body surface area ("TBSA") of a wound. This technology will be integrated into our DeepView System and applies the "rule of nines"; a method that divides the body's surface area into percentages to calculate the size of a burn or wound. For example, the front and back of the head and neck equal 9% of the body's surface area and the front and back of each arm and hand equal 9% of the body's surface area. This technology enhancement will not only generate the TBSA measurement, but will also indicate the "healthy" versus "unhealthy" tissue for advanced treatment applications to be applied to the burn or wound area. This is a critical step in assuring that these alternative medical solutions will be successful in-patient applications. The 3-D wound size measurement tool has completed the proof-of-concept phase. We are currently developing this technology in cooperation with BARDA.

Business Focus and Milestones

Our current focus is categorized in two parts: (1) we will continue to fulfill our contractual obligations and meet milestones under our BARDA PBS contract (described in further detail below); and (2) we will pursue the commercialization of the DFU application in the UK, United States and EU4. Our near-term goals related to the BARDA PBS contract are to deliver on the current phase of the contract (Phase 1a), and to complete the remaining phases of the BARDA PBS contract. Completion of these contractual phases support our long-term goal of entering into a federal procurement contract with BARDA.

We intend to submit a De Novo application to the FDA for market authorization of the burn application in early 2025. In 2023, we received our ISO 13485:2016 certification for Medical Devices. The certification audit is expected to occur in the first quarter of 2024. In parallel, we are in the process of scheduling the DeepView System Technical Documentation audit necessary to obtain the CE Mark and UKCA certificates to allow market access in the EU and UK, respectively. In March, Spectral completed its UKCA Mark registration for the full DeepView System for our burn indication. Figure 2 below provides a summary of our key anticipated regulatory submissions. There can be no assurance that we will be able to obtain market authorization in the US, UK or EU of our DeepView GEN 3 System with AI on our projected timeline, or at all.

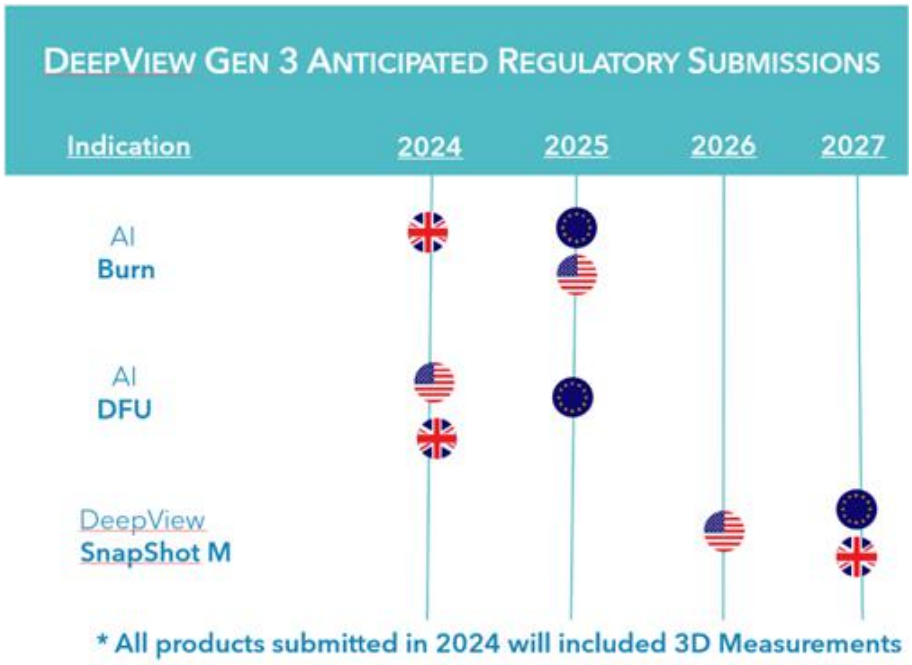

Figure 2 — Summary of key regulatory submissions

DeepView in Practice

DeepView is a predictive analytics platform that combines AI algorithms and MSI imaging for an assessment of wound healing potential. It is non-invasive, non-radiation, non-laser and does not require the use of injectable dye. This integration can be characterized into four distinct components: DeepView imaging, data extraction, AI model building and AI wound healing potential assessment. The DeepView AI®- Burn software is used with the DeepView SnapShot® imaging device, and it is intended to be used as an adjunctive tool to aid health care providers in the assessment of burn wound healing potential by differentiating non-healing from healing burned tissue within an image.

- The DeepView technology consists of patented proprietary multi-spectral optics and sensors that can classify wound tissue physiology and capture the viability of various biomarkers within the skin.

- The imaging technology extracts appropriate clinical data, processes the image and displays a comparison of the original image next to an image with a color overlay of the non-healing portions of the wound. The image acquisition takes 0.2 seconds and the output takes approximately 20 to 25 seconds.

- DeepView's proprietary optics can extract millions of pixels of data or AI model features from each raw image. This information is then used to build and continually improve the AI model, which is trained and tested against a proprietary and clinically validated database of approximately 340 billion pixels of DFU and burn data as of December 31, 2023.

- The AI algorithm then seeks to produce an objective, accurate, and immediate binary wound healing assessment. This assessment would be graphically represented to the clinician through a colored overlay of the original image that annotates the portion of the wound that is predicted to be non-healing over a specified period of time – 21 days (See Figure 4 below).

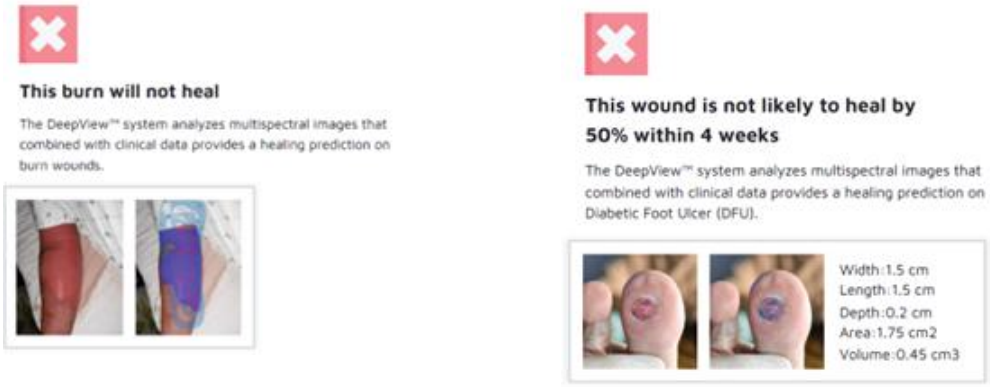

Figure 3 — Illustration of DeepView's binary decision assist output where the colored region marks the predicted non-healing portion of the wound.

The DeepView System is designed to assist clinicians in making accurate, timely, and informed decisions regarding the treatment of the patient's wound. In the case of DFUs, an assessment that the wound will not heal over time would provide the health care professional with the appropriate justification to use an advanced wound care therapy on "Day One" as opposed to waiting 30 days using standard of care and potentially losing the patient to follow-up or risking patient non-compliance with standard wound therapy. The current clinical accuracy of DeepView in ongoing clinical trials is 86% for DFUs compared with current physician accuracy as low as 50%. Subject to FDA market authorization of the product, for burn wounds, the clinician could make an immediate and objective determination for appropriate candidates for surgery as well as determining what specific areas of the burn wound will require skin grafting. In ongoing clinical trials, DeepView's current accuracy for burn wounds non-healing predictions is 92%, compared with current physician accuracy of 50 to 75%, according to industry literature. In addition, in head-to-head clinical trial evaluations, when compared to "ground truth" our DeepView System provided higher accuracy of burn wound analysis than the accuracy of burn specialists, reporting at 70 – 80% accuracy, and non-burn specialist physicians, reporting at 50 – 60% accuracy, when comparing "Day One" analysis to "ground truth" determined on day 21. We have conducted three large clinical studies with multiple sites across the United States, enrolling 413 patients, including 329 adult burn patients and 84 pediatric burn patients. Through these studies, we were able to determine burn assessment accuracy in both surgery and non-surgical treatment.

See the table below for an analysis of the current DeepView System's benefits to patient care:

	Burn	**DFU**
Current Time to Decision	21 Days	30 Days
DeepView® Time to Decision	Day 1	Day 1
Current Clinical Accuracy	50 – 75%	50%
DeepView® Accuracy in Ongoing Clinical Trials	92%	86%
DeepView® Estimated Cost savings	~$24,000 per stay	~$63,100 per stay

Key Strengths

We believe the following key strengths will help us to maintain and grow our business going forward:

Market Leading Technology

We have developed proprietary AI algorithms and imaging technology to assist clinicians to make more accurate and efficient treatment decisions in managing patient's wounds. This technology is the result of 13 years of research and development, thousands of hours of user feedback, and most importantly, the continual commitment to ensuring that the output from DeepView answers a clinical question that is to meaningful physicians. We own and control the entirety of our data pipeline. We only rely images and data that the DeepView System collects in a controlled clinical environment and do not rely on stock images or databases for our algorithms. All optical technology has been developed in-house and is specifically engineered to collect this imaging data. A current image of our cart-based DeepView System appears below in Figure 8.

Figure 4 — DeepView Generation 3 System

Unmet Clinical Need

The biggest unmet need for clinicians treating DFU and burn wounds is the lack of a diagnostic tool that provides an objective wound healing determination on "Day One." While burns and DFUs appear to be very different types of wounds, they are in fact similar from the perspective of assessment and diagnosis. The treatment pathways for each of these wounds can be generally characterized by a subjective initial assessment from the physician followed by multiple weeks of clinical observation to assess whether or not the wound responded to treatment. Both are primarily staged by their penetration depth into the skin and involvement of tissues below the skin in severe cases. Both DFUs and burns are diagnosed by expert clinical opinion without the aid of objective diagnostic tools that provide a wound healing prediction. Furthermore, the current methods of diagnosis rely on a "wait and see" approach that result in prolonged hospital stays and costly delays in the delivery of definitive treatment. Our goal is to eliminate these costly delays between initial screening and the delivery of a definitive treatment through the use of AI algorithms applied to our proprietary multispectral wound images.

Significant Market Opportunity

Geography — DeepView has the potential to service a large total addressable market. We estimate that there are over 57,000 sites of clinical care in which the technology could be placed in the United States and over 20,000 sites across the UK and EU4. For all geographies, these sites include both acute inpatient hospitals and outpatient sites of care, in order to include physician offices. As we expand from the United States into the UK and EU4, we will consider follow-on markets for commercial expansion, including the Middle East, among others.

Pipeline Applications — Though we are currently focused on the DFU and burn applications for DeepView, there are other pipeline applications that we are considering for future commercialization. As noted above, we have already received U.S. government funding for the development of our DeepView SnapShot® M fully handheld device for use in combat, military and home health care uses. In connection with our BARDA contract, we are working on expanding the indication usage of the DeepView System to incorporate a wound and burn measurement tool for clinicians. We have also explored the technology's potential for the assessment of critical limb ischemia, level of lower limb amputation selection, post-operative perfusion assessment for peripheral interventions, and military applications. For all future pipeline applications, we believe that the technology would remain constant, in that we will leverage our data analytics algorithms to improve predictive analyses. With any new application, we would need to conduct one or more clinical studies to collect enough patient data to appropriately support algorithm development for each new application. These new algorithms could easily be uploaded to existing machines in the future. From a regulatory perspective, we believe that these follow-on applications would all follow a 510(k) clearance process although in some cases, we may need to follow the De Novo classification or premarket approval pathway if we are not able to identify a predicate, or if use of the device for a new indication is classified as a Class III device.

Existing and future revenue base from long term U.S. Government Contracts — BARDA

On September 27, 2023, the Company executed a new contract with BARDA, providing the Company with additional funding of up to $150.0 million, including an initial award of approximately $54.9 million to support the clinical validation and application for FDA De Novo status of our DeepView System. This will include the distribution of up to 30 DeepView Systems in various emergency rooms and burn centers to support the clinical validation study. The contract also includes options, similar to our prior BARDA contracts, with an additional total value of approximately $95.1 million which can be exercised for additional product development, procurement and the expanded deployment of DeepView Systems at emergency rooms, trauma and burn centers. These deployments will enable the Company to conduct health economic and outcome research to support the broader clinical adoption of the DeepView System. This grant funding is non-dilutive to our stockholders, and we believe it validates the important nature of our mission and technology.

Significant Wound Data Repository from Artificial Neural Network

As of December 31, 2023, approximately 340 billion pixels of proprietary DFU and burn data have been acquired and utilized for the deep learning algorithms training. This presents a significant barrier to entry to would-be competitors in wound care healing assessments. The data collection to clinical output, the flow, quality and control of the data pipeline is managed entirely by us. Our DeepView System uses deep learning on its wound data repository to recognize patterns and correlations of injured tissue spectral signatures to produce reliable and reasonable assessment for clinicians to make accurate and faster treatment decisions. We believe that our strategic partnerships with various leading medical institutions and healthcare providers in the United States and Europe will enable us to access high quality image data and build the world's leading wound biopsy tissue database. Our AI algorithms are designed and trained to the clinical "ground truth" that has been verified and vetted by various U.S. government agencies and leading clinicians in their respective fields. They have not yet been reviewed or cleared by FDA.

Strategic Partnerships

We have developed strategic partnerships with multiple clinical and academic partners. In the United States, we are currently engaged with leading research hospitals that are enrolling subjects for our Burn AI training study. In the EU and UK, we have partnered with the Royal College of Surgeons Ireland, as well as key opinion leaders to provide us with greater knowledge in the wound care sector. Our partnerships with these institutions provide us with the opportunity to collaborate with leading wound care providers to develop effective early stage wound assessment technology. We utilize these strategic partnerships to support the ongoing clinical validation studies we are using to develop our algorithmic model. Each of our clinical study/trials include certain protocol requirements to ensure a uniform testing process for our technology.

Proven Experienced Management Team

Our board of directors and senior management team have significant experience in the technology and healthcare sectors, with a track record of successful entrepreneurship, operational acumen, strategic relationships and the ability to understand and navigate the complexities of healthcare. Our directors also bring significant expertise from previous public company experience along with financial, governance and technical oversight.

Respected Advisory Board

We have established an Advisory Board composed of industry experts and opinion leaders that will raise our profile. Its members provide us with external, industry-specific perspectives and technical support.

Competition

To our knowledge, no other predictive wound-healing diagnostic imaging technology is available to clinicians who treat wounds. DeepView's competitive advantage is that it is the only AI-enabled wound imaging technology that translates raw physiological data/images into an output that is directly correlated to predictive wound healing.

Several companies have developed wound imaging systems for burn injuries and DFUs; however, these systems incorporate technology such as spatial frequency domain imaging, thermal imaging, photographic documentation, hyperspectral imaging, and near-infrared imaging that provide physiologic data to the physician. Ultimately, this physiologic data appears to only provide an indirect linkage to wound healing and does not display a binary result of "healing vs. non-healing." Furthermore, the majority of systems in the wound care space are merely documentation tools that record measurements of the wound for health record purposes and still rely upon subjective clinician opinion for treatment decisions. The advent of a novel technology such as the DeepView System not only has the potential to disrupt the therapeutic pathway within the wound care market, but also to create a new diagnostic market for wound care that did not exist previously for clinics and physicians, subject to successful development of the device and FDA marketing authorization. As noted above, although our previous DeepView Systems received 510(k) clearance, and we have received FDA BDD clearance for our DeepView GEN 3 System, there can be no assurance that we will be able to obtain market authorization in the US, UK or EU.

Commercialization and Revenue Strategy

We intend to pursue the complete development of our DeepView System and, if marketing authorization is obtained, to commercialize it on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company commercializing products. However, if necessary, we intend to hire appropriately to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our DeepView System.

United States

Subject to our receipt of the necessary regulatory marketing authorization, we intend to market our DeepView System using internal and third party resources to inpatient and outpatient sites of care throughout the United States. Wound Care Centers are typically the first line of specialty care for DFUs in the United States, but vascular and cardiology groups and outpatient podiatry practices also treat wounds. Sales will initially target wound care centers and podiatry practices presiding in areas with high prevalence of diabetes such as the south and southeastern areas of the United States. As noted above, subject to our receipt of the necessary regulatory marketing authorization, our business is expected to have two revenue streams, a SaaS model component predicated on utilizing the regulatory method, SaMD (software as a medical device), and an imaging device component. The SaaS component will feature a software licensing fee that includes maintenance, image hosting, and access to algorithm updates. The capital sale component will be competitively priced for acceptance into independent practices and clinics.

Given our recent receipt of the UKCA mark for our burn indication, commercial sales are expected to commence in 2024 for the burn indication in the UK and in 2025 for DFU indication. In the United States, the Company will continue to perform under its new BARDA contract with respect to the burn indication and will receive significant governmental funding prior to seeking FDA clearance of the DeepView System in late 2025.

Reimbursement

We expect to utilize our post-market clinical evidence and health economic impact analysis to submit to NHS for reimbursement for its Burn indication in the United Kingdom. Upon more market penetration, we will apply for NICE certification. In the United States, we expect the DeepView System will be used in both inpatient and outpatient sites of service. The process of reimbursement varies greatly between the two. The DeepView burn indication will be used both in EDs and Burn Centers. As clinical evidence is developed and utilization increases over the next several years, we plan to apply for CPT^{Ò} codes.

Adoption

We view our DeepView technology as disruptive by nature and there will be those who will be slow to adopt it. This emphasizes the importance of having the right strategic partnerships, institutions, and physician key opinion leaders as early adopters. We plan to engage in relationships that can act as key opinion leaders to share their experience on why they adopted the DeepView technology. The adoption will be supported by a team of field clinical educators and digital marketing campaigns.

Manufacturing Arrangements

We currently outsource all of our manufacturing to a Contract Manufacturer. Cobalt Product Solutions (“Cobalt”), located in Plano, Texas, is involved with manufacturing the current generation DeepView System and we anticipate that they will continue to do so for the foreseeable future.

In addition to Cobalt, we partner with several other highly specialized contract manufacturers in the areas of optics, technology design, and electronics. We employ experienced regulatory and quality control personnel to ensure that our manufacturing processes and quality management systems are in compliance with FDA and EU regulations and standards. As we expand into the European market, we will most likely consider manufacturing devices in the EU in preparation for commercialization. We do not have any plans to develop our own manufacturing facility at this time.

Intellectual Property

We strive to protect and enhance the proprietary technologies that we believe are important to our business by seeking patents to cover our technology. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our technology is protected with issued and/or allowed patents across nine families of active patents:

- Burn/Wound Classification on MSI and PPG;
- Tissue classification on MSI and PPG;
- Amputation site analysis on MSI, ML and healthcare matrix;
- DFU healing potential prediction and wound assessment on MSI, ML and healthcare matrix;

- High-precision, multi-aperture, MSI snapshot imaging;
- Wound assessment based on MSI;
- Burn/histology assessment based on MSI and ML;
- High-precision, single-aperture MSI snapshot imaging; and
- Topological characterization and assessment of tissues using MSI and ML

We have 10 issued and allowed U.S. patents with 5 U.S. patent applications pending. We have 10 issued and allowed international patents with 29 foreign and international patent applications pending.

In addition, we support the development of our brand and product offerings through trademark protection at the United States Patent and Trademark Office. As of December 31, 2023, we maintain a portfolio of 64 trademarks and nine trademark applications pending relating to our DeepView System product offerings. Our trademarks and pending trademark applications are spread over nine jurisdictions mostly in the UK the EU and China. It is our intention to maintain these registrations indefinitely and to expand the number of jurisdictions in which we have registered trademarks as deemed necessary to protect our freedom to use the marks and/or block competitors in additional markets. We will continue to look to protect our intellectual property in the United States, UK and the EU as those are the first commercial markets for our products and rely on third party experts to assist in doing this.

Facilities

Our corporate headquarters is located in Dallas, Texas, where we occupy approximately 11,000 square feet of space under a lease agreement. The lease agreement for our corporate headquarters expires in in December 2024 with an additional three monthly extensions through March 31, 2025.

Human Capital Resources and Employees

We employ a growing and highly skilled employee base, including our sales force, and promote a culture of innovation to continuously iterate and enhance our products, systems and commercial footprint. Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees.

We anticipate the expansion of our business in 2024 as we continue to build a focused and highly skilled team. At December 31, 2023 had 78 full-time employees in the United States and UK. In 2024, we anticipate new hires will be made in all areas, in particular in operations, sales, marketing, and government contracts. This will further enable us to meet our technology, IP, clinical, regulatory, and commercial goals in 2024 and beyond.

We have designed and implemented our cash and stock compensation programs to attract, motivate, and retain our employees. We regularly review our compensation structure to ensure that we remain competitive, reward top performance, and ensure internal equity, while maintaining proper fiscal governance. Our compensation packages are designed based on market benchmarks. We offer robust benefits package including health (medical, dental and vision) insurance, paid time off, paid parental leave, a retirement plan and life and disability coverage.

Business Combination

On September 11, 2023, we consummated the business combination (the "Business Combination") contemplated by that certain Business Combination Agreement, dated as of April 11, 2023, by and among Rosecliff Acquisition Corp I ("RCLF"), Ghost Merger Sub I, Inc. ("Merger Sub I"), Ghost Merger Sub II, LLC ("Merger Sub II"), and Spectral MD Holdings, Ltd. ("Legacy Spectral"), whereby Merger Sub I merged with and into Legacy Spectral (the "First Merger"), with Legacy Spectral surviving the First Merger as a wholly owned subsidiary of RCLF and RCLF changed its name to "Spectral AI, Inc.", and, immediately following the First Merger, Legacy Spectral merged with and into Merger Sub II (the "Second Merger"), with Merger Sub II surviving the Second Merger as a wholly owned subsidiary of RCLF (collectively, the "Merger"). For additional information, please refer to our final prospectus, as amended, on Form S-4, filed with the SEC on August 10, 2023.

Available Information

Our internet address is www.spectral-ai.com. Our website and the information contained therein or linked thereto are not part of this Annual Report. We make available free of charge through our internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, registration statements and amendments to those reports filed or furnished pursuant to the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish them to the SEC. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC. These materials may be obtained electronically by accessing the SEC's website at www.sec.gov.

Item 1.A. Risk Factors.

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described in this prospectus or any prospectus supplement are not the only risks and uncertainties that we face. We may face additional risks and uncertainties that are not presently known to us, or that we currently deem immaterial, which may also impair our business, prospects, financial condition or operating results. The following discussion should be read in conjunction with our financial statements and the financial statements of the Company and notes to the financial statements included herein.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since inception and may not be able to achieve significant revenues or profitability.

We have incurred substantial net losses since our inception. For the year ended December 31, 2023 and the year ended December 31 2022, on a consolidated basis, we incurred a net loss of $20.9 million and $2.9 million, respectively, and on a consolidated basis our cash balance at December 31, 2023 was $4.8 million. We had an accumulated deficit of $32.8 million as of December 31, 2023. Our losses have resulted primarily from costs incurred in connection with our design, manufacturing and development activities, research and development activities, building our commercial infrastructure, legal, and general and administrative expenses associated with our operations.

On September 27, 2023, the Company executed a new contract with BARDA, providing the Company with additional funding of up to $150.0 million, including an initial award of approximately $54.9 million to support the clinical validation and FDA clearance of our DeepView System. The Company will utilize its existing cash balance and the initial award from BARDA for its near-term liquidity and operating needs. The Company believes that it has sufficient cash and revenue from its BARDA contract to support its operations until it is able to obtain equity or debt investments on terms acceptable to the Company to meet its expected operating cash-flow needs for its burn, DFU and other indication research and development.

We do not know whether or when we will become profitable. Our ability to generate revenue and achieve profitability will depend upon our ability, alone or with others, to complete the development of our DeepView System, including receipt of the necessary regulatory clearances, approvals, or classifications and thereafter to successfully commercialize our DeepView System. We may be unable to achieve these goals. We may also encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by medical device companies in rapidly evolving fields. In addition, the Company's ability to develop its DeepView System for multiple indications requires research and development costs that may exceed the Company's current cash balance. The Company may need to seek additional equity or debt investments to meet its projected operating costs for the timely development of the DeepView System. To the extent additional capital is necessary, there are no assurances that we will be able to raise additional capital on favorable terms or at all, and therefore we may not be able to execute our business plan. In addition, as a U.S. public company, we incur significant legal, accounting and other expenses. Accordingly, we expect to continue to incur significant operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance the capital requirements needed to operate our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations, and cause the market price of our common stock to decline.

We are devoting a significant portion of our efforts towards research and development of our DeepView System.

Our business, prospects, results of operations and financial condition depend upon our ability, alone or with others, to complete the development of our DeepView System, including receipt of the necessary regulatory clearances, approvals, or classifications and thereafter to successfully commercialize our DeepView System. In addition, though we are currently focused on the DFU and burn applications for DeepView, there are other pipeline applications that we are considering for future commercialization. However, we may be unable to achieve these goals. Approval or clearance from the FDA and comparable regulatory bodies may never be obtained. We also may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by medical device companies in rapidly evolving fields. Our failure to receive the necessary approvals and clearances and to successfully commercialize our DeepView System would have a material adverse effect on our business, prospects, results of operations and financial condition.

Further, our business plan and pipeline depend on, and, as further described below, funding under many of our existing contracts depend on, and future contracts may also depend on, our ability to meet certain milestones or achieve certain timelines with our applications and indications. Our ability to achieve these depends on numerous factors, including the factors described in this "*Risk Factors*" section, many of which may not be within our control. Our inability to achieve our milestones and timelines could have a material adverse impact on our business, prospects, results of operations and financial condition.

We depend on government funding, which if lost or reduced, could have a material adverse effect on our research and development activities and our ability to commercialize our DeepView technology. Our largest contract is with BARDA and is the largest single source of revenue for us. Our BARDA contract is not guaranteed to be extended.

We have not made any commercial sales of our DeepView System. We receive almost all of our revenue from fees and costs payable by BARDA, and to a lesser extent the Defense Health Agency ("DHA") of the United States Department of Defense. We currently have agreements with each of BARDA and the DHA to support continued development of the next generation of our DeepView technology. While we believe we have very good working relationships with BARDA and DHA, the loss of one or both of our contracts with BARDA and DHA would have an adverse impact on our business, prospects, results of operations and financial condition. While we expect diversification of customers in future years, assuming we are able to obtain the necessary regulatory clearances, approvals, De Novo classifications, or certifications (each of which cannot be guaranteed and may take longer than planned) to commercialize our product, for the time being we are substantially dependent on funding from BARDA and DHA.

Our BARDA contract is the largest single source of revenue for us. On September 27, 2023, the Company executed a new contract with BARDA, providing the Company with additional funding of up to $150.0 million, including an initial award of approximately $54.9 million to support the clinical validation and FDA clearance of our DeepView System, in place of the prior contract Option 2 award which was approximately $21.9 million. The contract also includes options, similar to our prior BARDA contracts, with an additional total value of approximately $95.1 million which can be exercised for additional product development, procurement and the expanded deployment of DeepView Systems at emergency rooms, trauma and burn centers. While we currently have no reason to believe that we will fail to achieve these contract milestones and decision gates or that these further options will not be exercised, and while the BARDA contract has been renewed or extended historically, there is no guarantee that the BARDA contract will be renewed or extended in the future, and there are no assurances that we will achieve the contract milestones and decision gates on a timely basis, or at all. As the BARDA contract is significant to us and is our largest single source of revenue, a decision by BARDA not to exercise further options would have a material adverse impact on our business, prospects, results of operations and financial condition.

Under the terms of the BARDA contract, the U.S. government has the right to terminate the contract for convenience or to terminate for default if we fail to meet our obligations as set forth in the contract. While the government has a right to terminate the BARDA contract for convenience, we believe that the government generally does not terminate funding awards unless there is reason, such as the funding contract becomes too costly, the agency seeks to avoid a dispute with another branch of government, or the agency decides to restructure its contractual arrangements and perform work in-house. We believe it is unlikely that BARDA will terminate its contract with us. However, there can be no guarantee that the BARDA contract will not be terminated.

If BARDA were to terminate its contract with us, we may be entitled to settlement costs for payment for work already performed, but not yet paid, including costs incurred in anticipation of performance, and costs arising from termination and settling the termination, for example. However, as the BARDA contract is critical to our business at this time, non-extension or termination of the BARDA contract would have a material adverse impact on our business, prospects, results of operations and financial condition.

We received a contract from the DHA within the U.S. Department of Defense, which enables us to research and develop a fully portable, handheld version of our DeepView solution and has been extended through the first quarter of 2024. We were previously awarded a $1.1 million, Sequential Phase II STTR contract by the DHA within the U.S. Department of Defense, which is paid to us monthly, as well as a STTR Phase I and initial Phase II contract from the DHA.

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 current period or that we will be offered a Phase III contract. As this contract is a key contract for the Company, non-extension of the contract, or a failure to enter into a new contract, could have a material adverse impact on the Company's business, prospects, results of operations and financial condition. Under the terms of the DHA contract, the U.S. government has the right to terminate the contract for convenience or to terminate for default if we fail to meet our obligations as set forth in the contract.

We also are party to a Research Project Award agreement with the Advanced Technology International as Consortium Manager for MTEC. This agreement extends the DHA Phase II contract for the development of the handheld device of the DeepView System. Under the terms of this agreement, MTEC will pay us a firm fixed fee based upon our achievement of certain milestones (such as development of the image technology in the handheld device, validation of the design and development of a handheld device from the current cart based system, completion of verification testing builds, and development of commercialization plan) through April 5, 2025. However, there are no assurances that we will achieve the contract milestones on a timely basis, or at all. Failure to receive the fee under the contract could have a material adverse impact on the Company's business, prospects, results of operations and financial condition.

We may need additional funding to finance our planned operations, and may not be able to raise capital when needed, which could force us to delay clinical trials necessary to market our products or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products.

On December 26, 2023, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with B. Riley Principal Capital II, LLC ("B. Riley"), pursuant to which, upon the terms and subject to the satisfaction of the conditions contained in the Purchase Agreement, the Company have the right to sell to B. Riley up to $10,000,000 of shares of the Common Stock (subject to certain limitations contained in the Purchase Agreement), from time to time during the term of the Purchase Agreement. Additionally, On March 20, 2024, the Company entered into the Standby Equity Purchase Agreement ("SEPA") with YA II PN, LTD, a Cayman Islands exempt limited partnership ("Yorkville") pursuant to which the Company has the right to sell to Yorkville up to $30,000,000 of its shares of Common Stock, subject to certain limitations and conditions set forth in the SEPA, from time to time during the term of the SEPA (such transaction, the "Yorkville Transaction"). In connection with the SEPA, and subject to the conditions set forth therein, Yorkville has agreed to advance to the Company in the form of convertible promissory notes (the "Convertible Notes") an aggregate principal amount of up to $12,500,000 (the "Pre-Paid Advance"), which will be paid in three tranches.

Based on our current operating plan, we believe that our cash and cash equivalents, together with the remaining funding available to us under the Purchase Agreement, the BARDA contract, the MTEC Agreement, and the Yorkville financing will be sufficient to meet our capital requirements and fund our operations through at least the next 12 months from the release date of the consolidated financial statements included in this annual report. However, we have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to raise capital sooner or in greater amounts than currently expected because of circumstances beyond our control.

We may require additional capital in the future to fund our operating expenses and to further our product development efforts, including seeking the necessary regulatory clearances, approvals, De Novo classifications, or certifications (each which cannot be guaranteed and may take longer than planned) for our DeepView System and growing our sales and marketing organization. To the extent additional capital is necessary, there are no assurances that we will be able to raise additional capital on favorable terms or at all, and therefore we may not be able to execute our business plan. Our future funding requirements will depend on many factors, including:

- the cost of our research and development activities;
- the scope, rate of progress and cost of our clinical studies;
- the cost and timing of additional regulatory clearances, approvals, De Novo classifications, or certifications;
- the degree and rate of market acceptance of our DeepView System, assuming we receive the necessary regulatory clearances, approvals, De Novo classifications, or certifications (each of which cannot be guaranteed and may take longer than planned);
- the scope and timing of investment in our sales force and expansion of our commercial organization;
- the costs associated with manufacturing our DeepView System at increased production levels;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs associated with any product recall that may occur;
- the costs of attaining, defending and enforcing our intellectual property rights;
- the emergence of competing new products or technologies or other adverse market developments; and
- the impact on our business from the global COVID-19 pandemic or any other pandemic, epidemic or outbreak of an infectious disease.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline, and the price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain rights related to our products or technologies that we otherwise would seek to develop or commercialize ourselves. In addition, we may be forced to work with a partner, which could lower the economic value of our programs to us.

If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may be required to terminate or delay the development of our DeepView technology or any future products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Product Development and Regulatory Review

The regulatory review process is expensive, time-consuming, and uncertain and we may be unable to obtain clearance, approval, De Novo classification, or certification for our DeepView technology.

The research, design, testing, manufacturing, labeling, selling, marketing and distribution of medical devices are subject to extensive regulation by country-specific regulatory authorities, which regulations differ from country to country.

There is no guarantee that our DeepView System or any future products will receive the requisite market authorization, approval, or De Novo classification for clinical testing, manufacturing, or marketing. While preliminary results have been encouraging and indicative of the potential performance of our DeepView System, data already obtained, or obtained in the future, from clinical studies do not necessarily predict the results that will be obtained from later clinical studies. We will be required to incur significant costs in obtaining market authorization, or De Novo classifications for our DeepView System.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive 510(k) clearance, approval of a pre-market approval application ("PMA") or be granted De Novo classification pursuant to the Federal Food, Drug, and Cosmetic Act (the "FDCA"), unless an exemption applies. Oftentimes the length of the time and expense are prohibitively long and high, respectively, and it may be impractical or impossible to pursue the PMA regulatory route should our De Novo request be denied.

In order to sell our device in member states of the European Union ("EU"), the device must also comply with the general safety and performance requirements of the EU Medical Devices Regulation (Regulation (EU) No 2017/745). Compliance with these requirements is a prerequisite to be able to affix the CE mark to our device, without which it cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and — where applicable — other persons; *provided* that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

In the United Kingdom ("UK"), post-Brexit, medical devices are regulated under the Medical Devices Regulations 2002 ("MDR 2002"), which implement the three EU Medical Devices Directives into UK law. The UK decided it would not give effect to the EU Medical Devices Regulation. Instead, the UK government and the Medical Devices and Healthcare Regulatory Authority ("MHRA") are currently considering amending the UK MDR. The device must comply with the MDR 2022 and any future UK MDR amendment in order to be sold of marketed in the UK.

Furthermore, market authorization, approval, De Novo classification, or certification by any regulatory authority does not ensure marketing authorization or similar registration, clearance, approval, or certification by regulatory authorities in other countries. However, failure to obtain or delay in obtaining authorization, registration, clearance, approval, or certification in one or more regulatory jurisdictions may have a negative effect on the regulatory process in others.

We may experience significant delays in completing clinical trials, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.

The completion of any clinical trials of our DeepView System, or other studies that we may be required to undertake in the future, could be delayed, suspended or terminated for several reasons, including:

- we may fail to or be unable to conduct the clinical trials in accordance with regulatory requirements;
- selection and onboarding of clinical sites or a Contract Research Organization ("CRO") may take longer than anticipated;
- sites participating in a clinical trial may drop out of the trial, which may require us to engage new sites for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not enroll in, remain in or complete, clinical trials at the rates we expect;
- adverse events or unexpected developments may occur that affect the patients' safety;
- supply issues may prevent us from continuing to use our investigational devices in clinical evaluations; and
- clinical investigators may not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices.

In addition, the FDA, applicable foreign regulatory entities or notified body can delay, limit or deny clearance, approval, De Novo classification, with regards to the US, or certification of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are (i) substantially equivalent, in the case of a 510(k) clearance, (ii) safe or effective for their intended uses, in the case of a PMA, or (iii) that general controls alone or general and special controls together provide reasonable assurance of safety and effectiveness for the intended use, in the case of De Novo classification;

- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials (including, for purposes of the EU, clinical investigations) or the interpretation of data from pre-clinical studies or clinical trials, as applicable and to the extent required to support marketing authorization or certification;

- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;

- the manufacturing process or facilities we use may not meet applicable requirements;

- unanticipated discovery of issues that relate to safety or effectiveness of the device during or after the regulatory review process; and

- the potential for policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data, as applicable, and/or regulatory filings insufficient for market authorization, De Novo classification, or certification.

If our clinical trials are delayed, it will take us longer to ultimately launch our DeepView System in the market and generate revenues. Moreover, our development costs will increase if we have material delays in our clinical trials or if we need to perform more or larger clinical trials than planned.

If the third parties on which we rely to conduct our clinical trials, to assist us with pre-clinical development or to prepare our regulatory submissions do not perform as contractually required or expected, we may not be able to obtain market authorization, De Novo classification, certification or other required regulatory authorizations or certifications to commercialize our products.

We do not have the ability to independently conduct all of our pre-clinical and clinical trials for our DeepView System and to prepare the associated regulatory submissions without the participation of third-party research hospitals, burn and wound centers. We must rely on third parties such as CROs, medical institutions and clinical investigators to conduct such trials. If these third parties do not successfully carry-out their contractual duties or comply with regulatory obligations, including compliance with Good Clinical Practice ("GCP") requirements or meet expected deadlines, if these third parties need to be replaced, if the quality or accuracy of the data they obtain is compromised due to a failure to adhere to our clinical protocols or regulatory requirements or for other reasons, or if the prepared regulatory submission does not meet the regulatory agencies' expectations or requirements, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control, including the COVID-19 pandemic, or another pandemic, epidemic or outbreak of an infectious disease. In the event of such extensions, delays, suspensions or terminations, we may not be able to obtain market authorization, De Novo classification, certification or other required regulatory authorizations or certifications for, or successfully commercialize, our DeepView System on a timely basis, if at all, and our business, financial condition and results of operations may be adversely affected.

New legislation and regulations and legislative and regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance, approval, De Novo classification, or certification of our DeepView System, or to manufacture, market and distribute our device after clearance, approval, or classification is obtained.

From time to time, legislation is drafted and introduced in the legislative bodies of the countries in which we intend to sell our DeepView System, assuming we receive the necessary market authorization. In addition, regulations and guidance are often revised or reinterpreted by the applicable competent authority in ways that may significantly affect our business and our products. For example, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

The FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business. Any new statutes or regulations or revisions or reinterpretations of existing statutes or regulations may impose additional costs or lengthen review times or make it more difficult to obtain market authorization for our DeepView System. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business. Such changes could, among other things, require: additional testing prior to obtaining marketing authorization; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance, approval, or De Novo classification of our DeepView System. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance, approval, or De Novo classification that we may have obtained and we may not achieve or sustain profitability.

In addition, the landscape concerning medical devices in the EU has evolved in recent years.

In the United Kingdom ("UK"), post-Brexit, medical devices are regulated under the Medical Devices Regulations 2002 ("MDR 2002"), which implement the three EU Medical Devices Directives into UK law. The UK decided it would not give effect to the EU Medical Devices Regulation. Instead, the UK government and the Medical Devices and Healthcare Regulatory Authority ("MHRA") are currently considering amending the UK MDR. This new regulatory framework for medical devices in the UK is expected to become applicable as from July 2024. It is not clear to what extent the future UK regulatory framework will align with the EU Medical Devices Regulation, which may lead to duplicative or divergent requirements.

Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products or limit our ability to sell to clinicians. It is impossible to predict whether legislative changes will be enacted or if regulations, guidance or interpretations will change and what the impact of such changes, if any, may be.

Disruptions at the FDA and foreign regulatory agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA, foreign regulatory agencies and the notified body, to review and clear, approve, certify, or grant De Novo classifications for new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at these organizations have fluctuated in recent years as a result. In addition, government funding of other government agencies that oversee clearances and approvals and that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at these agencies and bodies may slow the time necessary for new devices to be reviewed and/or cleared, approved or certified, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. It is possible that new COVID-19 variants or a new public health emergency will emerge in the future, further interrupting and affecting the agency's ability to carry out inspections in a timely manner. In such cases, regulatory authorities and certification bodies outside the United States may adopt similar restrictions, inspection priorities, or other policy measures in response to the COVID-19 or any other public health emergency or revert to relying on remote interactive evaluations, record requests or information from trusted regulatory partners if on-site inspections are not feasible.

In addition, the FDA reallocated its personnel and resources during the COVID-19 pandemic, including for reviewing applications for emergency use authorizations for certain medical devices that may be helpful in responding to the pandemic. If a prolonged government shutdown occurs in the future, or if future global health concerns prevent the FDA, and other foreign regulatory authorities and certification bodies from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, and other regulatory authorities and certification bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. While several notified bodies have been designated, the COVID-19 pandemic significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation, resulting in longer notified body review times. This situation could impact our ability to grow our business in the EU and EEA.

The ongoing labor shortage may limit our ability or the investigators' ability to find and retain medical staff that are needed to conduct the clinical studies

The COVID-19 pandemic has caused and, there still remains an ongoing shortage of labor force, including nurses, doctors, clinicians, and other medical personnel despite the changing economic and financial conditions. This shortage is causing medical institutions and other establishments to change their operations to accommodate the shortage, and in many cases, it results in increased personnel costs in finding and retaining the staff necessary to conduct the institutions' and establishments' operations. If the ongoing shortage continues or becomes worse, our ability to conduct clinical trials may be negatively affected, and we may need to modify or stop clinical trials, or expend greater resources in identifying and retaining the appropriate personnel necessary for the clinical investigations.

Risks Related to Ongoing Government Regulation

Even if we receive market authorization, or even if the FDA grants our De Novo classification request, we will continue to be subject to extensive ongoing regulation. If we fail to maintain necessary clearances, approvals, classifications, or certifications from the FDA, other applicable foreign regulatory authorities and notified bodies; or if there are state, federal or international level regulatory changes, our commercial operations could be harmed.

If the FDA grants our market authorization or grants the De Novo classification for our DeepView technology, our technology will be subject to extensive ongoing regulation in the United States by the FDA and by corresponding state regulatory agencies and authorities. It will also be subject to extensive regulation by EU institutions as well as EU member states' regulatory authorities and notified bodies and the regulatory bodies of any other countries in which we receive the necessary regulatory approvals. These regulations pertain to the design, development, evaluation, manufacturing, testing, labeling, marketing, sale, advertising, promotion, distribution, shipping and servicing of products. These entities regulate and oversee record-keeping procedures, safety alerts, recalls, market withdrawals, removals and field corrective actions, post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to reoccur, could lead to death or serious injury, and product import and export.

The regulations to which we will be subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. Such regulations, and interpretations thereof, may limit our ability to market or prevent us from marketing our products. Further, the FDA, foreign regulatory agencies and U.S. state agencies have broad enforcement powers, and our failure to comply with state, federal and international regulations could lead to enforcement actions such as warning letters or untitled letters; the imposition of injunctions, suspensions or loss of regulatory clearance or approvals; product recalls; safety alerts; termination of distribution; product seizures; consent decrees; civil penalties; or import detentions, import refusals, or import alerts. In the most extreme cases, criminal sanctions, administrative sanctions (e.g., seizure), injunctions, or closure of our manufacturing facilities are possible.

Even after clearance, approval, or De Novo classification, under the FDCA and FDA regulations, the scope of marketing claims we can make about cleared or approved devices, or devices that were granted De Novo classification is limited to the indications that were previously reviewed and permitted by the FDA. Other countries also have similar laws and regulations restricting marketing to such indications. If a regulatory agency determines that any of our marketing claims exceed the scope of permitted indications in a particular country, we may be subject to enforcement action and/or we may be required to cease making the challenged marketing claims, issue corrective communications, pay fines or stop selling products until the incorrect claims have been corrected.

Sales of our DeepView System outside the United States, if approved, will be subject to foreign regulatory requirements that vary widely from country to country, and such regulatory requirements have been changing and increasing in some countries. Complying with international regulatory requirements can be an expensive and time-consuming process. We may be unable to obtain or maintain regulatory clearances, approvals, De Novo classifications, or certifications in these countries. We may incur significant costs in attempting to obtain, renew, or modify foreign regulatory clearances or approvals, De Novo classifications, or certifications. If we experience difficulties in receiving, maintaining, renewing or modifying necessary clearances, approvals, De Novo classifications, or certifications to market our products outside the United States, or if we fail to receive, renew, modify or maintain those clearances, approvals, De Novo classifications, or certifications, we may be unable to market our products or enhancements in certain international markets effectively, or at all.

Modifications to our DeepView GEN 3 System may require new clearances, approvals, De Novo classifications, certifications, or new or amended certifications, and may require us to cease marketing or to recall the modified device until clearances, approvals, De Novo classifications, or the relevant certifications are obtained.

In the United States, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance, or depending on the type and extent of the modification, a De Novo classification or a PMA. If we wish to market modified versions of DeepView System, we will need to make this determination before doing so and document our conclusion regarding the necessity of further regulatory review. The FDA may review such determinations and may not agree with our decisions regarding whether new 510(k), PMA, or De Novo classifications are necessary. If we are found to be marketing our products for off-label uses or indications for use that have not received the requisite clearances, approvals, De Novo classifications, or certifications, we might become subject to FDA and other competent authorities' enforcement action or have other resulting liability. In addition, if the FDA or the competent authorities in the EU member states and EEA countries determine that our promotional materials or training constitute promotion of a use which is unapproved, not cleared, not covered by the De Novo classification order, not covered by a CE mark, or not in compliance with other regulatory authorities' requirements, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, an injunction, product seizures, consent decrees, civil fines, criminal penalties, import detention, import refusals, or import alerts.

If our DeepView System is found to cause or contribute to adverse medical events, this could interrupt, delay, or prevent its continued development, or negatively affect the market authorization, De Novo classification, or certification. We may be required to report them to the FDA or comparable regulatory authority, and if we fail to do so, we could be subject to sanctions that could harm our reputation, business, financial condition and results of operations, and become subject to further administrative and regulatory enforcement actions. The discovery of serious safety issues with our DeepView System, or a recall of our device either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

If our DeepView System is approved for commercialization, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA or comparable regulatory authorities when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. For investigational devices in clinical evaluation, investigators are required to submit a report of an unanticipated adverse device effect ("UADE") to the sponsor within 10 working days after becoming aware of the UADE. We, as the sponsor, must evaluate the UADE and report the result of the investigation to FDA, institutional review boards, and all participating investigators within 10 working days of receiving the notice of the UADE. In certain cases, we may be required to terminate the clinical investigation. The timing of our obligation to report is triggered by the date when we receive the notice or when we otherwise become aware of the event, as well as the nature of the event. We may fail to report within the prescribed timeframe events of which we become aware. The investigator in the clinical evaluation may not be aware of the reporting or notification requirements or may otherwise fail to report a UADE. We may also fail to recognize that a reportable event has occurred, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or comparable regulatory authorities could act, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, delay or termination of clinical investigations, revocation of our marketing authorizations, seizure of our products or delay in obtaining marketing authorizations or certifications for our product candidates.

The FDA and in certain cases, equivalent foreign regulatory bodies, have the authority to require the recall of products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if we determine that such reasonable probability exists, or otherwise, if any material deficiency is found. Such recalls, whether government-mandated or voluntary, could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. In addition, for investigational devices in development, non-compliance with the above or related requirements may have a negative effect on our application process, and the FDA or other foreign regulatory bodies may delay or refuse to clear, approve, issue the De Novo classification request, or issue a certification for our device.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or foreign regulatory authorities or bodies may require, or we may decide, that we need to obtain new clearances, approvals, De Novo classifications, or certifications for the device before we may market or distribute the corrected device. Seeking such clearances, approvals, De Novo classifications, or certifications may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA or foreign regulatory bodies' warning letters, product seizures, injunctions, administrative penalties or civil or criminal fines.

Quality problems and product liability claims could lead to recalls or safety alerts, reputational harm, adverse verdicts or costly settlements, and could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Quality is extremely important to us and our customers due to the impact on patients, and the serious and potentially costly consequences of product failure. Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical devices. Once commercialized, many of our products will be used in settings with seriously ill patients where the devices' failure may cause serious adverse effects on the patients. Component failures, manufacturing non-conformances, design defects, off-label or unapproved use, insufficient training of healthcare professionals, or inadequate disclosure of product-related risks or product-related information with respect to our products, if they were to occur, could result in an unsafe condition or injury to a patient. These problems could lead to recall of, or issuance of a safety alert relating to, our products, and could result in product liability claims and lawsuits, including class actions. If such problems occur during clinical investigations, FDA or other foreign regulatory agencies may refuse to grant market authorization or a De Novo classification request, or issue certifications for our products. In addition, negative publicity resulting from such problems may negatively affect or seriously hinder the sales of our products even after market authorization, De Novo classification, or certification. Any of the foregoing problems, including future product liability claims or recalls, regardless of their ultimate outcome, could harm our reputation and have a material adverse effect on our business, results of operations, financial condition and cash flows.

The FDA and other regulatory enforcement agencies actively enforce the laws and regulations prohibiting the promotion of off-label or unapproved uses. If we are found to have improperly promoted off-label or unapproved uses, we may become subject to significant liability.

If we decide to market any of our products, our marketing practices must stay within the scope of the permitted claims under the market authorization or De Novo classification order that we may receive in the future. The FDA and other regulatory enforcement agencies strictly regulate the promotional claims that may be made about medical devices. While we cannot restrict or dictate the healthcare professionals' use of our devices, we cannot market for any off-label uses, or any uses that FDA has not reviewed and permitted. The use of the DeepView System for indications other than those for which FDA cleared, approved, or granted De Novo classification requests, or otherwise were certified by a notified body or foreign regulatory enforcement authority, may not effectively diagnose conditions not referenced in product indications, which could harm our reputation in the marketplace among clinicians. If we are found to have promoted such off-label uses or unapproved uses, we may become subject to significant government fines and other related liability. For example, if the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine, or criminal penalties, among others. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion or promotion of unapproved uses. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, clinicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to misdiagnosis, injury, and an increased risk of product liability. If our device is misused or used with improper technique, we may become subject to costly litigation by clinicians or their patients. Even if we ultimately prevail, product liability claims could divert management's attention from our core business and be expensive to defend. If we do not prevail, such claims may result in sizeable damages awards against us that may not be covered by insurance.

We must comply with anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations.

If our DeepView System is approved for commercialization, our future operations will be subject to various federal and state healthcare laws and regulations. These laws will affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may develop with hospitals, clinicians or other potential purchasers or users of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws will influence, among other things, how we structure our sales, placement and rental offerings, including discount practices, clinician support, education and training programs and clinician consulting and other service arrangements. The laws that may affect our practices and arrangements include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of, or a specific intent to violate, the law. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly, and there is no exception or safe harbor for many common business activities. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability;

- the U.S. federal civil False Claims Act, which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds; knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. In addition, any claims submitted as a result of a violation of the federal Anti-Kickback Statute constitute false claims and are subject to enforcement under the False Claims Act. Actions under the False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government and to share in any monetary recovery. Qui tam actions are filed under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties (adjusted annually for inflation) per false claim or statement for violations. Because of the potential for large monetary exposure, healthcare companies often resolve allegations without admissions of liability for significant and sometimes large settlement amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Many device manufacturers have resolved investigations of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non reimbursable uses, and other interactions with prescribers and others including those that may have affected their billing or coding practices and submission to the federal government. Moreover, to avoid the risk of exclusion from federal healthcare programs as a result of a False Claims Act settlement, companies may enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim or statement to the federal government;

- criminal healthcare statutes that were added by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations, which impose criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate them in order to have committed a violation;

- the Eliminating Kickbacks in Recovery Act ("EKRA"), 18 U.S.C. § 220, makes it a federal crime for anyone, with respect to services covered by a health care benefit program, to knowingly and willfully solicit or receive any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or to pay or offer any remuneration to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory. EKRA applies more broadly than the federal Anti-Kickback Statute, as "health care benefit program" includes not only state and federal health care programs, but also private health plans. EKRA also has fewer statutory safe harbors and no regulatory state harbors. Violations of this provision may result in substantial fines and/or imprisonment. Additional violations that may be imposed include sanctions, licensure revocations, or the exclusion from participating in governmental healthcare programs;

- the Physician Payments Sunshine Act (the "Sunshine Act") and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning January 1, 2022, manufacturers will also be required to report payments and other transfers of value made during the prior calendar year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and anesthesiology assistants; and

- foreign and state laws and regulations, including state payment reporting, anti-kickback and false claims laws, that may apply to items or services reimbursed by any third-party payor, including private insurers; foreign and state laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government and other national governments, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and foreign and state laws and regulations that require drug and device manufacturers to report information related to payments and other transfers of value to dental practitioners and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The scope and enforcement of these laws is substantial and subject to rapid change. The shifting compliance environment and the need to build and maintain robust compliance programs, systems, and processes to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that we may run afoul of one or more of the requirements or that federal or state regulatory authorities might challenge our current or future activities under these laws. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our future activities could be subject to challenge under one or more of such laws. Any government investigation, even if we are able to successfully defend against it, will require the expenditure of significant resources, is likely to generate negative publicity, harm our reputation and potentially our financial condition and divert the attention of our management. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time-consuming response. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment of individuals, exclusion from government funded healthcare programs, such as Medicare and Medicaid, imposition of compliance obligations and monitoring, and the curtailment or restructuring of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare reform measures could hinder or prevent the commercial success of our DeepView System.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may harm our future revenues and profitability and the demand for our DeepView System, if it receives the necessary market authorization. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative and regulatory proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our DeepView System. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our DeepView System.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our DeepView System;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

We cannot predict what other laws and regulations will ultimately be enacted and implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition, prospects and results of operations. Future changes in healthcare policy could increase our costs and subject us to additional requirements that may interrupt commercialization of our current and future solutions, decrease our revenue and impact sales of and pricing for our current and future products.

If our manufacturers fail to comply with the regulatory quality system regulations or any applicable equivalent regulations, our proposed operations could be interrupted, and our operating results would suffer.

We currently outsource all of our manufacturing to a contract manufacturer and as such we are not in direct control of the manufacture of our products and are, therefore, exposed to the risk of poor product quality, non-adherence to applicable standards, disruptions in supply chain, or other matters.

Our third-party manufacturers and suppliers will be required, to the extent of applicable regulation, to follow the quality system regulations of each jurisdiction in which we will seek to market our products and also will be subject to the regulations of these jurisdictions regarding the manufacturing processes. If our manufacturers or suppliers are found to be in significant non-compliance or fail to take satisfactory corrective action in response to adverse regulatory findings in this regard, regulatory agencies could take enforcement actions against such manufacturers or suppliers, which could impair or prevent our ability to produce our products in a cost-effective and timely manner in order to meet customers' demands. Accordingly, our operating results would suffer.

In order to mitigate these risks, we perform regularly scheduled visits with our contract manufacturer and routinely inspect the quality and performance of the device in accordance with federally mandated standards and certification standards of the International Organization for Standardization ("ISO"). Our current contract manufacturer, Cobalt Product Solutions is located within a short driving distance from our headquarters and allows our employees to have hands-on interaction and timely inspections of the device. However, a future pandemic, epidemic or other infectious disease outbreak could hinder or prevent continued hands-on and timely inspections of the device and the facilities.

Actual or perceived failure to comply with data protection, privacy and security laws, regulations, standards and other requirements could negatively affect our business, financial condition or results of operations.

We may be subject to federal, state, and foreign data protection laws and regulations (*i.e.*, laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws, and consumer protection laws and regulations that govern the collection, processing, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and the regulations implemented thereunder, or collectively, HIPAA, imposes obligations on "covered entities," including certain health care providers, health plans, and health care clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information ("PHI") for or on behalf of a covered entity, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Entities that are found to be in violation of HIPAA, whether as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by HHS may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission (the "FTC"), failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation.

Foreign data protection laws, including the General Data Protection Regulation (the "GDPR"), which went into effect in May 2018, may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out. The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area (the "EEA"). The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect, process, and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA countries governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions involve the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA to jurisdictions deemed to have inadequate, security breach notifications and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. If necessary, we will be required to implement revised standard contractual clauses, in relation to relevant existing contracts and certain additional contracts and arrangements, within the relevant time frames. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR.

Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR (e.g., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover). The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and remains under review by the Commission during this period. The relationship between the UK and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure.

Implementing mechanisms that endeavor to ensure compliance with the GDPR and relevant local legislation in EEA countries and the UK, if necessary, may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, prospects and results of operations. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Compliance with applicable US and foreign data protection, privacy and security laws, regulations and standards could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can also be subject to varying interpretations. Any failure or perceived failure to comply could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity, and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Our employees, collaborators, independent contractors and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these persons could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA requirements, including those laws requiring the reporting of true, complete and accurate information to the FDA authorities, such as reporting of UADEs during clinical investigations;
- GCP that relate to clinical investigations, including financial disclosure, informed consent and protection of human subjects, and requirements that relate to investigational device exemptions;
- manufacturing standards, such as FDA's Quality System Regulation ("QSR") requirements;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an FDA debarment or exclusion by OIG could result in penalties, a loss of business from third parties, and severe reputational harm.

It is not always possible to identify and deter misconduct by our employees and other agents, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties; treble damages; monetary fines; disgorgement; imprisonment; possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs; contractual damages; reputational harm; diminished profits and future earnings; additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws; and curtailment of our operations.

As the regulatory framework for AI technology evolves, our business, financial condition and results of operation may be adversely affected.

We utilize artificial intelligence, including machine learning, in our predictive analytics platforms. In recent years, the use of AI has come under increased regulatory scrutiny. The regulatory framework for AI technology is evolving and remains uncertain. It is possible that new laws and regulations will be adopted in the United States and in non-U.S. jurisdictions, where we intend to do business subject to our receipt of the necessary market authorizations, or that existing laws and regulations may be interpreted in new ways that would affect our operations and the ways in which we may use our AI technology. Specifically, such laws and regulations may limit our ability to use our AI models or require us to make changes to our technology that may decrease our operational efficiency, result in an increase to operating costs, or hinder our ability to provide our services. Further, the cost to comply with such laws, rules or regulations could be significant and would increase our operating expenses, which could adversely affect our business, financial condition and results of operation.

Any failure or perceived failure by us to comply with AI technology-related laws, rules and regulations could result in proceedings or actions against us by individuals, consumer rights groups, government agencies or others. We could incur significant costs in investigating and defending such claims and, if found liable, pay significant damages or fines or be required to make changes to our technology and business. Further, any such proceedings and any subsequent adverse outcomes may subject us to significant negative publicity. If any of these events were to occur, our business, results of operations and financial condition could be materially adversely affected.

We must comply with environmental and occupational safety laws.

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to federal, state and local laws, as well as the laws of foreign countries, governing the use, handling and disposal of these materials. In the event of an accident or failure to comply with environmental or occupational safety laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage.

Risks Related to the Commercialization of our DeepView System

If approved, the commercial success of our DeepView System will depend upon the degree of market acceptance by clinicians.

Even if we receive the necessary regulatory approvals for commercialization, there is a risk that our DeepView System will not be accepted over competing products and that we will be unable to enter the marketplace or compete effectively. If the market for our DeepView System fails to develop or develops more slowly than expected, our business and operating results would be materially and adversely affected.

We believe that our DeepView System will allow clinicians to make more accurate and efficient treatment decisions in the wound care sector. Whether clinicians choose to use our device over other market alternatives, however, is likely to be based on a determination that, among other things, our system is effective, safe, cost-effective and represents an acceptable method of diagnosis. Even if we can prove the effectiveness of our DeepView System through clinical trials, there may not be broad adoption and use of our device and clinicians may elect not to use our DeepView System for any number of reasons, including:

- lack of experience with our DeepView System and concerns that we are new to market;
- perceived liability risk generally associated with the use of our device;
- lack or perceived lack of (i) sufficient clinical evidence regarding our claims of superior diagnostic assessment and (ii) long-term data, supporting clinical benefits or the cost-effectiveness of our device over existing diagnostic alternatives;
- the failure of key opinion leaders to provide recommendations regarding our device, or to assure clinicians and healthcare payors of the benefits of our device as an attractive alternative to other diagnostic options;
- long-standing relationships with companies and distributors that sell other diagnostic products for wound care assessment;
- concerns over the capital investment required to purchase our DeepView System and perform the DeepView procedure;
- lack of availability of adequate third-party payor coverage or reimbursement;
- competitive response and negative selling efforts from providers of alternative technologies;
- failure to obtain favorable coverage decisions from payors, including, but not limited to, Medicare or Medicaid; and
- limitations or warnings contained in the labeling cleared or approved by the FDA, if approved, or approved or certified by other authorities or bodies.

We believe that educating notable industry key opinion leaders and clinicians about the merits and benefits of our DeepView System, including safety, performance, ease of use and efficiency will be critical for increasing the adoption of our device. Widespread adoption of new medical device technologies typically follows early adoption and promotion by key opinion and thought leaders in the relevant sectors. We have taken steps to address this by establishing strong relationships with leading U.S. hospitals around the country. The Company has enrolled subjects in its DFU studies in clinical and academic sites across the US and the EU across well-known medical facilities. The Company has also signed with international partners, including well-respected institutions in the field. We believe that we will be able to leverage these relationships to access other institutions and individuals, which should increase awareness and early adoption of our technology in the United States, UK and EU. U.S. adoption will also benefit from the potential future BARDA funding of technology placement for burns applications.

If clinicians do not adopt our DeepView System for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and it will negatively affect our business, financial condition, prospects and results of operations. Even if our DeepView System achieves widespread market acceptance, it may not maintain such level of market acceptance over the long term if competing products or technologies, which are more cost-effective or received more favorably, are introduced. In addition, our limited commercialization experience makes it difficult to evaluate our current business and predict our future prospects. We cannot predict how quickly, if at all, clinicians will accept our DeepView System or, if accepted, how frequently it will be used. Failure to achieve or maintain market acceptance and/or market share could materially and adversely affect our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

We have no experience in marketing and selling our DeepView System and we may provide inadequate training, fail to increase our sales and marketing capabilities, or fail to develop and maintain broad brand awareness in a cost-effective manner.

We have no experience marketing and selling our DeepView System. If our DeepView System is approved for commercialization, we expect to rely on a direct sales force to sell our product in targeted geographic regions and territories. Any failure to grow and maintain our direct sales force could harm our business. The members of our direct sales force will receive extensive training on our DeepView System and will possess technical expertise with respect to our technology. The members of our sales force will be at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them when needed with individuals of comparable expertise and qualifications, or if we are unable to successfully instill such expertise in replacement personnel, our product sales, revenues and results of operations could be materially harmed.

Identifying and recruiting qualified sales and marketing professionals and training them on our DeepView System, on applicable federal and state laws and regulations, and on our internal policies and procedures will require significant time, expense and attention. It may take several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products that can utilize independent third parties, placing us at a competitive disadvantage. Our business may be harmed if our efforts to train and grow our sales force do not generate significant product sales and revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our technology. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition and results of operations.

If our DeepView System is approved for commercialization, our ability to achieve broader market acceptance of our device will depend, to a significant extent, on our sales, marketing and educational efforts. We plan to dedicate significant resources to our sales, marketing and educational programs. Our business may be harmed if these efforts and expenditures do not generate sufficient revenue. In addition, we believe that developing and maintaining broad awareness of our DeepView System in a cost-effective manner is critical to achieving broad acceptance of our device. Promotional and educational activities may not generate clinician awareness or generate sufficient revenue, and even if they do, any revenue generated may not offset the costs and expenses we incur. If we fail to successfully promote our DeepView System in a cost-effective manner, we may fail to attract or retain the market acceptance necessary to realize a sufficient return on our promotional and educational efforts, or to achieve broad adoption of our products.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our DeepView System, if approved.

We do not have any infrastructure currently in place for the sales, marketing or distribution of our DeepView System, or compliance functions related to such activities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market and successfully commercialize our DeepView System, if approved, we must build our sales, distribution, marketing, managerial, compliance, and other non-technical capabilities or make arrangements with third parties to perform these services. We expect to build a focused sales, distribution and marketing infrastructure to market the DeepView System, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities. Any failure or delay in the development of our internal sales, marketing, distribution and compliance capabilities could delay any product launch, which would adversely impact the commercialization of our product.

If third-party payors do not provide coverage and reimbursement for the use of our DeepView System, our business and prospects will be negatively impacted.

If we receive the necessary regulatory approval to commercialize our DeepView System, sales of our DeepView System will depend, in part, on the extent to which the use of our device is covered and reimbursed by third-party payors, including private insurers and government healthcare programs such as Medicare Advantage plans and plans purchased through the ACA marketplace. Where third-party payor coverage is not available, patients will be responsible for all of the costs associated with the use of our device. Even if a third-party payor covers a particular use of our device, the resulting reimbursement rate may not be adequate to cover a provider's cost to purchase our product or ensure such purchase is profitable for the provider.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in certain countries, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our device to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained.

Further, future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in relevant international markets in which we plan to operate, assuming we receive the necessary approvals. Third-party coverage and reimbursement for procedures using our DeepView System may not be available or adequate in either the United States or international markets. If demand for our DeepView System is adversely affected by changes in third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to achieve or maintain satisfactory pricing and margins for our DeepView technology.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our DeepView System, if it is approved for commercialization. We will be subject to a number of factors on our ability to maintain satisfactory pricing and margins, including, but not limited to, payor reimbursement, sale pricing of our DeepView System, wide-spread adoption of the DeepView System at hospitals, clinics and burn centers, as well as production cost increases from third party suppliers and our contract manufacturers. For example, any decline in the amount that payors reimburse clinicians for our DeepView System could make it difficult for them to continue using, or to adopt, our device and could create additional pricing pressure for us. If we are forced to lower the price we charge for our DeepView System, our revenue and gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our sales or our prices, including during any international expansion, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will be subject to significant pricing pressure, which could negatively affect our business, financial condition and results of operations.

We will face competition from many sources, including larger companies, and we may be unable to compete successfully.

We operate in a highly competitive industry that is significantly affected by the introduction of new products and technologies and other activities of industry participants. Our DeepView System will compete directly against conventional methods of wound care assessment. We will compete with manufacturers and suppliers of devices, instruments and other supplies used in connection with such conventional diagnoses. The market for these devices and instruments is highly fragmented with primary supply chains concentrated across a few larger manufacturers and distributors, such as Cobalt Product Solutions, Sanmina Corporation and Plexus Manufacturing.

Many of our competitors have longer, more established operating histories, and significantly greater name recognition and financial, technical, marketing, sales, distribution and other resources, which may prevent us from achieving significant market penetration. These companies may enjoy several other competitive advantages, including established relationships with clinicians who are familiar with other alternatives for wound care assessment, additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage and established sales, marketing and worldwide distribution networks.

We believe the primary competitive factors for companies that market new or alternative treatments and solutions in the wound care industry include acceptance by leading clinicians, patient outcomes and adverse event rates, patient experience and treatment time, ease-of-use and reliability, patient recovery time and level of discomfort, economic benefits and cost savings, intellectual property protection and the development of successful sales and marketing channels. One of the major hurdles to widespread adoption of our device will be overcoming established diagnostic patterns, which will require education of clinicians and their referral sources.

We may also compete with additional competitors and products outside the United States as well. Among other competitive advantages, such companies may have more established sales and marketing programs and networks, established relationships with clinicians and greater name recognition in such markets.

In addition, our current and potential competitors have established, or may establish, financial and strategic relationships among themselves or with existing or potential customers or other third parties to increase the ability of their products to address customer needs. Accordingly, it is possible that new competitors or alliances among competitors could emerge and acquire a significant market share. Existing and/or increased competition could, therefore, adversely affect our market share and/or force us to reduce the price of our products, which could have an adverse impact on our business, prospects, results of operations and financial condition.

If we are unable to continue to innovate and improve our products and services, we could lose market share.

The markets for our 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 our existing DeepView System obsolete, unmarketable or competitively impaired and may exert downward pressures on the pricing of our device. One of our key competitive advantages is that we are currently the only AI-enabled wound imaging technology that translates raw physiological data/images into an output that is directly correlated to a wound healing assessment. We intend to continue to invest in technical developments in order to mitigate the impact of future competition.

It is critical to our success to be able to anticipate changes in technology or in industry standards, to successfully develop and introduce new, enhanced and competitive products on a timely basis, and to keep pace with technological change. This may place excessive strain on our capital resources, which may adversely impact our revenues and profitability. We cannot assure you that we will successfully develop new products or services or enhance and improve our existing products or services on a timely basis. Neither can we be certain that new products and enhanced and improved existing products will achieve market acceptance or that the introduction of new products or enhancing existing products by others, or changing customer requirements, will not render our products or services obsolete. Our inability to develop products or services that are competitive in technology and price and that meet client needs could have an adverse impact on our business, prospects, results of operations and financial condition.

We will depend upon third-party suppliers, including contract manufacturers and single and sole source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.

If we receive the necessary regulatory approvals for commercialization, we will rely on third-party suppliers, including in some instances single or sole source suppliers, to provide us with certain components, sub-assemblies and finished products for our DeepView System. These components, sub-assemblies and finished products are critical and, for a small number of items, there are relatively few alternative sources of supply. For example, we primarily work with Cobalt Systems Product Solutions. We do not currently have long-term supply contracts with certain of the sole and single source suppliers of these key components, and there are no minimum purchase or payment requirements. Additionally, we believe we are not a major customer to many of our suppliers. Our suppliers may therefore give other customers' needs higher priority than ours, and we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms. These single or sole source suppliers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our product in a reliable manner and at the levels we anticipate or at levels adequate to satisfy demand for our product. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for such products and services, either because of acts of nature, the nature of our agreements with those suppliers or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us.

We have not been qualified or obtained necessary regulatory clearances for additional suppliers for most of these components, sub-assemblies and materials. While we currently believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers or providers would be able to provide the quantity and quality of components and materials that we would need to manufacture and ship our products if our existing suppliers and providers were unable to satisfy our requirements.

To utilize other sources, we would need to identify and qualify new providers to our quality standards and obtain any additional regulatory clearances or approvals required to change providers, which could result in manufacturing delays and increase our expenses.

Although we believe that we have stable relationships with our existing suppliers, we cannot assure you that we will be able to secure a stable supply of components or materials going forward. In the event that any adverse developments occur with our suppliers, in particular for those components that are single or sole sourced, or if any of our suppliers modifies any of the components they supply to us, our ability to supply our products may be temporarily or permanently interrupted. Obtaining substitute components could be difficult, time and resource-consuming and costly. Also, there can be no assurance that we will be able to secure a supply of alternative components at reasonable prices without experiencing interruptions in our business operations.

Our dependence on third parties subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a third party's operations;
- delays in product shipments resulting from uncorrected defects or errors, reliability issues or a third party's failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our third parties for key components;
- inability to obtain adequate supply or services in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative third parties for the supply of components of our products in a timely manner;
- inability of third parties to comply with applicable provisions of the FDA's QSR or other applicable laws or regulations enforced by the FDA, state, local and global regulatory authorities;
- inability to ensure the quality of products manufactured by third parties;
- shipping and manufacture delays and interruptions caused by the ongoing COVID-19 crisis that we are not able to address, prepare for, or prevent;
- production delays related to the evaluation and testing of products and services from alternative third parties and corresponding regulatory qualifications;
- trends towards consolidation within the medical device manufacturing supplier industry; and
- delays in delivery by our suppliers and service providers.

In addition, quarantines, shelter-in-place and similar government orders resulting from any future pandemic, epidemic or other infectious disease outbreak, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could impact the suppliers upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our products.

Although we require our third-party suppliers and providers to supply us with components and services that meet our specifications and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that these third parties will not always act consistent with our best interests, and may not always supply components or provide services that meet our requirements or in a timely manner. In addition, we cannot assure you that our suppliers have obtained and will be able to obtain or maintain all licenses, permits, clearances and approvals necessary for their operations or comply with all applicable laws and regulations, and failure to do so by them may lead to interruption in their business operations, which in turn may result in shortages of components supplied to us.

If we receive a significant number of warranty claims or our DeepView System requires significant amounts of service after sale, our operating expenses may substantially increase and our business and financial results will be adversely affected.

If our DeepView System is approved for commercialization, we intend to warrant each DeepView system against defects in materials and workmanship. We also expect to provide technical and other services beyond the warranty period pursuant to a supplemental service plan that we sell for our DeepView system. We have no history of commercial placements from which to judge our rate of warranty claims, and we expect that the number of warranty claims we receive may increase as we scale our operations and as commercial placements age. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated reductions in sales or additional operating expenditures for parts and service. In addition, our reputation could be damaged and our device may not achieve the level of market acceptance that we are targeting in order to achieve and maintain profitability. Unforeseen warranty exposure could negatively impact our business and financial results.

We need to ensure strong product performance and reliability to maintain and grow our business.

We need to maintain and continuously improve the performance and reliability of our DeepView System to achieve our profitability objectives. Poor product performance and reliability could lead to clinician dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. In addition, software and hardware incorporated into our DeepView System may contain errors or defects, especially when first introduced and while we have made efforts to test this software and hardware extensively, we cannot assure that the software and hardware, or software and hardware developed in the future, will not experience errors or performance problems.

Our reputation and the public image of our products, services and technologies may be impaired if our products or services fail to perform as expected. If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation, and business will suffer, including due to the costs associated with replacing products and decreased demand for our product offering. Any of the foregoing could have a material adverse effect on our business, financial condition, prospects and results of operations.

Although we intend to test our products prior to shipment, defects or errors could nonetheless occur. Our operating results will depend on our ability to execute and, when necessary, improve our quality management strategy and systems and our ability to effectively train and maintain our employee base with respect to quality management. The failure of our quality control systems or those of our third-party suppliers could result in problems with facility operations or preparation or provision of products. In each case, such problems could arise for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with off-the-shelf materials, sub-assemblies, parts and other components or environmental factors and damage to, or loss of, manufacturing operations.

Our results of operations will be materially harmed if we are unable to accurately forecast demand for, and utilization of, our DeepView System and manage our inventory.

If our DeepView System is approved for commercialization, we will be required to forecast inventory needs and manufacture our DeepView System based on our estimates of future demand for, and utilization of, our device. Our ability to accurately forecast demand and utilization could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in demand for our products or for products of our competitors, our failure to accurately forecast acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate demand and utilization, our supply chain, manufacturing partners and/or internal manufacturing team may not be able to deliver components and products to meet our requirements, and this could result in damage to our reputation and relationships with clinicians and dental practitioners. In addition, if we experience a significant increase in demand or utilization, additional supplies of off-the-shelf materials, sub-assemblies, parts and other components or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements. We currently outsource all of our manufacturing through an original equipment manufacturer. Cobalt, located in Plano, Texas, is involved with manufacturing the current generation DeepView System and we anticipate that they will continue to do so for the foreseeable future. In addition to Cobalt, we integrate several other highly specialized contract manufacturers in the areas of optics, technology design and electronics. If any of these suppliers were unable to meet our requirements, we would need to find a replacement or supplemental supplier, which we may not be able to do on a timely basis, or at all. Any of the foregoing would materially which will adversely affect our business, financial condition, prospects and results of operations.

Risks Related to Our Business Operations

We may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced substantial growth in our operations, and we expect to experience continued substantial growth in our business. Over the next several years, we expect to significantly increase the scope of our operations, particularly in the areas of manufacturing, sales and support, research and development, product development, regulatory affairs, marketing and other functional areas, including finance, accounting, quality control, and legal. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are highly dependent on our senior management, directors and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We depend to a significant degree on the continued services of our senior management, directors and key personnel. Their knowledge of both the market and their skills and experience are critical elements to our success. Our senior management team, directors and employees are engaged with us on an ‘at will’ basis, meaning that both they and we are able to terminate the arrangement without notice. The loss of key personnel could have an adverse impact on our business, prospects, results of operations and financial condition.

If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully.

We will rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments would have a negative effect on our operating results. Competition for experienced, high-quality personnel is intense and we cannot assure you that we will be able to recruit and retain such personnel. We may not be able to hire or retain the necessary personnel to implement our business strategy. Our failure to hire and retain such personnel could impair our ability to develop new products and manage our business effectively.

Our growth plans may place a significant strain on our management and operational, financial and personnel resources. In order to execute our strategy, we will need to hire additional individuals. These hires include product management, marketing and highly technical engineering roles. Furthermore, some of these hires will be in the UK and/or Europe to support our European strategy. Though we have never undertaken this level of growth, our management, including our Human Resources Manager have instituted a long-term hiring plan with key dates that ensure the individual is hired and trained months before the strategy must be executed. Furthermore, our ability to implement our strategy requires effective planning and management control systems. Therefore, our future growth and prospects will depend on our ability to manage this growth.

We expect to significantly increase the size of our organization over the next several years. As a result, we may encounter difficulties in managing our growth, which could disrupt our operations and/or increase our net losses.

As of March 25, 2024, we had 80 employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs, clinical and sales and marketing. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities. Any failure or delay in the development of our internal sales, marketing, distribution and compliance capabilities could delay any product launch, which would adversely impact the commercialization of our product. We also intend to continue to improve our operational, financial and management controls, reporting systems and procedures, which may require additional personnel. Such growth could place a strain on our administrative and operational infrastructure, and/or our managerial abilities, and we may not be able to make improvements to our management information and control systems in an efficient or timely manner. We may discover deficiencies in existing systems and controls.

Some of these employees will also be in countries outside of our corporate headquarters, which adds additional complexity. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage these activities. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources.

Our software and our internal computer systems may fail and such failure could negatively affect our business, financial condition and results of operations.

The continued development, maintenance and operation of our software and technologies are important factors impacting the success of our products and level of market acceptance. These efforts are expensive and complex and may involve unforeseen difficulties, including material performance problems and undetected defects or other technical or human errors. We may encounter technical obstacles, and it is possible that we may discover additional problems that prevent our software and technologies from operating properly. If our software or technologies, individually or collectively, do not function reliably or fail to meet clinician or payor expectations of performance or outcomes, then clinicians may stop using our products and payors could attempt to cancel their contracts with us.

Proprietary software development is time-consuming, expensive and complex, and may involve unforeseen difficulties. Our software may contain errors or vulnerabilities. Any real or perceived errors, failures, bugs or other vulnerabilities discovered in our existing or new software could result in negative publicity and damage to our reputation, loss of customers, loss of or delay in market acceptance of our products, loss of competitive position, loss of revenue or liability for damages, overpayments and/or underpayments, any of which could harm our business and results of operation.

Our information technology systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards, the increasing need to protect patient and customer information, changes in the techniques used to obtain unauthorized access to data and information systems, and the information technology needs associated with any new products and services. There can be no assurance that our process of consolidating, protecting, upgrading and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future.

We will rely on the proper function, security and availability of our information technology systems and data to operate our business, and a breach, cyber-attack or other disruption to these systems or data could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation or competitive position.

We rely on information technology systems to conduct our operations. In the ordinary course of our business, we use third parties to process and store, sensitive intellectual property and other proprietary business information. Because of this, we and our software are at risk for cyber-attacks. Cyber-attacks can result from deliberate attacks or unintentional events and may include (but are not limited to) malicious third parties gaining unauthorized access to our software for the purpose of misappropriating financial assets, intellectual property or sensitive information (such as patient data), corrupting data, or causing operational disruption.

In the future, we may rely on third-party vendors to supply and/or support certain aspects of our information technology systems. These third-party systems could also become vulnerable to cyber-attack, malicious intrusions, breakdowns, interference or other significant disruptions, and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems.

We have taken numerous steps to ensure the protection of our devices and technology. We regularly engage each of our employees in data protection training, have enabled two-factor authentication, and do not distribute or share data across external systems. Furthermore, we take measures to ensure that our employees who come in contact with data or patients do not violate any standards involving the HIPAA or compromise a patient's private health information.

While we believe that we have taken appropriate steps to protect our systems, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful access or disclosure of confidential information that could have an adverse impact on our business, prospects, results of operations and financial condition or result in the loss, dissemination, or misuse of critical or sensitive information. If we suffer from a cyber-attack, whether by a third party or insider, we may incur significant costs (including liability for stolen assets or information) and repairing any damage caused to our network infrastructure and systems. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through our disclosure of our proprietary business information, and such loss may not be capable of remedying. We may also suffer reputational damage and loss of investor confidence. We could also be exposed to potential financial and reputational harm if we experience a cyber-attack.

Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often were not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate timely, we may suffer interruptions in our ability to manage operations, and would also be exposed to a risk of loss, including financial assets or litigation and potential liability. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems or data or systems of our commercial partners, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability and suffer reputational harm. Failure to maintain or protect our information technology systems effectively could negatively affect our business, financial condition and results of operations.

There has been a developing trend of civil lawsuits and class actions relating to breaches of consumer data held by large companies or incidents arising from other cyber-attacks. Any data security breaches, cyber-attacks, malicious intrusions or significant disruptions could result in actions by regulatory bodies and/or civil litigation, any of which could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation or competitive position.

While we maintain certain insurance coverage, our insurance may be insufficient or may not cover all liabilities incurred by such attacks. We also cannot be certain that our insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceeds available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation.

The use of artificial intelligence, including machine learning, in our analytics platforms may result in reputational harm or liability.

AI is enabled by or integrated into the predictive analytics inherent in our DeepView platforms and will continue to be a substantial element of our product offerings going forward. As with many developing technologies, AI presents risks and challenges that could affect its further development, adoption, and use, and therefore our business. AI algorithms may be flawed and continual data propagation may prove ineffective. Data sets may be insufficient, of poor quality, or contain biased information. If the analyses that AI applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability, and brand or reputational harm. Some uses of AI present ethical issues, and our judgment as to the ethical concerns may not be accurate. If we use AI as part of our predictive analytics in a manner that is controversial because of the purported or real impact on our business or vendors, this may lead to adverse results for our financial condition and operations or the financial condition and operations of our business, which may further lead to us experiencing competitive harm, legal liability and brand or reputational harm.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our DeepView system. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If we supply products or services that are defectively designed or manufactured, or our products contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our technology or failing to adhere to the operating guidelines or our device producing inaccurate or unreliable readings could cause significant harm to patients. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we maintain product liability insurance, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

To the extent that a claim or claims of a significant nature were made against us, we may be required to expend substantial management resources and litigation costs in defending such claim(s) and such claim(s), if successful, could reduce margins, harm our reputation in the market, and increase future insurance premiums, the occurrence of each of which could have an adverse impact on our business, prospects, results of operations and financial condition.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

While we maintain commercial insurance at a level we believe is appropriate against certain risks commonly insured in the industry in which we operate, there is no guarantee that our insurer will cover costs or that we will be able to obtain the desired level of coverage on acceptable terms in the future. The potential costs that could be associated with any shortfall of insurance coverage may cause delays and disruptions to our operations and the additional expenditure that we may incur could affect our earnings and competitive position in the future and, potentially, our financial position. We could suffer losses that may not be fully compensated by insurance. In addition, certain types of risk may be, or may become, either uninsurable or not economically insurable, or may not be currently or in the future covered by our insurance policies. Any of the foregoing could have an adverse impact on our business, prospects, results of operations and financial condition.

Operating as a U.S. public company can make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

The success of our algorithms depends on our significant repository of proprietary DFU and burn data.

As of December 31, 2023, approximately 340 billion pixels of proprietary DFU and burn data have been acquired and utilized for the deep learning algorithms training. We believe this presents a significant barrier to entry to would-be competitors in wound care healing assessments. The data collection to clinical output, the flow, quality and control of the data pipeline is managed entirely by us. Our DeepView System uses deep learning on its wound data repository to recognize patterns and correlations of injured tissue spectral signatures to produce reliable and reasonable assessment for clinicians to make accurate and efficient treatment decisions.

We have developed strategic partnerships with multiple clinical and academic partners in the United States and Europe. Through our strategic partnerships with multiple clinical and academic partners, we are able to access large, diverse and specific sets of wound data inputs to develop, validate and improve our DeepView algorithms efficiently and effectively. We believe we have the pre-eminent proprietary clinical wound database. The depth and quality of our proprietary data is critical to developing a leading wound assessment technology with demonstrated clinical need across burn, DFU and other indications with a positive impact on health economics and patient outcomes, while safeguarding patient data and privacy. If we were no longer able to access or receive this data, it would have a material adverse effect on our business, prospects, results of operations and financial condition.

We may further seek strategic alliances, joint ventures or collaborations, or enter into licensing or partnership arrangements in the future and may not be successful in doing so, and even if we are, we may not realize the benefits or costs of such relationships.

We have developed strategic partnerships with multiple clinical and academic partners and, in the future, we may further form or seek strategic alliances, create joint ventures or collaborations or enter into licensing or partnership arrangements with third parties that we believe will complement or augment our sales and marketing efforts with respect to our DeepView System or future products. We may not be successful in our efforts to establish such collaborations, and we may not achieve the benefits expected from our current strategic partnerships or future collaborations. Any of these relationships may require us to incur non-recurring and other charges, indemnify the counterparty, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for our products. We cannot be certain that, following a strategic alliance or similar arrangement, we will achieve the revenue or specific net income that justifies such transaction. In addition, any potential future collaborations may be terminable by our collaborators, and we may not be able to adequately protect our rights under these agreements. Any termination of collaborations we enter into in the future, or delays in entering into new strategic partnership agreements could delay tour sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

Additionally, we may not have sole decision-making authority with respect to any such collaboration or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be averse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products and technologies.

As international expansion of our business occurs in future years, it will expose us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our long-term strategy is to increase our international presence, including securing regulatory clearances or approvals in targeted countries outside the United States. This strategy may include establishing and maintaining clinician outreach and education capabilities outside of the United States and expanding our relationships with international payors. Doing business internationally involves a number of risks, including:

- difficulties in staffing and managing our international operations;
- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental clearances, approvals, permits and licenses;
- reduced or varied protection for intellectual property rights in some countries;
- obtaining regulatory clearance, approval or certification where required for our products in various countries;

- requirements to maintain data and the processing of that data on servers located within such countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- restrictions on the site-of-service for use of our products and the economics related thereto for clinicians, providers and payors;
- natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent or other intellectual property protection for any products we develop or for our technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be harmed.

We believe that one of our key strengths is our market leading technology, including our proprietary AI algorithms and optical technology. In order to remain competitive, we must develop, maintain, and protect the proprietary aspects of our brands, technologies, data, and products. We rely on a combination of contractual provisions, confidentiality procedures, patent, copyright, trademark, trade secret, and other intellectual property laws to protect the proprietary aspects of our brands, technologies, data, and products. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Any failure to obtain or maintain patent and other intellectual property protection with respect to our products could harm our business, financial condition and results of operations.

Our technology is protected with issued and/or allowed patents across nine families of active patents: (i) Burn/Wound Classification on MSI and PPG; (ii) Tissue classification on MSI and PPG; (iii) Amputation site analysis on MSI, ML and healthcare matrix; (iv) DFU healing potential prediction and wound assessment on MSI, ML and healthcare matrix; (v) High-precision, multi-aperture, MSI snapshot imaging; (vi) Wound assessment based on MSI; (vii) Burn/histology assessment based on MSI and ML; (viii) High-precision, single-aperture MSI snapshot imaging; and (ix) Topological characterization and assessment of tissues using MSI and ML.

As of the date of this annual report, we have 10 issued and allowed U.S. patents with five U.S. patent applications pending. We have 10 issued and allowed international patents with 29 foreign and international patent applications pending. We protect our DeepView System trademarks primarily in four classes: pre-recorded/downloadable software, surgical, medical apparatus, computer and scientific services and medical and healthcare services. As of December 31, 2023, we maintain a portfolio of 64 trademarks and nine trademark applications pending relating to our DeepView and SnapShot product offerings. Our trademarks and pending trademark applications are spread over nine jurisdictions mostly in China, the UK and the EU. It is our intention to maintain these registrations indefinitely and to expand the number of jurisdictions in which we have registered trademarks as deemed necessary to protect our freedom to use the marks and/or block competitors in additional markets. We will continue to primarily focus on protecting our intellectual property in the United States, UK and the EU as those are the first commercial markets for our products.

We cannot assure you that our intellectual property position will not be challenged or that all patents for which we have applied will be granted. As with other medical device companies, our success depends, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, maintaining, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents or patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection.

We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our products or research and development results before it is too late to obtain patent protection. While the imaging modality — SnapShot MSI system and proprietary illumination system — are patent protected, our AI algorithm used in the system is not patent protected. The device performance is supported by the proprietary clinical data owned by Spectral. The loss or disclosure of both the data and the algorithm could be detrimental to the future development and competitive advantage of our DeepView System.

In addition, our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent is not conclusive as to its inventorship, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad, so even if we obtain patents, they may not provide us with adequate proprietary protection or competitive advantage against our competitors with similar products. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology or to prevent competitive technologies. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, certain countries outside of the United States do not allow patents for methods of treating the human body. This may preclude us from obtaining method patents outside of the United States having similar scope to those we have obtained or may obtain in the future in the United States. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value or validity of our intellectual property or narrow the scope of our patent protection. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal, factual and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability, or scope of such patents, which may result in such patents being narrowed, invalidated, or held unenforceable. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. We may not be aware of all third-party intellectual property rights (for example, not be aware of a patent or not be aware of a patent's scope) potentially relating to our products, product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our ability to market our products without infringing third party patent rights, is highly uncertain. We cannot ensure that we do not infringe any patents or other proprietary rights held by others. If our products were found to infringe any proprietary right of another party, we could be required to pay significant damages or license fees to such party and/or cease production, marketing and distribution of those products.

Litigation may also be necessary to defend infringement claims of third parties or to enforce patent rights we hold or protect trade secrets or techniques we own. Further, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable, or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Our success will also depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how, and obtaining and maintaining other intellectual property rights. We rely on trade secret protection and confidentiality agreements for strategic purposes, to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. There can be no assurances that we can meaningfully protect or maintain intellectual property, trade secrets or other unpatented proprietary rights necessary to our business or in a form that provides us with a competitive advantage, or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our proprietary technology. In addition, our trade secrets, data, and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients, and other vendors who have access to such information, and could otherwise become known or be independently developed or discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition, and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated.

Additionally, we may find it necessary or prudent to acquire or obtain licenses from third-party intellectual property holders. However, we may be unable to acquire or secure such licenses to any intellectual property rights from third parties that we identify as necessary for our products or any future products we may develop. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary, and our competitors could market competing products and technology. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product, and our customers may be forced to stop using the relevant product, which could harm our business, financial condition, prospects and results of operations.

We may, in the future, be a party to intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products.

The medical device industry is highly competitive and has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents, along with pending patent applications or trademarks controlled by third parties, may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell, import, and/or export our products (or components thereof) or to use our technologies or our product names.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims relating to our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending that may result in issued patents that our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time-consuming, costly to defend, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from which we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Because patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents in court, at an administrative agency, or at the patent office, if issued, by proving that the invention was not original, was not novel, was obvious, or was obtained without disclosing all pertinent material prior art information to the patent office, among other reasons. For example, in litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons or are unenforceable due to inequitable conduct. If a court agreed, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Further, if third party claims of patent or trademark infringement or trade secret misappropriation are successfully asserted against us, such claims may harm our business, result in injunctions preventing us from selling our products, and require payment of license fees, damages, attorneys' fees, and court costs, which may be substantial and have a material adverse impact on our business. In addition, if we are found to have willfully infringed third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties that may substantially erode our margins. Further, we may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement, and as such may need to stop selling the infringing products, which would have a significant adverse impact on our business, financial condition, prospects and results of operations.

Similarly, interference, derivation, cancellation, and opposition proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (USPTO) may be necessary to determine priority with respect to our patents, patent applications, trademarks, or trademark applications. We may also become involved in other proceedings, such as reexamination, inter partes review, post-grant review, derivation, interference, supplemental examination, cancellation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Such challenges may result in loss of exclusivity or ability to make, use, and sell our products without infringing third-party intellectual property rights, or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques without payment to us, or limit the duration of the patent protection of our technology. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses or rights could prevent us from using, selling, manufacturing, or importing our products or using product names, which would have a significant adverse impact on our business, financial condition, prospects and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents, trademarks, or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Former, current, or future licensees may violate the terms of their licenses and thereby infringe our intellectual property. Competitors may infringe our issued patents, trademarks, or other intellectual property. To counter infringement or unauthorized use by licensees, competitors, or other parties, we may be required to file infringement or misuse claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims or file administrative actions against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Furthermore, even if our patents or trademarks are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market, and an adverse result in any litigation proceeding or administrative action could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition, and results of operations. In addition, although we make efforts to comply with the patent marking provisions of 35 U.S.C. § 287(a), a court may decide that we have not met the requirements of the patent marking statute, which may prevent us from obtaining monetary damages that would otherwise have been due to us if we had complied with the marking statute.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Protracted litigation to defend or prosecute our intellectual property rights could also result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition, prospects and results of operations.

In addition, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or indemnify our customers for any costs associated with their own initiation or defense of infringement claims, regardless of the merits of these claims. If any of these claims succeeds or settles, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

Obtaining and maintaining intellectual property, including patent protection, depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental agencies, and our intellectual property, including patent protection, could be reduced or eliminated for non-compliance with these requirements.

The USPTO, United States Copyright Office (USCO) and various foreign governmental agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees often must be paid to the USPTO, USCO and foreign agencies over the lifetime of any registered or applied-for intellectual property rights we may obtain in the future. While an unintentional lapse of an intellectual property registration or application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the registration or application, resulting in partial or complete loss of intellectual property rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a registration or application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the intellectual property registrations and applications covering our products, we may not be able to stop a competitor from developing or marketing products that are the same as or similar to our products, which would have a material adverse effect on our business. We also have a duty to disclose to the USPTO any prior art known to us that may be material to the patentability of our patents. If we failed to submit any such material prior art, a court or administrative agency may deem one or more of our patents unenforceable.

Additionally, certain of our patent applications relate to software inventions. Software-related patents in general are susceptible to validity or patentability challenges before the USPTO or in other judicial or quasi-judicial proceedings for being directed to non-statutory subject matter under 35 U.S.C. § 101.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a utility patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, voluntary disclaimer of patent term to obtain a patent's allowance, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products, which may harm our business prospects.

In addition, although upon issuance in the United States a patent's term can be extended based on certain delays caused by the USPTO, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent terms to protect our products, proprietary technologies and their uses, our business would be seriously harmed. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in patent law or its interpretation could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post-grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. A third-party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, prospects and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Our patent rights and other intellectual property may be subject to priority, ownership or inventorship disputes, interferences, and similar proceedings.

We may also be subject to claims that former employees, collaborators, or other third parties have an interest in our patents and patent applications or other intellectual property as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents and patent applications, such co-owners' rights may be subject, or in the future subject, to assignment or license to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any such patents and any patents issuing from such patent applications against third parties, and such cooperation may not be provided to us. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, for example, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity, despite our inclusion of valid, present-tense intellectual property assignment obligations. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim.

If we or our licensors are unsuccessful in any priority, validity (including any patent oppositions), ownership or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our patents, or such patent claims may be narrowed, invalidated, or held unenforceable, or through loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we are successful in priority, inventorship or ownership disputes, it could result in substantial costs and be a distraction to management and other employees. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. Any of the foregoing could result in a material adverse effect on our business, financial condition, prospects and results of operations.

We may be subject to claims that our employees, consultants, advisors, or contractors have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of a non-competition or non-solicitation agreement with our competitors, and third parties may claim an ownership interest in intellectual property we regard as our own. Such claims could harm our business, financial condition, prospects and results of operations.

As is common in the medical device industry, our employees, consultants, and advisors may be currently or previously employed or engaged at universities or other medical device or healthcare companies, including our competitors and potential competitors. Some of these employees, consultants, advisors, and contractors may have executed proprietary rights, non-disclosure, and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants, advisors, and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property, including trade secrets or other proprietary information, of their current or former employers, competitors or other third parties. Also, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. Litigation may be necessary to defend against these claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees, vendors, and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, may be ineffective under current or future case law, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such defects in assignment or resulting claims could harm our business, financial condition, prospects and results of operations.

If we fail to validly execute invention assignment agreements with our employees and contractors involved in the development of intellectual property or are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our products our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how, and other confidential and proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we generally have confidentiality and invention assignment provisions in contracts with our employees, consultants, suppliers, contract manufacturers, collaborators, and others upon the commencement of their relationship with us. However, we may not enter into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other confidential or proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets or proprietary technology and processes will not otherwise become known or independently developed by competitors. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Despite the protections we do place on our intellectual property or other confidential and proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third-party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand, and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in research and development or acquisitions could be reduced, and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition, prospects and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets, and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any such breach.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our current or future products or trademarks, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, may not favor the enforcement of patents, trademarks, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademark rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and many other countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We rely on trademarks and trade names to build brand recognition and to promote, distinguish and market our products and services. Our current or future registered and unregistered trademarks or trade names may be challenged, opposed, infringed, circumvented or declared generic or descriptive, determined to be not entitled to registration, or determined to be infringing other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names or logos, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. If our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may in the future license our trademarks and trade names to third parties. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, and service marks may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Trademark litigation can be expensive, and the outcome can be highly uncertain. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease the use of such trademarks.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Moreover, some of our patents and patent applications in the future may be jointly owned with third parties. If we are unable to obtain an exclusive license to any such third-party joint owners' interest in such patents or patent applications, such joint owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such joint owners in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations.

If our third-party manufacturers do not respect our intellectual property and trade secrets and produce or sell competitive products using our designs or intellectual property, our business, financial condition, prospects and results of operation would be harmed.

Although our agreements with third-party manufacturing partners generally seek to preclude them from misusing our intellectual property and trade secrets, or using our designs to manufacture products for our competitors, we may be unsuccessful in monitoring and enforcing our intellectual property rights and may find counterfeit goods in the market being sold as our products and any future products similar to ours produced for our competitors using our intellectual property. Additionally, any steps to stop counterfeits may not be successful and customers who purchase these counterfeit goods may experience product defects or failures, harming our reputation and brand and causing us to lose future sales. Any of the foregoing could harm our business, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition, prospects and results of operations.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our patents or patent applications omit individuals who should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- claims of our patents or patent applications, if and when issued, may not cover our products or technologies or competitive products or technologies;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Any of the foregoing could harm our business, financial condition, prospects and results of operations.

Our contracts with BARDA and DHA may affect our intellectual property rights.

Our contracts with BARDA and DHA include provisions that implement the Bayh-Dole Act of 1980 relating to a uniform patent policy among the many federal agencies funding research, which grants the U.S. government certain rights in inventions that may be conceived or first actually reduced to practice under the contract. In particular, pursuant to the Federal Acquisition Regulations which governs executive agencies acquisition of services with appropriated funds, the U.S. government is granted a nonexclusive, nontransferable, irrevocable, paid-up, worldwide license to practice such inventions or have such inventions practiced for or on behalf of the U.S. government. In addition to our intellectual property rights, the BARDA and DHA contracts each provide certain data rights to the U.S. government with unlimited rights in: (i) data first produced in the performance of this contract; (ii) form, fit, and function data delivered under the contract; (iii) data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and (iv) all other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software.

Nasdaq may delist our securities from trading on its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

We cannot assure you that our securities will continue to be listed on Nasdaq. If any of our securities are delisted from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect such securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our Common Stock are a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The listing of our securities on Nasdaq did not benefit from the process undertaken in connection with an underwritten initial public offering.

Our Common Stock and our Warrants are listed on the Nasdaq under the symbols "MDAI" and "MDAIW," respectively. Unlike an underwritten initial public offering of our securities, the initial listing of our securities as a result of the Business Combination did not benefit from the following:

- the book-building process undertaken by underwriters that helps to inform efficient price discovery with respect to opening trades of newly listed securities;
- underwriter support to help stabilize, maintain or affect the public price of the new issue immediately after listing; and
- potential underwriter liability for material misstatements or omissions of fact in a prospectus used in connection with the securities being offered or for statements made by the underwriters' securities analysts or other personnel.

The lack of such a process in connection with the listing of our securities could result in diminished investor demand, inefficiencies in pricing and a more volatile public price for our securities in the near future than in connection with an underwritten initial public offering.

We have incurred increased costs as a result of operating as a U.S. public company, and the Company's management is required to devote substantial time to new compliance and investor relations initiatives.

As a U.S. public company, the Company has and will continue to incur significant legal, accounting and other expenses. The Company is subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, require, among other things, that a public company establish and maintain effective disclosure and financial controls. As a result, the Company has and will continue to incur significant legal, accounting and other expenses. The Company's entire management team and many of its other employees need to devote substantial time to compliance.

Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to the Company when the Company ceases to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which the Company operates its business in ways it cannot currently anticipate.

If these requirements divert the attention of the Company's management and personnel from other business concerns, they could have a material adverse effect on the Company's business, financial condition and results of operations. The increased costs will decrease the Company's net income or increase the Company's net loss and may require the Company to reduce costs in other areas of the Company's business or increase the prices of the Company's services. The Company cannot predict or estimate the amount or timing of additional costs it may incur to respond to these requirements. The impact of these requirements could also make it more difficult for the Company to attract and retain qualified persons to serve on its board of directors, board committees or as executive officers.

The Charter provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

The Charter provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery (the "Chancery Court") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action, suit or proceeding asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee, agent or stockholder of the Company to the Company or to the Company's stockholders, (iii) any action, suit or proceeding asserting a claim against the Company, its current or former directors, officers, or employees, agents or stockholders arising pursuant to any provision of the DGCL or our Charter or Bylaws, or (iv) any action, suit or proceeding asserting a claim against the Company, its current or former directors, officers, or employees, agents or stockholders governed by the internal affairs doctrine.

The exclusive forum provision set forth above does not apply to, and does not preclude or contract the scope of, either (i) exclusive federal jurisdiction pursuant to Section 27 of the Exchange Act for claims seeking to enforce any liability or duty created by the Exchange Act or the rules and regulations thereunder, or any other claim for which the U.S. federal courts have exclusive jurisdiction, or (ii) concurrent jurisdiction under Section 22 of the Securities Act for federal and state courts over all claims seeking to enforce any liability or duty created by the Securities Act or the rules and regulations thereunder. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The choice of forum provision may limit a stockholder's ability to bring, and increase the cost of, a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in the Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

The failure of any bank in which we deposit our funds could have an adverse effect on our financial condition.

We deposit substantial funds in financial institutions and may, from time to time, maintain cash balances at such financial institutions in excess of the Federal Deposit Insurance Corporation limit. Should one or more of the financial institutions at which deposits are maintained fail, there is no guarantee as to the extent that we would recover the funds deposited, whether through Federal Deposit Insurance Corporation coverage or otherwise, or the timing of any recovery.

Risks Relating to the Ownership of Our Securities

The price of Common Stock and Warrants may be volatile.

Fluctuations in the price of the Company's securities could contribute to the loss of all or part of your investment. The valuation ascribed to the Company in the Business Combination may not be indicative of the price that will prevail in the trading market. If an active market for our securities develops and continues, the trading price of the Company's securities could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on your investment in our securities and the Company's securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of the Company's securities may include:

- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about the Company's operating results;
- success of competitors;
- the public's reaction to our press releases, other public announcements and filings with the SEC,
- operating results failing to meet the expectations of securities analysts or investors in a particular period;

- changes in financial estimates and recommendations by securities analysts concerning the Company or the industry in which the Company operates in general;
- operating and stock price performance of other companies that investors deem comparable to the Company;
- ability to market new and enhanced products and services on a timely basis;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving the Company;
- changes in the Company's capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of the Company's common stock available for public sale;
- any major change in the Company's board or management;
- sales of substantial amounts of the Company's common stock by our directors, executive officers or significant stockholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, changes in interest rates, changes in fuel prices, international currency fluctuations and acts of war or terrorism.

Broad market and industry factors may materially harm the market price of our securities irrespective of our operating performance. The stock market in general, and Nasdaq specifically, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our investors may not be able to sell your securities at or above the price at which they were acquired. A loss of investor confidence in the market for the stocks of other companies which investors perceive to be similar to the Company could depress our stock price regardless of our business, prospects, financial conditions or results of operations. A decline in the market price of our securities also could adversely affect our ability to issue additional securities and our ability to obtain additional financing in the future.

Changes in laws, regulations or rules, or a failure to comply with any laws, regulations or rules, may adversely affect our business, investments and results of operations.

The Company is subject to laws, regulations and rules enacted by national, regional and local governments and the Nasdaq. In particular, Company is required to comply with certain SEC, Nasdaq and other legal or regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules may be difficult, time consuming and costly. Those laws, regulations or rules and their interpretation and application may also change from time to time and those changes could have a material adverse effect on Company's business, investments and results of operations. In addition, a failure to comply with applicable laws, regulations or rules, as interpreted and applied, could have a material adverse effect on Company's business and results of operations.

If we fail to maintain proper and effective internal controls over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our Common Stock may decline.

Effective internal controls over financial reporting are necessary for the Company to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause the Company to fail to meet its reporting obligations. In addition, any testing by the Company conducted in connection with Section 404 of the Sarbanes-Oxley Act ("Section 404") or any subsequent testing by the Company's independent registered public accounting firm, may reveal deficiencies in the Company's internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to the Company's financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in the Company's reported financial information, which could have a negative effect on the trading price of the Company's stock.

For as long as the Company is an emerging growth company, its independent registered public accounting firm will not be required to attest to the effectiveness of its internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of the Company's internal controls over financial reporting could detect problems that the Company's management's assessment might not detect. Undetected material weaknesses in the Company's internal controls over financial reporting could lead to restatements of the Company's consolidated financial statements and require the Company to incur the expense of remediation.

If the Company is not able to comply with the requirements of Section 404 in a timely manner or it is unable to maintain proper and effective internal controls over financial reporting may not be able to produce timely and accurate consolidated financial statements. As a result, the Company's investors could lose confidence in its reported financial information, the market price of the Common Stock could decline and the Company could be subject to sanctions or investigations by the SEC or other regulatory authorities.

Our internal controls over financial reporting currently do not meet all of the standards contemplated by Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("SOX"), and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of SOX could impair our ability to produce timely and accurate financial statements or comply with applicable regulations and have a material adverse effect on our business. In the future, our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we are subject to certain reporting requirements of the Exchange Act and have significant requirements for enhanced financial reporting and internal controls. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments, and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. If we are unable to maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis, result in material misstatements in our consolidated financial statements, and harm our operating results. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. In addition, we are required, pursuant to Section 404 of the Sarbanes–Oxley Act of 2002, as amended ("SOX"), to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. Testing and maintaining internal controls may divert management's attention from other matters that are important to our business. As an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until our annual report for any fiscal year following such date that we are no longer an emerging growth company. If we are not able to complete our initial assessment of our internal controls and otherwise implement the requirements of Section 404 of SOX in a timely manner or with adequate compliance, our independent registered public accounting firm may not be able to certify as to the adequacy of our internal controls over financial reporting. Additionally, when required, an independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. Matters impacting our internal controls may cause us to be unable to report our financial information on a timely basis and thereby subject us to adverse regulatory consequences, including sanctions by the SEC or violations of applicable stock exchange listing rules, which may result in a breach of the covenants under existing or future financing arrangements. There also could be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our consolidated financial statements. Confidence in the reliability of our consolidated financial statements also could suffer if we or our independent registered public accounting firm report a material weakness in our internal controls over financial reporting. In connection with the preparation of our consolidated financial statements for the year ended December 31, 2023, we identified the following material weaknesses:(i) there was a lack of communication within management and internal departments regarding complex and unusual arrangements; (ii) the Company did not maintain adequately designed controls to ensure the proper recording of operating expenses, related accruals and unbilled revenue in the correct period; and (iii) our financial statement close process controls which relate to all financial statement accounts, did not consistently operate effectively or lacked appropriate evidence, to ensure account reconciliations, transactions, and journal entries were performed or reviewed at the appropriate level of precision and on a timely basis.

We have implemented, and are continuing to implement, measures designed to improve our internal control over financial reporting to remediate these material weaknesses. These measures include formalizing our processes and internal control documentation, strengthening supervisory reviews by our financial management, engaging financial consultants to enable the implementation of internal control over financial reporting, and enhancing the functionality of our enterprise resource planning system to support certain key financial processes and controls and enforce certain segregation of duties through automation and approval workflows. We expect to incur additional costs to remediate the control deficiencies identified, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities. Our internal resources and personnel may in the future be insufficient to avoid accounting errors and there can be no assurance that we will not have additional material weaknesses in the future. Any failure to develop or maintain effective controls or any difficulties encountered implementing required new or improved controls could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our consolidated financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls, procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

If securities analysts do not publish research or reports about us, or if they issue unfavorable commentary about us or our industry or downgrade our Common Stock, the price of our Common Stock could decline.

The trading market for our Common Stock will depend in part on the research and reports that third-party securities analysts publish about us and the industries in which we operate. We may be unable or slow to attract new research coverage and if one or more analysts cease coverage of us, the price and trading volume of our securities would likely be negatively impacted. If any of the analysts that may cover us change their recommendation regarding our securities adversely, or provide more favorable relative recommendations about our competitors, the price of our securities would likely decline. If any analyst that may cover us ceases covering us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the price or trading volume of our securities to decline. Moreover, if one or more of the analysts who cover us downgrades our Common Stock, or if our reporting results do not meet their expectations, the market price of our Common Stock could decline.

Sales, or the perception of sales, of our common stock by us or our existing stockholders in the public market could cause the market price for our common stock to decline.

The sale of substantial amounts of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Upon the expiration or waiver of certain lock-up restrictions, shares held by certain of our stockholders will be eligible for resale, subject to, in the case of certain stockholders, volume, manner of sale and other limitations under Rule 144. As restrictions on resale end, the market price of shares of our Common Stock could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our shares of Common Stock or other securities.

In addition, the shares of our Common Stock reserved for future issuance under the Spectral AI, Inc. 2023 Equity Incentive Plan, which will be approved and adopted by the Company at its first annual meeting following the Business Combination ("Equity Incentive Plan") will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale by affiliates under Rule 144, as applicable. The number of shares to be reserved for future issuance under the Equity Incentive Plan is expected to equal approximately 8,000,000 shares.

We have filed a registration statement on Form S-8 under the Securities Act to register shares of our common stock or securities convertible into or exchangeable for shares of our common stock issued pursuant to our equity incentive plans. Form S-8 registration statements automatically become effective upon filing. Accordingly, the initial registration statement on Form S-8 covered approximately 5,466,000 shares of our common stock.

Warrants will become exercisable for Company common stock, which would increase the number of shares eligible for resale in the public market and result in dilution to our stockholders.

Outstanding warrants to purchase an aggregate of 8,433,333 shares of Common Stock will become exercisable in accordance with the terms of the Warrant Agreement governing those securities. Each warrant entitles the registered holder to purchase one share of Common Stock at a price of $11.50 per full share. Pursuant to the Warrant Agreement, a holder of Warrants may exercise its Warrants only for a whole number of shares. This means that only a whole warrant may be exercised at any given time by a holder of Warrants. To the extent such warrants are exercised, additional shares of the Common Stock will be issued, which will result in dilution to the holders of the Common Stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of the Common Stock. The Company maintains a redemption right with respect to the warrants in that the Company can redeem some or all of the warrants for $0.10 per warrant based on certain market conditions and the market price of the Common Stock.

Item 1.B. Unresolved Staff Comments.

None.

Item 1.C. Cybersecurity

Risk Management and Strategy

The Company manages cybersecurity risk as part of our overall enterprise risk management strategy, which is overseen by the Audit Committee and the Board. The Company employs robust cybersecurity and data privacy programs to assess, identify and manage material risks from cybersecurity threats.

We are constantly evolving our cyber defenses to minimize impacts from cyber threats by using a multi-pronged approach that helps safeguard our assets and data. We are particularly focused on addressing emerging cybersecurity risks, including human risk, as phishing attacks remain one of the most common causes of data breaches; third-party supply chain risks, as threat actors continue to target supply chains to compromise a greater number of victims; and geopolitical risk, as tensions and conflicts around the world are often accompanied by an increase in sabotage, espionage and cyber-attacks. As threat actors frequently target employees to gain access to information and systems, we have a comprehensive human risk management program that educates our workforce on threats they face as a first line of defense, and includes elements addressing phishing, malware, data handling, device security, cybersecurity education, password security, internet browsing and defenses to physical threats. Our employees are exposed to cybersecurity awareness training and training to keep pace with industry standards, evolving challenges and innovative solutions with respect to information security, data privacy, and cybersecurity risks to the organization. Additionally, we employ a multi-layered approach in our application of cybersecurity technologies to help safeguard our systems, networks, and data from potential cybersecurity threats.

To support our preparedness, we have a cybersecurity incident response plan ("CIRP") that we regularly update as business needs and the security landscapes change. In the event of a cybersecurity incident, our incident response team refers to our CIRP and existing management internal controls and disclosure processes. Pursuant to this process, designated personnel are responsible for assessing the severity of the incident and any associated threats, containing and resolving the incident as quickly as possible, managing any damage to the Company's systems and networks, minimizing the impact on the Company's stakeholders, analyzing and executing upon internal reporting obligations, escalating information about the incident to senior management, as appropriate, and performing post-incident analysis and program enhancements, as needed. We perform periodic tabletop exercises annually to test our incident response procedures, identify gaps and improvement opportunities and exercise team preparedness.

We recognize that third parties that provide services to the Company can be subject to cybersecurity incidents that could impact the Company. To manage third-party risk, we maintain a third-party risk management program, which is designed to assess the security controls of our third parties. The assessment methodology is based on risk and relies on the data, access, connectivity, and criticality of the services that the third-party offers.

We maintain relationships with legal counsel to inform our cybersecurity and data privacy programs.

As of December 31, 2023, and through the date of this filing, we are not aware of any material cybersecurity incidents that have impacted the Company. We face risks of incidents, whether through cyber attacks or cyber intrusions through the Cloud, the Internet, phishing attempts, ransomware and other forms of malware, computer viruses, email attachments, extortion, and other scams. Although we make efforts to maintain the security and integrity of our information technology systems, these systems and the proprietary, confidential and personal information that resides on or is transmitted through them, are subject to the risk of a cybersecurity incident or disruption, and there can be no assurance that our security efforts and measures, and those of our third-party vendors, will prevent breakdowns or incidents to our or our third-party vendors' systems that could adversely affect our business.

Governance

The Company's cybersecurity and data privacy programs are implemented and overseen by the Company's designated director of information systems ("IT Director") and senior management. The information security team responsible for managing and implementing the Company's cybersecurity and data privacy programs has many years of valuable business experience managing risks from cybersecurity threats and data privacy breaches and developing and implementing cybersecurity and data privacy policies and procedures.

Our Audit Committee, which consists solely of independent directors, oversees the Company's overall enterprise risk assessment and risk management policies and guidelines, including risks related to cybersecurity matters. Our Audit Committee reviews, discusses with management and oversees the Company's information security and data protection programs. In particular, the Audit Committee receives periodic updates from the IT Director, internal audit function and other members of management on significant cybersecurity and data privacy threats to our systems and the potential impact on the Company's business, financial results, operations, and reputation, risk management strategies, including information governance and security policies and programs, program assessments, planned improvements, major legislative and regulatory developments that could materially impact the Company's cybersecurity and data privacy policies and programs, and status of information security initiatives, including an appropriate threat assessment relating to information technology risks. The Board also receives similar cybersecurity updates directly from the IT Director and other members of management at least annually, and as needed from time to time.

Item 2. Properties.

We currently maintain our executive offices, which are located at 2515 McKinney Avenue, Suite 1000, Dallas, TX 75201. The cost for this space is approximately $105,000 per month. We also maintain an office space in the United Kingdom at Orion House, Bessemer Road, Welwyn Garden City, Herts Al7 1HH. The cost for this space is $14,000 per month. We consider our current office space adequate for our current operations.

Item 3. Legal Proceedings.

The Company is not a party to any material legal proceedings or pending claims. The Company is aware of a material threatened claim that it believes is without merit. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. To our knowledge, there is not any material legal proceeding threatened against any of our officers or directors in their corporate capacity.

Item 4. Mine Safety Disclosures.

None.

PART II.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Following the Business Combination, our Common Stock began trading on Nasdaq on September 12, 2023. The shares of Common Stock and our redeemable warrants trade on Nasdaq under the symbols "MDAI" and "MDAIW", respectively.

Holders

As of March 25, 2024, there were at least 4,893 holders of record of 17,466,871 shares of our Common Stock and 25 holders of record of our redeemable warrants.

Dividends

We have not declared or paid any dividends on our capital stock to date. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our business prospects, results of operations, financial condition, cash requirements and availability, debt repayment obligations, capital expenditure needs, contractual restrictions, covenants in the agreements governing current and future indebtedness, industry trends, the provisions of Delaware law affecting the payment of dividends and distributions to stockholders and any other factors or considerations the Board deems relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

We previously maintained the Spectral MD Holdings, Ltd. 2018 Long Term Incentive Plan (the "2018 Plan"), which provided for the discretionary grant of incentive stock options, 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 to our eligible employees, directors and consultants, including the named executive officers. 3,526,200 shares of our Common Stock are issuable upon the exercise of outstanding options under the 2018 Long Term Incentive Plan.

We also previously maintained the Spectral MD Holdings, Ltd. 2022 Long Term Incentive Plan (the "2022 Plan"). The 2022 Plan provides for the discretionary grant of incentive stock options, 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 to our employees, directors and consultants. Under the 2022 Long Term Incentive Plan, 88,749 shares of common stock are issuable upon the exercise of outstanding options and 58,197 RSUs are issuable. As of December 31, 2023, 1,792,918 shares remain available for issuance through grants of future options.

In 2023, we awarded options to key employees (including our named executive officers) for retention, engagement and bonus compensation awards. These awards are designed to align a portion of our named executive officers' compensation with the interests of our existing stockholders and to build retention value by incentivizing our named executive officers to remain in our service.

As part of the Business Combination Agreement, the outstanding securities issuable under the 2018 Plan and 2022 Plan will be exchanged for shares of the Company's 2023 Long-Term Incentive Plan upon approval by the Company's stockholders at the next annual meeting. Information related to this item will be contained in our 2024 Proxy Statement under the heading "Proposal 2 – Ratification of the 2023 Long Term Incentive Plan.

Performance Graph

The performance graph has been omitted as permitted under rules applicable to smaller reporting companies.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Offerings

Unregistered Securities

Yorkville Standby Equity Purchase Agreement

On March 20, 2024, the Company entered into the Standby Equity Purchase Agreement ("SEPA") with YA II PN, LTD, a Cayman Islands exempt limited partnership ("Yorkville") pursuant to which the Company has the right to sell to Yorkville up to $30,000,000 of its shares of Common Stock, subject to certain limitations and conditions set forth in the SEPA, from time to time during the term of the SEPA (such transaction, the "Yorkville Transaction"). Sales of the shares of Common Stock to Yorkville under the SEPA, and the timing of any such sales, are at the Company's option, and the Company is under no obligation to sell any shares of Common Stock to Yorkville under the SEPA except in connection with notices that may be submitted by Yorkville, as described in the SEPA.

In connection with the SEPA, and subject to the conditions set forth therein, Yorkville has agreed to advance to the Company in the form of convertible promissory notes (the "Convertible Notes") an aggregate principal amount of up to $12,500,000 million (the "Pre-Paid Advance"), which will be paid in three tranches. The first Pre-Paid Advance was disbursed on March 20, 2024 in the amount of $5,000,000 with a fixed conversion price of $3.16, the second Pre-Paid Advance shall be in a principal amount of $5,000,000 and advanced after the earlier of the registration statement registering the resale of the shares of Common Stock issuable under the SEPA being declared effective and or shareholder approval to exceed the 19.99% threshold of the aggregate number of shares of Common Stock issued pursuant to the SEPA (the "Exchange Cap") with a fixed conversion price equal to 120% of the average VWAP during the three trading days immediately prior to the issuance of the note (the "Second Pre-Advance Closing"), and the third Pre-Paid Advance shall be in a principal amount of $2,500,000 and advanced sixty days following the Second Pre-Advance Closing with a fixed conversion price equal to 120% of the average VWAP during the three trading days immediately prior to the issuance of the note. The purchase price for the Pre-Paid Advance is 92.0% of the principal amount of the Pre-Paid Advance. Interest shall accrue on the outstanding balance of any Pre-Paid Advance at an annual rate equal to 0%, subject to an increase to 18% upon an event of default as described in the Convertible Notes. The maturity date of the Convertible Note issue in connection with each Pre-Paid Advance will be 12 months after the issuance date of such Convertible Note.

Beginning on the forty-fifth (45th) day following the issuance date of Convertible Note issued in connection with the first Pre-Paid Advance, and continuing on the same day of each successive month thereafter, (each, an "Installment Date"), the Company shall repay a portion of the outstanding balance of the Pre-Paid Advance in an amount equal to (i) $1,750,000, provided however, in respect of any Installment Date prior to the closing of the second Pre-Paid Advance, $750,000 (the "Installment Principal Amount"), plus (ii) the a payment premium of 7% of such Installment Principal Amount, and (iii) accrued and unpaid interest hereunder as of each Installment Date.

B. Riley Committed Equity Facility

On December 26, 2023, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with B. Riley Principal Capital II, LLC ("B. Riley"), pursuant to which, upon the terms and subject to the satisfaction of the conditions contained in the Purchase Agreement, we have the right, in our sole discretion, to sell to B. Riley up to $10,000,000 of shares of the Common Stock (subject to certain limitations contained in the Purchase Agreement), from time to time during the term of the Purchase Agreement through a Market Open Purchase or an Intraday Purchase on any Purchase Date (each term as defined in the Purchase Agreement). Sales of Common Stock pursuant to the Purchase Agreement, and the timing of any sales, are solely at our option, and we are under no obligation to sell any securities to B. Riley under the Purchase Agreement (such transaction, the "B. Riley Transaction").

Use of Proceeds

There has been no material change in the planned use of the proceeds from the Business Combination, as is described in the Company's final prospectus (Registration No. 333-275218), as filed with the SEC on January 2, 2024. Additionally, there has been no material change in the planned use of proceeds from the B. Riley Transaction or the Yorkville Transaction, as is described in the Company's final prospectus (Registration No. 333-2764-6), as filed with the SEC on February 1, 2024. For a description of the use of the proceeds generated from the different financings, see "Item 1. Business."

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K (the "Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are an AI company focused on predictive medical diagnostics. We operate in one segment. Currently, we are devoting substantially all of our efforts towards research and development of our DeepView System, an internally developed multi-spectral imaging ("MSI") device that has FDA breakthrough device designation ("BDD") status. Given our recent receipt of the UKCA mark for burn indication on our DeepView System, we expect to begin commercialization activities in the United Kingdom in the second half of 2024. Our DeepView System uses proprietary algorithms to distinguish between damaged and healthy human tissue invisible to the naked eye, providing "Day One" healing assessments. DeepView'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. Our focus from 2013 through 2021 was on the burn indication, which we expanded to also include the diabetic foot ulcer ("DFU") indication in 2022.

In the case of DFUs, our DeepView System provides an assessment in seconds as to the non-healing portions of a DFU. The non-healing assessment would provide the physician with an objective assessment 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 such clinical assessment.

For burn wounds, a non-healing assessment could aid the clinician in making an immediate and objective determination for appropriate candidates for surgery, as well as determining what specific areas of the burn wound will require excision and skin grafting. DeepView's current accuracy for burn wounds is 92% for adults and 88% for pediatrics, compared with current physician accuracy in evaluation of all burn wounds of 50% to 75%, respectively, at best, according to industry literature.[1] In addition, in head-to-head clinical trial evaluations, our DeepView System provided higher accuracy to "ground truth" on burn wound analysis than the accuracy of burn specialists, who reported 70-80% accuracy, or non-burn specialist physicians, who reported 50-60% accuracy.[2] We have conducted three large clinical studies with multiple sites across the United States, enrolling 413 burn patients, including 329 adult and 84 pediatric patients. Through these studies, we were able to quantify the burn assessment accuracy in both surgical and non-surgical treatment. Beginning in 2023, we have initiated a pivotal clinical study seeking enrollment of 240 patients, including 180 adult and 60 pediatric patients through multiple sites across the United States.

We have not generated any product revenue to date. We have received substantial support from the U.S. government for our DeepView System's application for burn wounds, particularly from the Biomedical Advanced Research and Development Authority ("BARDA"), which is part of the HHS Office of the Assistant Secretary for Preparedness and Response in the United States, established to aid in securing the United States from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases. We have also received funding from the National Science Foundation (the "NSF"), the National Institute of Health (the "NIH") and the Defense Health Agency (the "DHA"). Since 2013, we have received approximately $279.6 million in funding commitments from government contracts, primarily from BARDA, which accounts for $272.9 million. This has allowed us to develop our technology and further our clinical trials.

In September 2023, we executed our third contract with BARDA for a multi-year Project BioShield ("PBS") agreement, valued at up to approximately $150.0 million (the "PBS BARDA Contract"). This multi-year contract includes an initial award of nearly $54.9 million to support the clinical validation and FDA clearance of DeepView® for commercial marketing and distribution purposes, which we expect to continue through the first quarter of 2026. This grant funding is non-dilutive to our shareholders, and we believe it validates the important nature of our mission and technology.

In addition to our BARDA contract, we received a $4.0 million grant award from the Medical Technology Enterprise Consortium ("MTEC") in April 2023, which, building on prior awards from DHA, is to be used to support military battlefield burn evaluation via a handheld DeepView device (the "MTEC Agreement"). The MTEC Agreement is currently intended to run through April 2025 with funding dependent on various milestones.

Once commercialized, we anticipate that the DeepView System will have two revenue streams, a SaMD (software as a medical device) model, and an imaging device component. The SaMD model applies a SaaS (software as a service) treatment for the DeepView System which will feature a software licensing fee that includes maintenance, image hosting, and access to algorithm updates. The proprietary imaging device accesses 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.

Business Combination

On September 11, 2023, we consummated a business combination, pursuant to the business combination agreement dated April 11, 2023 (the "Business Combination Agreement") by and among the Company (previously, Rosecliff Acquisition Corp I ("Rosecliff")), Ghost Merger Sub I (a wholly owned subsidiary of Rosecliff), Ghost Merger Sub II (a wholly owned subsidiary of Rosecliff) and Spectral MD Holdings, Ltd. ("Legacy Spectral"). Upon the closing of the Business Combination (the "Closing"), in sequential order: (a) Ghost Merger Sub I merged with and into Legacy Spectral, with Legacy Spectral continuing as the surviving company as our wholly owned subsidiary (the "Spectral Merger") and then, (b) Legacy Spectral merged with and into Ghost Merger Sub II (the "SPAC Merger", together with the Spectral Merger (the "Business Combination")), with Ghost Merger Sub II (renamed Spectral MD Holdings LLC) surviving the SPAC Merger as our direct wholly-owned subsidiary. Upon the Closing, we changed our name from Rosecliff Acquisition Corp I to Spectral AI, Inc. In addition to our Common Stock, we currently have 8,433,333 redeemable warrants (the "Public Warrants") and 73,978 warrants ("Angel Warrants") to SP Angel Corporate Finance LLP ("SP Angel") remaining outstanding.

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1 Henk Hoeksema, Karlien Van de Sijpe, Thiery Tondu, Moustapha Hamdi, Koenraad Van Landuyt, Phillip Blondeel, Stan Monstrey, Accuracy of early burn depth assessment by laser Doppler imaging on different days post burn, Burns, Volume 35, Issue 1, 2009, Pages 36-45, ISSN 0305-4179. The above article was exploring laser doppler imaging as an objective technique to determine the depth of a burn wound and states "as has been demonstrated in several studies, a purely clinical, bedside evaluation of the burn depth in dermal burns is accurate only in about 50-75% of the cases."

2 Rise of the (Learning) Machines: An Interim Analysis Assessing Burn Wound Healing; Jeffrey E. Carter, MD, FACS, et.al., *https://clinicaltrials.gov/ct2/show/NCT05023135*.

On September 12, 2023, the Company began trading its shares of the Company Common Stock and the Public Warrants on the Nasdaq Global Market (the "Nasdaq") under the symbols "MDAI" and "MDAIW", respectively.

The Business Combination was accounted for as a reverse recapitalization in accordance with GAAP. Under the guidance in Accounting Standards Codification ("ASC") 805, Business Combinations, Rosecliff, which is the legal acquirer, has been treated as the "acquired" company for financial reporting purposes and the Company has been treated as the accounting acquirer. This determination was primarily based on the following:

(i) Legacy Spectral's former shareholders maintained a majority of the voting power of the Company;

(ii) Legacy Spectral's senior management comprises all of the senior management of the Company;

(iii) Legacy Spectral selected five of the six of the directors for the Board of Directors of the Company;

(iv) Legacy Spectral's relative size of assets and operations compared to Rosecliff; and

(v) Legacy Spectral's operations comprised the ongoing operations of the Company.

Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of a capital transaction in which Legacy Spectral issued stock for the net assets of Rosecliff prior to the Closing. Upon the Closing, the net assets of Rosecliff are stated at fair value, with no goodwill or other intangible assets recorded. All historical financial information presented in the consolidated financial statements represents the accounts of Legacy Spectral at their historical cost as if Legacy Spectral is the predecessor to the Company. Upon consummation of the Business Combination, Spectral AI has continued as an SEC-registered and Nasdaq-listed company. The consolidated financial statements following the Closing reflect the results of the Combined Company's operations.

Financial Operations Overview

Research and Development Revenue

To date we have not generated any revenues from the sale or license of our products. Our primary source of revenue is research and development revenue. Currently, we are highly dependent upon the reimbursements from BARDA for the burn diagnostic testing of our DeepView System and other U.S. government awards. Our research and development revenue is affected by the amount of research and development that is expended each month with respect to our contract with BARDA and other U.S. governmental contract awards, such as our grant under the MTEC Agreement which we earn based on the achievement of milestones. Our revenue growth is dependent upon a number of factors including expanding the research and development activities under the BARDA contract, research and development reimbursed expenses relating to other contract awards from U.S. governmental agencies and the intended future commercial sales of our DeepView System. See "Liquidity and Capital Resources" for additional information.

Cost of Revenue

Our cost of revenues consists primarily of direct and indirect costs associated with the research and development activities relating to the BARDA and MTEC contracts. Our cost of revenue is affected by the extent of research and development activities as well as expansion of work on other U.S. governmental projects and the expanded applications for our DeepView System.

Gross Profit

Gross profit may vary from period-to-period and is primarily affected by the current reimbursement rates under the BARDA contract and other U.S. governmental contract awards. These reimbursement rates are fixed under the BARDA contract. Under the BARDA contract our gross profit represents this reimbursement rate plus a fixed fee component relating to non-reimbursed expenses incurred in connection with the work completed. Under the other fixed fee U.S. governmental contract awards our gross profit corresponds to the achievement of pre-determined milestones.

Operating Expenses

Operating costs and expenses consist of general and administrative expenses. These expenses primarily relate to salaries and related costs of our organization's support and operations staff, consulting fees, rent, insurance and office expenses, and our non-revenue generating research and development expenses, primarily related to salaries and related costs and consulting fees.

Other Income (Expense)

Other income (expense) primarily consists of transaction costs, primarily related to the Business Combination, net interest income, change in fair value of warrant liabilities and foreign exchange transaction gains/losses. Historic foreign exchange transaction loss primarily relates to changes in the exchange rate between the U.S. dollar, the Euro and the British pound sterling for our deposit accounts that are denominated in British pound sterling. In addition, this amount includes costs associated with buying British pound sterling for payment of our employees and vendors in the UK.

Key Operating and Financial Metrics

We regularly review a number of metrics, including the following key operating and financial metrics, to evaluate our business, measure our performance, identify trends in our business, prepare financial projections and make strategic decisions. We believe the operating and financial metrics presented are useful in evaluating our operating performance, as they are similar to measures by our public competitors and are regularly used by security analysts, institutional investors, and other interested parties in analyzing operating performance and prospects. Adjusted EBITDA is a non-GAAP measure, as it is not a financial measure calculated in accordance with GAAP and should not be considered as a substitute for net (loss) income, calculated in accordance with GAAP. See "Non-GAAP Financial Measures" for additional information on adopted non-GAAP financial measures and a reconciliation of these non-GAAP measures to the most comparable GAAP measures.

Comparison of Years Ended December 31, 2023 and 2022

The following table summarizes these metrics for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	**2022**	**Change**
Research and development revenue	$ 18,056	$ 25,368	$ (7,312)
Gross profit	7,880	10,837	(2,957)
Gross margin	43.6%	42.7%	0.9%
Operating loss	(12,984)	(2,647)	(10,337)
Net loss	(20,854)	(2,912)	(17,942)
Adjusted EBITDA	(11,732)	(1,481)	(10,251)

See "Non-GAAP Financial Measures" below for a reconciliation of net loss to Adjusted EBITDA.

Research and Development Revenue

We define research and development revenue as revenue generated from the research, testing and development of our DeepView System as utilized in connection with our burn indication. This research and development revenue reflects applied research and experimental development costs relating to our burn application as developed in connection with our BARDA, MTEC and DHA contracts.

Gross Profit and Gross Margin

We define gross profit as research and development revenue, less cost of revenue, and define gross margin, expressed as a percentage, as the ratio of gross profit to revenue. Gross profit and gross margin can be used to understand our financial performance and efficiency and as we begin commercialization, it will allow investors to evaluate our pricing strategy and compare against our competitors. Our management uses these metrics to make strategic decisions, pricing decisions, identifying areas for improvement, set targets for future performance and make informed decisions about how to allocate resources going forward.

Adjusted EBITDA

We define adjusted earnings before interest, tax, depreciation and amortization ("Adjusted EBITDA") as net loss excluding income taxes, depreciation of property and equipment, net interest income, stock compensation, transaction costs and any non-operating financial income and expense. See "Non-GAAP Financial Measures" for a reconciliation of GAAP net loss to Adjusted EBITDA.

Key Factors that May Influence Future Results of Operations

Our financial results of operations may not be comparable from period to period due to several factors. Key factors affecting our results of operations are summarized below.

Revenue Sources. As a pre-commercialization company, we currently generate revenue almost exclusively from two U.S. governmental agencies. We are highly dependent upon the continuation of the existing U.S. governmental contract awards, as well as future governmental procurement or other awards. Our operating results may not be comparable between periods as the timing and amount of awards or procurements from the U.S. government may be inconsistent with the timing of prior awards and the phasing of the development study schedules may be different. Our revenues may continue to be almost exclusively dependent upon the terms of those awards.

Gross Margin. When we begin commercial sales of the DeepView System, we may need to determine lower pricing and incentives to accelerate adoption and implementation of the DeepView System, which may negatively impact future revenue and gross margin percentages.

Managing our Supply Chain. We are reliant on contract manufacturers and suppliers to produce our components. While we have not been subject to any disruptions in our current limited production, we may be subject to component shortages, which may cause delays in critical components and inventory, longer lead times, increased costs and delays in product shipments. Our ability to grow depends, in part, on the ability of our contract manufacturers and suppliers to provide high quality services and deliver components and finished products on time and at reasonable costs. While we do not maintain sole-source suppliers, there is a concentration of suppliers which could lead to supply shortages, long lead times for components and supply changes. In the event we are unable to mitigate the impact of delays and/or price increases in raw materials, electronic components and freight, it could delay the manufacturing and installation of our products, which would adversely impact our cash flows and results of operations, including revenue and gross margin.

Results of Operations

The following table summarizes of our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Research and development revenue	$ 18,056	$ 25,368	$ (7,312)
Cost of revenue	(10,176)	(14,531)	4,355
Gross profit	7,880	10,837	(2,957)
Operating costs and expenses:			
General and administrative	20,864	13,484	7,380
Total operating costs and expenses	20,864	13,484	7,380
Operating loss	(12,984)	(2,647)	(10,337)
Other income (expense):			
Net interest income	172	21	151
Change in fair value of warrant liability	335	57	278
Foreign exchange transaction loss	(24)	(237)	213
Transaction costs	(8,342)	-	(8,342)
Total other expense, net	(7,859)	(159)	(7,700)
Loss before income taxes	(20,843)	(2,806)	(18,037)
Income tax provision	(11)	(106)	95
Net loss	$ (20,854)	$ (2,912)	$ (17,942)

Research and development revenue

	Year Ended December 31,		Change in	
	2023	2022	$	%
Research and development revenue	$ 18,056	$ 25,368	$ (7,312)	(28.8)%

Research and development revenue was $18.1 million, for the year ended December 31, 2023, a decrease of 28.8% compared to the comparable period in 2022, reflecting less activity as we completed work under the BARDA Burn II contact. Additionally, we initiated work on the BARDA PBS contract in the fourth quarter of 2023.

For the year ended December 31, 2023 and 2022, the Company's revenues disaggregated by the major sources was as follows:

	Year Ended December 31,		Change in	
	2023	2022	$	%
BARDA	$ 17,027	$ 24,827	$ (7,800)	(31.4)%
Other U.S. governmental authorities	1,029	541	488	90.2%
Total research and development revenue	$ 18,056	$ 25,368	$ (7,312)	(28.8)%

Cost of Revenues and Gross Profit

	Year Ended December 31,		Change in	
	2023	2022	$	%
Cost of revenue	$ 10,176	$ 14,531	$ (4,355)	(30.0)%
Gross profit	7,880	10,837	(2,957)	(27.3)%
Gross margin	43.6%	42.7%		

Cost of revenue for the year ended December 31, 2023 was $10.2 million, a decrease of 30.0% compared to the comparable period in 2022, due to decreased activity to fulfill our U.S. governmental contracts, consistent with decreased research and development revenue.

Gross margin for the year ended December 31, 2023 was 43.6%, an increase of 0.9% as compared to the comparable period in 2022. The reimbursement rate under the BARDA PBS Contract, executed in September 2023, is higher than the rate in the BARDA Burn II contact.

General and Administrative Expense

	Year Ended December 31,		Change in	
	2023	2022	$	%
General and administrative expense	$ 20,864	$ 13,484	$ 7,380	54.7%

General and administrative expense was $20.9 million, for the year ended December 31, 2023, an increase of 54.7% as compared to the comparable period in 2022. The increase reflects. our headcount growth from 71 employees as of December 31, 2022 to 78 full-time employees as of December 31, 2023. Increased personnel cost in general and administrative expense was approximately $3.8 million for the year ended December 31, 2023. Additionally, non-revenue generating research and development activities, primarily related to salaries and related costs and consulting fees, have increased by approximately $3.3 million for the year ended December 31, 2023 compared to the comparable period in 2022.

Other income (expense)

	Year Ended December 31,		Change in
	2023	2022	$
Net interest income	$ 172	$ 21	$ 151
Change in fair value of warrant liability	335	57	278
Foreign exchange transaction loss	(24)	(237)	213
Transaction costs	(8,342)	-	(8,342)
Total other expense, net	$ (7,859)	$ (159)	$ (7,700)

Net interest income for the year ended December 31, 2023 primarily relates to cash interest received by us from our deposit accounts.

Change in fair value of warrant liability increased by approximately $0.3 million for the year ended December 31, 2023 as compared to the comparable period in 2022. The decrease reflects changes in the fair value of the Public Warrants from the closing of the Business Combination in September 2023.

Foreign exchange transaction loss for year ended December 31, 2023 is immaterial due to lower balances in our deposit accounts and accounts payable denominated in British pound sterling and less fluctuation in the exchange rate between the U.S. dollar and the British pound sterling. Foreign exchange transaction loss for the year ended December 31, 2022 relates to the decreased exchange rate between the U.S. dollar and the British pound sterling during 2022 for our deposit accounts that are denominated in British pound sterling. In addition, this amount includes costs associated with buying British pound sterling for payment of our employees and vendors in the UK.

Transaction costs for the year ended December 31, 2023 primarily relate to non-recurring legal, accounting, and consulting costs expended for the Business Combination.

Non-GAAP Financial Measures

We use Adjusted EBITDA as a non-GAAP metric when measuring performance, including when measuring current period results against prior periods' Adjusted EBITDA. This non-GAAP financial measure should be considered in addition to results prepared in accordance with GAAP and should not be considered as a substitute for, or superior to, GAAP results. In addition, Adjusted EBITDA should not be construed as an indicator of our operating performance, liquidity or cash flows generated by operating, investing and financing activities, as there may be significant factors or trends that it fails to address.

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. We caution investors that non-GAAP financial information, by its nature, departs from traditional accounting conventions. Supplemental non-GAAP measures are presented solely to permit investors to more fully understand how Spectral AI's management assesses underlying performance.

Adjusted EBITDA

We define Adjusted EBITDA as net loss excluding income taxes, depreciation of property and equipment, net interest income, stock compensation, transaction costs and any non-operating financial income and expense.

The following table presents our Adjusted EBITDA for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (20,854)	$ (2,912)
Adjust:		
Depreciation expense	9	11
Provision for income taxes	13	106
Net interest income	(172)	(21)
EBITDA	**(20,789)**	**(2,816)**
Additional adjustments:		
Stock-based compensation	1,243	1,155
Change in fair value of warrant liability	(335)	(57)
Foreign exchange transaction loss	24	237
Transaction costs	8,342	-
Adjusted EBITDA	**$ (11,732)**	**$ (1,481)**

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2023 we had approximately $4.8 million in cash, notes payable of $0.4 million and no long-term debt. We had an accumulated deficit of approximately $32.8 million. Additionally, on December 26, 2023, we entered into a Common Stock Purchase Agreement and related Registration Rights Agreement with B. Riley Principal Capital II, LLC. Upon the terms and subject to the satisfaction of the conditions set forth in the Common Stock Purchase Agreement, the Company has the right, in our sole discretion, to sell to B. Riley Capital II up to $10.0 million in aggregate gross purchase price of newly issued shares of the Company's Common Stock (the "ELOC"). On March 20, 2024, the Company also entered into a Standby Equity Purchase Agreement ("SEPA") with YA II PN, LTD, a Cayman Islands exempt limited partnership ("Yorkville") pursuant to which the Company has the right to sell to Yorkville up to $30.0 million of its shares of Common Stock, subject to certain limitations and conditions set forth in the SEPA. In connection with the SEPA, and subject to the conditions set forth therein, Yorkville has agreed to advance to the Company in the form of convertible promissory notes an aggregate principal amount of up to $12.5 million (the "Pre-Paid Advance"), which will be paid in three tranches. The first Pre-Paid Advance was disbursed on March 20, 2024 in the amount of $5.0 million with a fixed conversion price of $3.16, the second Pre-Paid Advance shall be in a principal amount of $5.0 million and advanced after the earlier of the registration statement registering the resale of the shares of Common Stock issuable under the SEPA being declared effective and or shareholder approval to exceed the 19.99% threshold of the aggregate number of shares of Common Stock issued pursuant to the SEPA (the "Exchange Cap") (the "Second Pre-Advance Closing"), and the third Pre-Paid Advance shall be in a principal amount of $2.5 million and advanced sixty days following the Second Pre-Advance Closing. The Company is authorized to drawdown an additional $3.0 million from the ELOC prior to utilizing the SEPA.

We have historically funded our operations through the issuance of notes and the sale of preferred stock and common stock, along with payments under governmental contracts for research and development activity.

The new PBS BARDA Contract, executed in September 2023, has a total value of up to approximately $150.0 million if all future options are executed. The base phase of the PBS BARDA Contract, valued at $54.9 million, was exercised concurrently with the contract award in September 2023. To date, our total potential support from BARDA is nearly $251.0 million for our 2013, 2019, and 2023 awards. In April 2023, we received a $4.0 million grant under the MTEC Agreement. See "*Research and Development Revenue*" above. With the PBS BARDA Contract, the ELOC and funding available through the SEPA, 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.

Our future capital requirements will depend on many factors, including the revenue growth rate, the success of future product development and capital investment required, and the timing and extent of spending to support further sales and marketing and research and development efforts. In addition, we expect to incur additional costs as a result of operating as a U.S. public company. There can be no assurance that we will be successful in raising any additional capital. If additional financing is required from outside sources, we cannot be sure that any additional financing will be available to us on acceptable terms, if at all. If we are unable to raise additional capital when desired, our business, operating results, and financial condition could be adversely affected.

Cash Flows

The following table summarizes our cash flows for the year ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (13,240)	$ (1,162)
Net cash provided by (used in) financing activities	3,844	(785)

Cash Flows Used in Operating Activities

Net cash used in operating activities increased by approximately $12.1 million for the year ended December 31, 2023, as compared to the year ended December 31, 2022 primarily driven by (a) increased spending on general and administrative expenses of approximately $3.6 million for our increased staff and approximately $3.3 million for our higher non-revenue generating research and development costs, (b) decreased gross profit of approximately $2.7 million from less research and development work performed pursuant to the BARDA Burn II contract as clinical trials under this contract were nearing completion, partially offset by cash receipts in excess of cash payments, and (c) cash paid for transaction costs for the Business Combination of $0.8 million.

Cash Flows Provided by (Used in) Financing Activities

Net cash provided by financing activities increased approximately $4.6 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. This was primarily attributable to the proceeds of $3.4 million from the Equity Raise and operating cash received upon the Closing of the Business Combination of $0.7 million.

Current Indebtedness

In September 2023, we entered into a financing arrangement for a portion of our insurance premium for approximately $0.6 million (the "Note"). The Note bears interest at 8.6% per annum and is payable in equal monthly payments of principal and interest, maturing in June 2024. As of December 31, 2023, we owed $0.4 million for the Note.

Related Party Transactions

For the years ended December 31, 2023 and 2022, we did not have any transactions with related parties.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Critical Accounting Policies

There have been no material changes to the Company's critical accounting policies and estimates discussed in Legacy Spectral's Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies for the years ended December 31, 2022 and 2021 included in the Prospectus.

Our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report. We believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary.

Determination of the Fair Value of Equity-Based Awards

We measure stock options and other stock-based awards granted to directors, employees, and non-employees based on their fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have only issued stock options, restricted stock awards and restricted stock units with time-based vesting conditions and record the expense for these awards using the ratable method. We determine the fair value of restricted stock awards granted based on the fair value of our common stock. We estimate the fair value of stock option awards granted using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and subjective assumptions we make, including the expected stock price volatility, the expected term of the award, the risk-free interest rate and expected dividends.

Due to insufficient trade history of our common stock, we are unable to estimate the future volatility of our share price and instead estimate our expected volatility from the historical volatility of a representative group of publicly traded companies for which historical information is available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumption. We use the simplified method to calculate the expected term for options granted to employees and directors, which is based on the average of the time-to-vesting and the contractual life of the options. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For grants to non-employees, ASU 2018-07 allows entities to use the expected term to measure non-employee options or elect to use the contractual term as the expected term, on an award-by-award basis. The risk-free interest rate is based on a U.S. treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on our common stock.

See Note 11 to our audited consolidated financial statements included elsewhere in this Annual Report for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2023 and 2022.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, of the notes to our consolidated financial statements included elsewhere in this Form 10-K for recently adopted accounting standards and recently issued accounting standards as of the dates of the statement of financial position included in this Form 10-K.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period under the JOBS Act for the adoption of certain accounting standards until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply more promptly with new or revised accounting pronouncements as of public company effective dates.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited consolidated financial statements in addition to any required unaudited interim consolidated financial statements, with correspondingly reduced disclosure in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations";

- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;

- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and

We may take advantage of these provisions until the last day of the fiscal year ending after the fifth anniversary of Rosecliff's initial public offering or such earlier time that we no longer qualify as an emerging growth company. We will cease to qualify as an emerging growth company on the date that is the earliest of: (i) December 31, 2026; (ii) the last day of the fiscal year in which we have more than $1.235 billion in total annual gross revenues; (iii) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th and we have been a public company for at least 12 months and have filed one annual report on Form 10-K; or (iv) the date on which we have issued more than $1.0 billion of non-convertible debt over the prior three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. Accordingly, the information contained herein may be different than you might obtain from other public companies in which you hold equity interests.

We are also a "smaller reporting company." If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7.A. Quantitative and Qualitative Disclosures about Market Risk

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9.A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this Annual Report on Form 10-K. Based on management's evaluation as of the year ended December 31, 2023, our Chief Executive Officer and Chief Financial Officer have concluded that, as a result of the material weaknesses in our internal control over financial reporting as described below and in Part II, Item 1A. Risk Factors, our disclosure controls and procedures were not effective as of December 31, 2023. In connection with the preparation of our consolidated financial statements for the year ended December 31, 2023, we identified material weaknesses in: (i) lack of communication within management and internal departments regarding complex and unusual arrangements. This resulted in communication failures of relevant facts necessary for the accounting group to properly conclude and apply the required accounting treatment of certain stock transactions; (ii) the Company did not maintain adequately designed controls to ensure the proper recording of operating expenses, related accruals and unbilled revenue in the correct period. As a result, certain control activities in the accrual and unbilled revenue processes were not designed and implemented effectively; and (iii) our financial statement close process controls which relate to all financial statement accounts, did not consistently operate effectively or lacked appropriate evidence, to ensure account reconciliations, transactions, and journal entries were performed or reviewed at the appropriate level of precision and on a timely basis. These control deficiencies could result in a material misstatement of our accounts or disclosures that would not be prevented or detected on a timely basis, and accordingly, we determined that these control deficiencies in aggregate constitute a material weakness.

Notwithstanding the identified material weaknesses, our management believes that the condensed consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with U.S. GAAP.

Remediation Plan for Material Weaknesses

Remediation generally requires making changes to how controls are designed and implemented and then adhering to those changes for a sufficient period of time such that the effectiveness of those changes is demonstrated with an appropriate amount of consistency. In response to the material weaknesses, we implemented, and are continuing to implement, measures designed to improve our internal control over financial reporting. These efforts include:

- engaging a professional accounting services firm to help us assess and commence documentation of our internal controls for complying with the Sarbanes-Oxley Act of 2002;

- strengthening, formalizing, documenting and testing accounting processes and internal controls, specifically regarding accrued expenses and contract reviews and improving the information flow throughout the organization to allow for timely communication of new agreements and transactions;

- enhancing functionality of our enterprise resource planning system to support certain key financial processes and controls and enforce certain segregation of duties through automation and approval workflows.

The measures we are implementing are subject to continued management review supported by confirmation and testing, as well as audit committee oversight. Management and the Audit Committee remain committed to the implementation of remediation efforts to address the material weaknesses. We will continue to implement measures to remedy our internal control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. In addition, until remediation steps have been completed and are operated for a sufficient period of time, and subsequent evaluation of their effectiveness is completed, the material weaknesses previously disclosed, and as described above, will continue to exist.

Management's Annual Report on Internal Control over Financial Reporting

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated 2013 Framework.

Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was not effective at the reasonable assurance level, due to the material weaknesses outlined above.

We believe progress was made in 2023 to enhance and strengthen our internal control over financial reporting. The measures we are implementing are subject to continued management review supported by confirmation and testing, as well as audit committee oversight. Management remains committed to remediating these material weaknesses. We will continue to implement measures to remedy our internal control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

Except for the remediation efforts in connection with the material weaknesses described above, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the year ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9.B. Other Information.

None.

Item 9.C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection.

Not Applicable.

PART III.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is set forth under the captions "Executive Officers of the Registrant", "Proposal No. 1 – Election of Directors" and "Board of Directors and Committees" in our Definitive Proxy Statement with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have opted to comply with the scaled disclosure requirements applicable to emerging growth companies.

The information required by this Item 11 is set forth under the caption "Executive Officer and Director Compensation" in our Definitive Proxy Statement with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 is set forth under the captions "Share Ownership" and "Outstanding Equity Awards at Fiscal Year End 2023" in our Definitive Proxy Statement with respect to our 2024 Annual Meeting of Stockholders and is incorporated by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 is set forth under the captions "Certain Relationships and Related Transactions" and "Board of Directors and Committees" in our Definitive Proxy Statement with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be set forth under the caption "Proposal No. 3: Ratification of Independent Registered Public Accounting Firm" in our Definitive Proxy Statement with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV.

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

SPECTRAL AI, INC.
INDEX TO FINANCIAL STATEMENTS

KPMG LLP
Suite 1400
2323 Ross Avenue
Dallas, TX 75201-2721

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Spectral AI, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Spectral AI, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

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. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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
March 29, 2024

SPECTRAL AI, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 4,790	$ 14,174
Accounts receivable, net	2,346	2,294
Inventory	230	-
Unbilled revenue	-	618
Deferred offering costs	283	-
Prepaid expenses	1,452	331
Other current assets	801	270
Total current assets	9,902	17,687
Non-current assets:		
Property and equipment, net	12	21
Right-of-use assets	778	1,008
Total Assets	$ 10,692	$ 18,716
Commitments and contingencies (Note 8)		
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,683	$ 2,759
Accrued expenses	4,300	2,631
Deferred revenue	2,311	-
Lease liabilities, short-term	853	680
Notes payable	436	175
Warrant liabilities	1,818	129
Total current liabilities	12,401	6,374
Lease liabilities, long-term	-	346
Total Liabilities	12,401	6,720
Stockholders' Equity (Deficit)		
Preferred stock ($0.0001 par value); 1,000,000 shares authorized; no shares issued and outstanding as of December 31, 2023 and December 31, 2022	-	-
Common stock ($0.0001 par value); 80,000,000 shares authorized; 16,294,935 and 13,170,148 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	2	1
Additional paid-in capital	31,065	23,929
Accumulated other comprehensive income	12	-
Accumulated deficit	(32,788)	(11,934)
Total Stockholders' Equity (Deficit)	(1,709)	11,996
Total Liabilities and Stockholders' Equity (Deficit)	$ 10,692	$ 18,716

The accompanying notes are an integral part of these consolidated financial statements

SPECTRAL AI, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Research and development revenue	$ 18,056	$ 25,368
Cost of revenue	(10,176)	(14,531)
Gross profit	7,880	10,837
Operating costs and expenses:		
General and administrative	20,864	13,484
Total operating costs and expenses	20,864	13,484
Operating loss	(12,984)	(2,647)
Other income (expense):		
Net interest income	172	21
Change in fair value of warrant liability	335	57
Foreign exchange transaction loss, net	(24)	(237)
Transaction costs	(8,342)	-
Total other expense, net	(7,859)	(159)
Loss before income taxes	(20,843)	(2,806)
Income tax provision	(11)	(106)
Net loss	$ (20,854)	$ (2,912)
Net loss per share of common stock		
Basic and Diluted	$ (1.48)	$ (0.22)
Weighted-average common shares outstanding		
Basic and Diluted	14,087,586	13,136,965
Other comprehensive income:		
Foreign currency translation adjustments	$ 12	$ -
Total comprehensive loss	$ (20,842)	$ (2,912)

The accompanying notes are an integral part of these consolidated financial statements

SPECTRAL AI, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	135,034,564	$ 135	$ 22,640	$ -	$ (9,022)	$ 13,753
Retroactive application of recapitalization	(121,937,160)	(134)	134	-	-	-
Balance at December 31, 2021, after effect of Business Combination	13,097,404	1	22,774	-	(9,022)	13,753
Stock-based compensation	72,744	-	1,155	-	-	1,155
Net loss	-	-	-	-	(2,912)	(2,912)
Balance at December 31, 2022	13,170,148	$ 1	$ 23,929	$ -	$ (11,934)	$ 11,996
Issuance of common stock upon Business Combination	1,154,173	1	(2,375)	-	-	(2,374)
Issuance of common stock to settle accounts payable	33,333	-	150	-	-	150
Issuance of shares for transaction costs	966,667	-	4,350	-	-	4,350
Private placement equity issuance	744,667	-	3,351	-	-	3,351
Financing equity issuance	40,000	-	101	-	-	101
Stock-based compensation	30,318	-	1,243	-	-	1,243
Stock option exercises	155,629	-	316	-	-	316
Cumulative translation adjustment	-	-	-	12	-	12
Net loss	-	-	-	-	(20,854)	(20,854)
Balance at December 31, 2023	16,294,935	$ 2	$ 31,065	$ 12	$ (32,788)	$ (1,709)

The accompanying notes are an integral part of these consolidated financial statements

SPECTRAL AI, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (20,854)	$ (2,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	9	11
Stock-based compensation	1,243	1,155
Amortization of right-of-use assets	713	557
Issuance of shares for transaction costs	4,350	-
Change in fair value of warrant liabilities	(335)	(57)
Changes in operating assets and liabilities:		
Accounts receivable	(52)	(859)
Inventory	(230)	-
Unbilled revenue	618	(547)
Prepaid expenses	(377)	615
Other assets	(404)	40
Accounts payable	(935)	1,345
Accrued expenses	1,359	51
Deferred revenue	2,311	-
Lease liabilities	(656)	(561)
Net cash used in operating activities	(13,240)	(1,162)
Cash flows from financing activities:		
Proceeds from issuance of common stock for Equity Raise	3,351	-
Cash received in Business Combination	660	-
Payments for notes payable	(483)	(785)
Stock option exercises	316	-
Net cash provided by (used in) financing activities	3,844	(785)
Effect of exchange rate changes on cash	12	-
Net decrease in cash	(9,384)	(1,947)
Cash, beginning of period	14,174	16,121
Cash, end of period	$ 4,790	$ 14,174
Supplemental cash flow information:		
Cash paid for interest	$ 29	$ 23
Cash paid for taxes	$ 114	$ 53
Noncash operating and financing activities disclosure:		
Recognition of Right-of-use assets and related lease liabilities upon adoption of ASC 842	$ -	$ 610
Recognition of Right-of-use assets and related lease liabilities upon lease amendment	$ 483	$ 955
Issuance of common stock for net liabilities upon Business Combination	$ 3,034	$ -
Prepaid asset acquired, net of cancellation, for debt and accounts payable	$ 744	$ 376
Issuance of common stock to settle accounts payable	$ 150	$ -
Deferred offering costs included in accrued expenses	$ 182	$ -
Issuance of common stock to settle deferred offering costs	$ 101	$ -

1. NATURE OF THE BUSINESS

Business Combination

Spectral AI, Inc., a Delaware corporation formerly known as Rosecliff Acquisition Corp I ("Spectral AI" or the "Company") was formed as a blank check company on November 17, 2020. The Company was formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses.

On September 11, 2023, the Company consummated a business combination (the "Business Combination"), pursuant to the business combination agreement dated April 11, 2023 (the "Business Combination Agreement") by and among the Company, Ghost Merger Sub I, a Delaware Corporation, Ghost Merger Sub II, a Delaware corporation and Spectral MD Holdings, Ltd., a Delaware corporation incorporated on March 9, 2009 and headquartered in Dallas, Texas ("Legacy Spectral"). Upon closing of the Business Combination (the "Closing"), in sequential order: (a) Ghost Merger Sub I merged with and into the Legacy Spectral, with Legacy Spectral continuing as the surviving company as a wholly owned subsidiary of the Company (the "Spectral Merger") and then, (b) Legacy Spectral merged with and into Ghost Merger Sub II (renamed Spectral MD Holdings LLC) (the "SPAC Merger", together with the Spectral Merger (the "Business Combination")), with Ghost Merger Sub II surviving the SPAC Merger as a direct wholly-owned subsidiary of the Company. See Note 3. Upon the Closing, the Company changed its name from Rosecliff Acquisition Corp I to Spectral AI, Inc.

In conjunction with the Business Combination, the Company cancelled the redeemable warrants that it issued to Rosecliff Acquisition Sponsor I LLC, a Delaware limited liability company (the "Sponsor"), in a private placement (the "Private Warrants") in connection with the Company's initial public offering on February 17, 2021 (the "Initial Public Offering") at Closing, but the 8,433,333 redeemable warrants issued to the public in the Initial Public Offering (the "Public Warrants") remain outstanding.

Prior to the Business Combination, Rosecliff Acquisition Corp I ("Rosecliff") had 280,485 shares of Class A common stock, par value $0.0001 per share, issued and outstanding and held by public shareholders (the "Public Shares") and 6,325,000 shares of Class B common stock, par value $0.0001 per share, issued and outstanding and held by the Sponsor (the "Sponsor Shares"). Upon the Closing, 5,445,000 of the Sponsor Shares were forfeited, in accordance with a letter agreement with the Sponsor, and the remaining 880,000 Sponsor Shares and 280,485 Public Shares, no longer designated Class A and Class B, were included in shares of the Company's common stock, par value $0.0001 per share (the "Company Common Stock").

Prior to the Business Combination, Legacy Spectral's shares of common stock, par value $0.001 per share ("Legacy Spectral Common Stock") were listed on the AIM market on the London Stock Exchange (delisted on September 7, 2023). In September 2023, prior to the Closing, Legacy Spectral issued 7,679,198 shares of Legacy Spectral Common Stock to certain investors in a private placement, in exchange for $3.4 million (the "Equity Raise").Upon the Closing, all of Legacy Spectral's issued and outstanding 145,380,871 shares of Legacy Spectral Common Stock, including the shares from the Equity Raise, were exchanged for 14,094,450 shares of Company Common Stock at an exchange ratio of 10.31 (the "Exchange Ratio"), meaning that the Company issued one share of Company Common Stock in exchange for 10.31 shares of Legacy Spectral Common Stock.

On September 12, 2023, the Company began trading the Company Common Stock and the Public Warrants on the NASDAQ Capital Market ("NASDAQ") under the symbols "MDAI" and "MDAIW", respectively. Prior to the Business Combination, the Company's shares of Company Common Stock and Public Warrants were listed on the NASDAQ under the symbols "RCLF" and "RCLFW", respectively.

Nature of Operations

Spectral AI is devoting substantially all of its efforts towards research and development of its DeepView® Wound Imaging System, currently focused on burn wounds and diabetic foot ulcer ("DFU") indications, specifically engineered to allow physicians to make a more accurate, timely and informed decision for treatment options. 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") and under a contract with Medical Technology Enterprise Consortium ("MTEC").

In September 2023, the Company executed its third contract with BARDA for a multi-year Project BioShield ("PBS") contract, valued at up to approximately $150.0 million. This multi-year contract includes an initial award of nearly $54.9 million to support the clinical validation and FDA clearance of DeepView® for commercial marketing and distribution purposes. The Company completed the second contract with BARDA, referred to as BARDA Burn II, which was signed in July 2019 and completed in November 2023. Under this contract, the Company furthered the DeepView System design, developed the AI algorithm, and took steps to obtain FDA approval for its DeepView GEN 3 System.

In April, 2023, the Company received a $4.0 million grant from MTEC for a project that is expected to be completed by April 2025 (the "MTEC Agreement"). The MTEC project is for the development of a handheld device for the DeepView System which is to be used to support military battlefield burn evaluation. The project has three phases, beginning with planning, design and testing; followed by development, design modification and buildout of the handheld device; and then the manufacturing of the handheld device.

The Company operates in one segment.

Risks and Uncertainties

The Company is subject to a number of risks common to development stage companies in the medical technology industry, including, but not limited to, risks of failure of preclinical studies and clinical trials, dependence on key personnel, protection of proprietary technology, reliance on third party organizations, risks of obtaining regulatory approval for any products that it may develop, development by competitors of technological innovations, compliance with government regulations and the need to obtain additional financing.

Liquidity

As of December 31, 2023 and December 31, 2022, the Company had approximately $4.8 million and $14.2 million, respectively, in cash, and an accumulated deficit of $32.8 million and $11.9 million, respectively. The Company has historically funded its operations through the issuance of notes and the sale of preferred stock and common stock. In December 2023, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") and a related Registration Rights Agreement (the "Registration Rights Agreement"), each dated as of December 26, 2023, with B. Riley Principal Capital II, LLC ("B. Riley Principal Capital II"). Upon the terms and subject to the satisfaction of the conditions set forth in the Purchase Agreement, the Company will have the right, in its sole discretion, to sell to B. Riley Principal Capital II up to $10.0 million in aggregate gross purchase price of newly issued shares of the Company's common stock, par value $0.0001 per share (the "B. Riley Common Stock"). This amount of newly issued shares is subject to the 19.99% threshold of the aggregate number of shares of Common Stock issued pursuant to the relative agreement (the "Exchange Cap"), unless approval of the Company's shareholders is otherwise received. Together with the new PBS BARDA Contract, executed in September 2023, for a total value of up to approximately $150.0 million, the Company's total potential support from BARDA is nearly $251.0 million if all future options are executed. The base phase of the PBS BARDA Contract, valued at $54.9 million, was exercised concurrently with the contract award in September 2023. To date, for the 2013, 2019, and 2023 BARDA contracts, the Company has committed funding of $155.9 million of which the Company has received $106.5 million. In April 2023, the Company received a $4.0 million grant under the MTEC Agreement.

In March 2024, the Company entered into a Standby Equity Purchase Agreement ("SEPA") with YA II PN, Ltd. ("Yorkville"), whereby the Company has the right, but not the obligation, to sell to Yorkville up to $30.0 million of Common Stock. This amount of newly issued shares is subject to the Exchange Cap (as previously defined), unless approval of the Company's shareholders is otherwise received. In connection with the SEPA, Yorkville has agreed to a prepaid advance of $12.5 million (the "Pre-Paid Advance"), $5.0 million of which was funded on March 20, 2024 with a fixed conversion price of $3.16 for newly issued shares of the Company's Common Stock, par value $0.0001 per share ("Yorkville Common Stock"). The Purchase Price for the Pre-Paid Advance is 92.0% of the principal amount of the Pre-Paid Advance.

With the PBS BARDA Contract, the MTEC Agreement, the B. Riley financing, and the Yorkville financing, 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

The Business Combination was accounted for as a reverse recapitalization in accordance with GAAP. Legacy Spectral was determined as the accounting acquirer and the Company as the acquired company for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination is treated as the equivalent of a capital transaction in which Legacy Spectral issued stock for the net assets of the Company. Upon the Closing, the net assets of the Company are stated at fair value, with no goodwill or other intangible assets recorded. See Note 3.

Legacy Spectral was determined to be the accounting acquiror based on evaluation of the following facts and circumstances:

(i) Legacy Spectral's former shareholders have a majority of the voting power of Spectral AI;

(ii) Legacy Spectral's senior management comprises all of the senior management of Spectral AI;

(iii) Legacy Spectral selected five of the six directors for the Board of Directors of Spectral AI;

(iv) Legacy Spectral's relative size of assets and operations compared to Rosecliff; and

(v) Legacy Spectral's operations comprise the ongoing operations of Spectral AI.

All historical financial information presented in the consolidated financial statements represents the accounts of Legacy Spectral at their historical values as if Legacy Spectral is the predecessor to the Company. The consolidated financial statements following the Closing reflect the results of the combined entity's operations.

All issued and outstanding shares of Legacy Spectral Common Stock and warrants, stock options, restricted stock units ("RSUs") and restricted stock awards ("RSAs") of Legacy Spectral and the per share amounts contained in the consolidated financial statements for the periods presented prior to the Closing have been retroactively restated to reflect the Exchange Ratio (as defined in Note 1).

Principles of Consolidation

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

Use of Estimates

The preparation of the 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 liabilities, stock-based compensation expense, stock issued for transaction costs, the net realizable value of inventory, right-of-use assets and income tax valuation allowances. Actual results could differ from these estimates.

Segments

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on an aggregate basis for the purpose of allocating resources.

Cash

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash is held in US, UK, & Ireland 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.

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, 2023 and December 31, 2022.

Certain third-party costs that are prepaid per the terms of the contract are billable to customers prior to recognition of related expenses. The Company records deferred revenue when the customers have been billed prior to recognizing revenue. The Company records unbilled revenue when revenue is recognized prior to billing customers.

Comprehensive Loss

Comprehensive loss includes net loss, as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash and accounts receivable. Primarily all cash is 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.

Additional credit risk is related to the Company's concentration of receivables. As of December 31, 2023 and December 31, 2022, receivables were concentrated from one customer (which is a US. government agency) representing 92% and 96% of total net receivables, respectively. No allowance for doubtful accounts were recorded as of December 31, 2023 and December 31, 2022.

One customer (which is a U.S. government agency) accounted for 95% for the year ended December 31, 2023 and 98% for the year ended December 31, 2022 of the recognized research and development revenue.

Inventory

Inventory is comprised of finished goods, purchased from a third-party manufacturer, and is stated at the lower of cost (average cost) or net realizable value. For the year ended December 31, 2023, the Company did not have write-downs for obsolete inventory.

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).

Foreign Currency

The reporting currency for the consolidated financial statements of the Company is the US dollar. The functional currency of the Company and its wholly owned subsidiaries Spectral MD Holdings LLC and Spectral MD, Inc. is the US dollar. The functional currency of Spectral MD UK is its local currency, the British pound. The functional currency of Spectral DeepView Ltd. is its local currency, the Euro. The assets and liabilities of Spectral MD UK and Spectral DeepView Ltd, are translated into US. dollars at exchange rates in effect at the end of each reporting period, and the revenues and expenses 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, 2023 and December 31, 2022, 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 (expense), net in the consolidated statements of operations. For the year ended December 31, 2023 the Company recorded approximately $24,000 of net foreign exchange transaction losses. For the year ended December 31, 2022, the Company recorded approximately $0.2 million of net foreign exchange transaction losses primarily related to the Company's bank account denominated in British Pounds and accounts payable denominated in British Pounds.

Property and Equipment, Net

Property and equipment, net is recorded at cost less accumulated depreciation. Depreciation expense is recorded using the straight-line method over the estimated useful lives of the related assets, which are as follows:

	Estimated Useful Life
Computer equipment	3 years
Manufacturing equipment	5 years
Furniture and equipment	5 years
Laboratory equipment	5 years
Leasehold improvements	Shorter of remaining lease term or useful life

Purchased assets that are not yet in service are recorded to construction-in-process and no depreciation expense is recorded. Once they are placed in service, they are reclassified to the appropriate asset class. When assets are retired or otherwise disposed of, the assets and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in the Company's consolidated statements of operation and comprehensive loss. Expenditures for maintenance and repairs are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may not be recoverable. If circumstances require that a long-lived asset or asset group be tested for impairment, the Company first compares the estimated undiscounted future cash flows expected to result from the use or disposition of that asset or asset group to its carrying amount. If the carrying amount of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment loss would be recognized to the extent the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market prices and third-party independent appraisals, as considered necessary.

Leases

Under lease guidance, arrangements meeting the definition of a lease are classified as operating or financing leases. Operating leases 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. In calculating the right-of-use assets and lease liabilities, the Company has elected to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the requirement to capitalize right-of-use assets and liabilities as an accounting policy election.

During the years ended December 31, 2023 and 2022, the Company did not have any financing leases.

Warrant Liabilities

On September 11, 2023, in conjunction with the Business Combination, the Company assumed the Public Warrants which have an exercise price of $11.50 per share, are exercisable 30 days after the Business Combination and expire five years after the Business Combination or upon redemption. The Company may redeem the Public Warrants if the Company's common stock equals or exceeds $18.00 per share for 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which the Company sends the notice of redemption to the holders of Public Warrants. As of December 31, 2023, there are 8,433,333 Public Warrants Outstanding. Each warrant entitles the registered holder to purchase one share of Common Stock at a price of $11.50 per full share. Pursuant to the Warrant Agreement, a holder of Warrants may exercise its Warrants only for a whole number of shares. This means that only a whole warrant may be exercised at any given time by a holder of Warrants. The Company maintains a redemption right with respect to the warrants in that the Company can redeem some or all of the warrants for $0.10 per warrant based on certain market conditions and the market price of the Common Stock.

In September 2021, Legacy Spectral issued 73,978 warrants, with a strike price of $7.75 and a five-year life, to SP Angel Corporate Finance LLP ("SP Angel"), who acted as nominated adviser and broker to the Company for the purposes of the AIM Rules ("Angel Warrants"). In conjunction with the Business Combination, the Angel Warrants were converted into warrants to purchase Company Common Stock based on the Exchange Ratio. As of December 31, 2023, there are 73,978 Angel Warrants to purchase Company Common Stock outstanding.

The Company accounts for its Public Warrants and the Angel Warrants as derivative liabilities. Accordingly, the Company recognizes the instruments as liabilities at fair value, determined using the closing price of the observable market quote in an active market (the NASDAQ) for the Public Warrants and the Black-Scholes option-pricing model for the Angel Warrants, 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, redeemed or expired, and any change in fair value is recognized in the Company's consolidated statements of operations within other income (expense).

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.

The Company generates research and development revenue, primarily from the contracts with BARDA and MTEC. Each contract for BARDA and MTEC has a single performance obligation.

The contracts with BARDA are cost-plus-fee contracts associated with development of certain product candidates. BARDA reimburses the Company based on allowable costs plus any recognizable earned fee. Revenues from these reimbursable costs are recognized as the costs are incurred.

The MTEC Agreement provides for installment payments after the completion of milestone events. The installment payments are considered variable consideration as the entitlement depends on successful completion of research. However, the payments are not constrained from inclusion in the transaction price as it not probable that a significant reversal of cumulative revenue will be reversed when the underlying uncertainty is resolved. Revenue for the MTEC Agreement is recognized over time based upon the cost-to-cost measure of progress, using 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. The Company measures progress of performance by comparing the actual costs incurred to-date to the total estimated cost of the project. The Company will adjust the measure of progress at the end of each reporting period and reflect any changes to the estimated cost of the project on a prospective basis.

The Company elected the practical expedient not to adjust the transaction price for the effects of a significant financing component as the period between performance (satisfaction of a performance obligation) and payment is one year or less. Payments from customers are generally received within 30 days of when the invoice is sent.

Research and Development Expense

The Company expenses research and development costs 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. For the years ended December 31, 2023 and 2022, research and development expense was $15.1 million and $16.5 million, respectively, of which $10.2 million and $14.5 million, respectively, is related to the combined BARDA and MTEC contracts and included in cost of revenue and $5.3 million and $2.0 million, respectively, is included in general and administrative expenses.

Stock-Based Compensation

The Company accounts for all stock-based payments to employees and non-employees, including grants of stock options, RSUs and RSAs based on their respective grant date fair values. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The RSUs and 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-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, RSUs 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

The Company records its 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 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.

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, 2023 and December 31, 2022 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. The Company did not have any interest and penalties during the years ended December 31, 2023 and 2022 and did not have any interest or penalties accrued as of December 31, 2023.

Net Loss per Share of Common Stock

Basic net loss per 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 and warrants. 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.

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss), which includes foreign currency translation adjustments. For the purposes of comprehensive income (loss) disclosures, the Company does not record tax provisions or benefits for the net changes in the foreign currency translation adjustment, as it intends to indefinitely reinvest undistributed earnings of its foreign subsidiaries. Accumulated other comprehensive income (loss) is reported as a component of stockholders' equity.

Recently Adopted Accounting Standards

In September 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. The Company adopted this standard on January 1, 2023, with no impact on its consolidated financial statements and related disclosures.

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 right-of-use assets and lease liabilities each of approximately $0.6 million upon the adoption of ASU 2016-02. See Note 9.

Recently Issued Accounting Standards

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 ("ASU 2022-03"). The FASB issued 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.

In October 2023, the FASB issued ASU 2023-06 Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative ("ASU 2023-06"), which modifies certain disclosure and presentation requirements of a variety of Topics in the Codification and is intended to both clarify or improve such requirements and align the requirements with the SEC's regulations. The effective date for each amendment is the effective date of the removal of the related disclosure from Regulation S-X or Regulation S-K, with early adoption prohibited. The Company will apply the provisions prospectively as such provisions become effective and does not expect ASU 2023-06 to have a material impact on the consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). ASU 2023-07 updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. This update is effective for the Company in the consolidated financial statements for the year ending December 31, 2024, and interim periods beginning after January 1, 2025. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 requires more detailed income tax disclosures, requiring entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. This update will be effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements and disclosures.

3. RECAPITALIZATION

As discussed in Note 1, on September 11, 2023, the Company consummated the Business Combination, with Legacy Spectral surviving the merger as a wholly-owned subsidiary of the Company.

On the date of the Business Combination, the Company recorded net liabilities of $2.4 million, with an offsetting decrease to additional paid-in capital. The following table provides the elements of the Business Combination and reconciles these elements to the consolidated statements of stockholders' equity and the consolidated statements of cash flows for the year ended December 31, 2023:

Cash	$ 660
Other current assets	127
Accounts payable	(860)
Accrued expenses	(277)
Warrant liabilities	(2,024)
Net liabilities assumed in exchange for common stock	(2,374)
Less: Cash	(660)
Non-cash net liabilities assumed in exchange for common stock	$ (3,034)

Upon the Closing, the Company issued 33,333 shares of Company Common Stock, with a fair value of $0.2 million, to settle an assumed liability to the Sponsor as a payment for an administrative fee.

The Company recorded transaction costs, consisting of legal, accounting and other professional services incurred by Legacy Spectral related to the Business Combination, of $7.6 million (the "Transaction Costs"), in other income (expense) in the consolidated statement of operations for the year ended December 31, 2023 and no costs were capitalized. As of December 31, 2023, $0.8 million of the Transaction Costs are included accounts payable and $0.5 million are included in accrued expenses. The Company paid $1.9 million of Transaction Costs in cash and issued 966,667 shares of Company Common Stock with a fair value of $4.4 million.

Prior to the Business Combination the Company incurred $0.7 million of transaction costs, included in other income (expense) in the consolidated statement of operations for the year ended December 31, 2023, for professional services incurred by Legacy Spectral that were related to potential business combinations that did not occur.

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, 2023 and December 31, 2022, by level within the fair value hierarchy (in thousands):

	Fair value measured as of December 31, 2023			
	Fair value at December 31, 2023	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
Warrant liabilities	$ 1,818	$ 1,771	$ -	$ 47

	Fair value measured as of December 31, 2022			
	Fair value at December 31, 2022	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
Warrant liabilities	$ 129	$ -	$ -	$ 129

There were no transfers between Level 1, 2 or 3 during the years ended December 31, 2023 and 2022.

Fair values of cash, accounts receivable, accounts payable, accrued expenses and short-term debt are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of the Public Warrants, which trade in active markets, is based on quoted market prices and classified in Level 1 of the fair value hierarchy. The Angel Warrants are classified within Level 3 of the fair value hierarchy because their fair values are based on significant inputs that are unobservable in the market.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2023 and 2022 (in thousands):

Balance - January 1, 2022	$ 186
Change in fair value	(57)
Balance - January 1, 2023	$ 129
Change in fair value	(82)
Balance - December 31, 2023	$ 47

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

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

	December 31, 2023	**December 31, 2022**
Strike price (per share)	$ 7.32	$ 7.32
Contractual term (years)	3.5	4.5
Volatility (annual)	71.2%	72.6%
Risk-free rate	4.0%	4.0%
Dividend yield (per share)	0.0%	0.0%

5. RESEARCH AND DEVELOPMENT REVENUE

For the years ended December 31, 2023 and 2022, the Company's revenues disaggregated by the major sources was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
BARDA	$ 17,027	$ 24,827
Other U.S governmental authorities	1,029	541
Total revenue	$ 18,056	$ 25,368

6. ACCRUED EXPENSES

Accrued expenses consist of the following as of December 31, 2023 and December 31, 2022 (in thousands):

	December 31, 2023	December 31, 2022
Salary and wages	$ 1,910	$ 1,135
Operating expenses	1,563	736
Benefits	720	650
Taxes	107	110
Total accrued expenses	$ 4,300	$ 2,631

7. NOTES PAYABLE

Insurance Note

The Company entered into financing arrangements for a portion of its Directors and Officers ("D&O") insurance premiums, as follows (in thousands):

			Principal Repayments		Outstanding Balance	
			Year Ended December 31,		December 31,	December 31,
	Amount Financed	Interest Rate	2023	2022	2023	2022
New 2023 Insurance Note	$ 632	8.6%	$ 195	$ -	$ 436	$ -
2023 Insurance Note	151	9.7%	113	-	-	-
2022 Insurance Note	376	6.7%	175	201	-	175
2021 Insurance Note	474	5.7%	-	160	-	-
			$ 483	$ 361	$ 436	$ 175

In September 2023, in connection with the Business Combination, the Company cancelled the 2023 Insurance Note and replaced it with the New 2023 Insurance Note. Accordingly, the Company reversed the unpaid balance of approximately $38,000 from notes payable and prepaid expenses.

The Company determined that the carrying amounts of all of the insurance notes approximate fair value due to the short-term nature of borrowings and current market rates of interest.

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 $0.7 million (the "PPP Loan"). The PPP Loan matured on April 13, 2022 and bore interest at 1% per annum. 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 was 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 the year ended December 31, 2022, the Company repaid the remaining $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

The Company is not a party to any material legal proceedings or pending claims. The Company is aware of a material threatened claim that it believes is without merit. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities, none of which we believe are material or would be expected to have, individually or in the aggregate, a material adverse effect on our business, financial condition, cash flows or results of operations.

9. LEASES

The Company adopted ASC 842 on January 1, 2022 using the modified retrospective approach with no restatement of prior periods or cumulative adjustment to accumulated deficit. The reported results for 2023 and 2022 reflect the application of ASC 842. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases, and initial direct costs for existing leases. The Company also made an accounting policy election not to recognize leases with an initial term of 12 months or less within its consolidated balance sheets and to recognize those lease payments on a straight-line basis in its consolidated statements of operations and comprehensive loss over the lease term.

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

During 2023, the Company entered into a lease for office space in the United Kingdom for annual payments of $0.1 million under a lease that expires in March 2024. The lease has been excluded from the tables below as the term is twelve months.

The following table summarizes quantitative information about the Company's operating leases for the years ended December 31, 2023 and 2022 (dollars in thousands):

	Year Ended December 31,	
	2023	**2022**
Operating cash flows used in operating leases	$ 744	$ 594
Right-of-use assets exchanged for operating lease liabilities	$ 483	$ 1,565
Weighted average remaining lease term (in years)	1.0	1.5
Weighted average discount rate	8.5%	8.5%

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):

	Year Ended December 31,	
	2023	**2022**
Operating leases		
Operating lease cost	$ 802	$ 590
Variable lease cost	357	126
Operating lease expense	1,159	716
Short-term lease rent expense	110	-
Total rent expense	$ 1,269	$ 716

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

As of December 31, 2023, future minimum payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31, 2024	$ 894
Total	894
Less: imputed interest	(41)
Operating lease liabilities	$ 853

10. STOCKHOLDERS' EQUITY

In conjunction with the Closing, the Company's certificate of incorporation was amended and restated to authorize the issuance of 80,000,000 shares of Company Common Stock, $0.0001 par value and 1,000,000 shares of preferred stock, $0.0001 par value (the "Company Preferred Stock").

11. STOCK-BASED COMPENSATION

Each option and warrant to purchase common stock of Legacy Spectral was converted into an option and warrant, respectively, to purchase Spectral AI's common stock based on the Exchange Ratio, with corresponding adjustments to the exercise price. Accordingly, the options and warrants to purchase 46,592,862 and 762,712, respectively, shares of the common stock of Legacy Spectral were converted into options and warrants to purchase 4,519,191 and 73,978, respectively, shares of Spectral AI's common stock. Legacy Spectral's 600,000 RSUs were converted into 58,197 Spectral AI RSUs, based on the Exchange Ratio.

2018 Long Term Incentive Plan

On July 24, 2018, Legacy Spectral's Board of Directors adopted the 2018 Long Term Incentive Plan (the "2018 Plan") which permits granting of incentive stock options (which must meet all statutory requirements), non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, and other cash-based or stock-based awards. Pursuant to the 2018 Plan, stock options must expire within 10 years and must be granted with exercise prices of no less than the fair value of the common stock on the grant date, as determined by Legacy Spectral's Board of Directors. As of December 31, 2023, 3,526,200 shares of common stock were authorized for issuance under the 2018 Plan, of which 193,889 remain available for issuance.

2022 Long Term Incentive Plan

On September 27, 2022, Legacy Spectral'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 Legacy Spectral's Board of Directors. As of December 31, 2023, under the 2022 Plan, 88,749 shares of common stock were issuable upon the exercise of outstanding options and 58,197 restricted stock units ("RSUs") were issuable. Under the 2022 Plan, 1,792,918 shares remain available for issuance through grants of future options.

Restricted Stock Awards

The RSAs generally vest over four years. A summary of RSA activities for the year ended December 31, 2023 are presented below:

	Number of Shares	*Weighted Average Grant Date Fair Value per Share*
Nonvested as of January 1, 2023	30,318	$ 1.07
Vested	(30,318)	$ 1.07
Nonvested as of December 31, 2023	-	$ -

Restricted Stock Units

The RSUs generally vest over three years. A summary of RSU activities for the year ended December 31, 2023 are presented below:

	Number of Shares	*Weighted Average Grant Date Fair Value per Share*
Nonvested as of January 1, 2023	-	$ -
Granted	58,197	$ 4.65
Nonvested as of December 31, 2023	58,197	$ 4.65

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. Legacy Spectral's stock became publicly traded on July 22, 2021 on the AIM, and lacks company-specific historical and implied volatility information. On September 11, 2023 the Company completed the Business Combination and was listed on the NASDAQ under symbol MDAI. Legacy Spectral estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Spectral AI continues to estimate 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 Legacy Spectral's and Spectral AI's stock options for employees has been determined utilizing the simplified method by taking an average of the vesting periods and the original contractual terms for each award. 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 Legacy Spectral and Spectral AI have never paid cash dividends and Spectral AI does not expect to pay any cash dividends in the foreseeable future.

The Company's stock options generally vest ratably annually over 3 years and have a contractual term of 10 years. The weighted-average assumptions used in determining the fair value of options granted were as follows in the years ended December 31, 2023 and 2022:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Fair value of common stock	$ 4.57	$ 4.52
Expected term (years)	6.0	5.9
Expected volatility (annual)	72%	68%
Risk-free interest rate	3.6%	2.7%
Dividend yield (per share)	0%	0%

A summary of stock options activity for the year ended December 31, 2023 is presented below:

	Stock Options	*Weighted Average Exercise Price*	*Weighted Average Remaining Contractual Life (in years)*	*Aggregate Intrinsic Value (in thousands)*
Outstanding at January 1, 2023	3,503,790	$ 2.06	7.3	$ 6,831
Options granted	253,250	$ 4.57		
Options forfeited	(31,846)	$ 6.30		
Options cancelled	(20,368)	$ 2.23		
Options exercised	(126,247)	$ 2.13		
Outstanding as of December 31, 2023	3,578,579	$ 2.20	6.5	$ 8,041
Options vested and exercisable as of December 31, 2023	2,898,508	$ 1.76	6.1	$ 6,636

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the respective date.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2023 and 2022 was $3.20 and $2.79 per share, respectively.

The Company recorded stock-based compensation expense for stock options, RSUs and restricted stock awards of $1.2 million for the years ended December 31, 2023 and December 31, 2022 in general and administrative expenses in the consolidated statements of operations.

As of December 31, 2023, there was approximately $1.2 million and $0.2 million of unrecognized stock-based compensation related to stock option grants and restricted stock unit grants, respectively, that will be amortized over a weighted average period of 0.8 years and 1.0 years, respectively.

During the year ended December 31, 2018, the Company granted of 973,803 stock options to investors (the "Investor Options") that were approved by the Board of Directors outside of the 2018 Plan, of which 939,024 Investor Options were outstanding as of December 31, 2022. During the year ended December 31, 2023, 34,779 of the Investor Options were exercised and the remaining 904,245 Investor Options expired in November 2023. The Investor Options had an exercise price of $2.06 per share. As of December 31, 2023, there is no unrecognized stock-based compensation expense related to the Investor Options.

As of December 31, 2023, the stock options issued to an investor to purchase 20,368 shares of the Company's common stock (the "Options") at a price of $1.96 per share expired. The Options had a grant date fair value of $2.17 per share and were equity-classified stock options. As of December 31, 2023, there is no unrecognized stock-based compensation expense related to the Investor Options.

On December 26, 2023, the Company entered into the Purchase Agreement and related Registration Rights Agreement with B. Riley Principal Capital II. Upon the terms and subject to the satisfaction of the conditions contained in the Purchase Agreement, the Company has the right to sell to B. Riley Principal Capital II up to $10.0 million of shares of Common Stock. In accordance with the Company's obligations under the Registration Rights Agreement, the Company filed the registration statement to register under the Securities Act, the offer and resale by B. Riley Principal Capital II of up to 3,249,360 shares of Common Stock, consisting of (i) up to 3,209,360 shares of Common Stock that the Company may elect sell to B. Riley Principal Capital II, from time to time and (ii) 40,000 shares of Common Stock the Company issued to B. Riley Principal Capital II upon the execution of the Purchase Agreement on December 26, 2023.

On March 20, 2024, the Company entered into the SEPA and related Registration Rights Agreement with Yorkville. Upon the terms and subject to the conditions contained in the SEPA, the Company has the right to sell to Yorkville up to $30.0 million of shares of Common Stock. In accordance with the Company's obligations under the Registration Rights Agreement, the Company is required to file a registration statement to register under the Securities Act, the offer and resale by Yorkville of up to 6,369,937 shares of Common Stock, consisting of (i) up to 6,275,000 shares of Common Stock (the "Purchase Shares") that the Company may elect sell to Yorkville from time to time and (ii) 94,937 shares of Common Stock the Company issued to Yorkville upon the execution of the SEPA on March 20, 2024.

12. INCOME TAXES

Effective Tax Rate

The overall effective tax rate ("ETR") for the Company, as calculated under ASC 740 guidance for the tax period ended December 31, 2023, and 2022 is (0.05%) and (3.80%), respectively. The following table reconciles the federal statutory income rate to the Company's effective income tax rate:

	2023	*2022*
Federal income tax rate	21.00%	21.00%
State income tax benefit	(0.06)%	(2.80)%
Permanent items	(9.27)%	(7.30)%
Return to provision adjustments	0.02%	(2.50)%
Other	0.08%	-%
Change in valuation allowance	(11.82)%	(12.20)%
Effective income tax rate	**(0.05)%**	**(3.80)%**

The above schedule beaks out the key components of the ETR. The main drivers between the federal statutory rate of 21.00% and ETR of (0.06%) are permanent adjustments and change in valuation allowance.

Components of Income Tax Expense

The components of income tax expense for the periods ended December 31, 2023 and 2022 are as follows (in thousands):

	2023	*2022*
Current		
US Federal	$ (5)	$ 5
US State	16	101
Total current provision	11	106
Total provision for income taxes	**$ 11**	**$ 106**

The company is in a taxable loss position for the year ending December 31, 2023. The current tax expense results from the gross margin tax for the Company's state filing in Texas.

Deferred Income Taxes

The main components of deferred tax assets/(liabilities) for the periods ended December 31, 2023 and 2022, are as follows (in thousands):

	2023	*2022*
Deferred income tax assets:		
Net operating loss carryforwards	$ 2,403	$ 429
Capitalized research expenses	717	420
Intangible assets	437	-
Stock-based compensation	278	262
Lease liabilities	179	216
Tax credits	44	10
Other	438	269
Total deferred income tax assets	4,496	1,606
Valuation allowance	(4,333)	(1,388)
Net deferred tax assets	$ 163	$ 218
Deferred income tax liabilities:		
Right-of-use assets	(163)	(212)
Other	-	(6)
Total deferred income tax liabilities	$ (163)	$ (218)
Net deferred income tax assets	$ -	$ -

Valuation Allowance Considerations

A valuation allowance against a deferred tax asset must 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, 2023 and 2022. The net change in valuation allowance for the years ended December 31, 2023 and 2022 was an increase of $2.9 million and $0.3 million, respectively.

Section 174 Capitalization

The Tax Cuts and Jobs Act of 2017 ("TCJA") made a significant change to Section 174 that went into effect for taxable years beginning after December 31, 2021. The change eliminated the ability to currently deduct R&D expenses. Instead, taxpayers must now capitalize and amortize these costs. Capitalized Section 174 costs must be amortized over 5 years (15 years for expenditures attributable to foreign research) beginning with the midpoint of the tax year in which the expenditures are paid or incurred.

The Company had an estimated $3.0 million and $1.7 million of domestic R&D expenses for the tax years ending December 31, 2023 and 2022, respectively. The domestic R&D expenses will be capitalized and amortized over a five-year period for federal income tax purposes.

Net Operating Losses

As of December 31, 2023 and 2022, the Company had available federal net operating loss carryforwards ("NOLs") of $11.0 million and $3.1 million, respectively, which are available to offset future federal taxable income. Under the TCJA, all NOLs incurred after December 31, 2017 are carried forward indefinitely for federal tax purposes. Utilization of net operating losses and credits may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization.

Section 382 of the Internal Revenue Code limits the utilization of U.S. NOL carryforwards following a change of control. The Company has not performed an analysis of whether a change of control defined under Section 382 may have occurred. Upon performing an analysis of whether an ownership change has occurred, any future NOL deductions may be limited. However, the NOL carryforward discussed above does not expire.

The Company is subject to taxation in the U.S and in various state, local and foreign jurisdictions. The Company's tax returns for years 2020 through present are open to tax examinations by U.S. Federal, state, local, and foreign tax authorities; however, carryforward attributes that were generated prior to January 1, 2018, remain subject to adjustment upon examination if they either have been utilized or will be utilized in a future period.

13. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share attributable to common stockholders are the same for the years ended December 31, 2023 and 2022, 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.

	2023	2022
Common stock options	3,578,579	4,442,770
Common stock warrants	8,507,311	73,978
Unvested restricted stock units	58,197	-
Unvested restricted stock	-	30,318
Potentially dilutive securities	12,144,087	4,547,066

14. RELATED PARTY TRANSACTIONS

For the years ended December 31, 2023 and 2022, the Company did not have any transactions with related parties.

15. SUBSEQUENT EVENTS

Proceeds from sales of Common Stock through B. Riley Committed Equity Facility

Through March 25, 2024, the Company utilized the B Riley Committed Equity Facility to sell 1,187,398 shares of Common Stock for proceeds totaling $2.7 million. The Company incurred $0.7 million in offering costs associated with these transactions with $0.6 million payable in cash and $0.1 million payable in Common Stock.

Proceeds from New Government Contract

On March 12, 2024, the Company entered into a new contract with the Defense Health Agency that provides significant additional support for the development of the handheld version of the Company's Deepview System. The contract was valued at approximately $500,000 and will build on the previous awards from other governmental agencies focused on advancing the handheld version of the Deepview System.

Spectral IP, Inc.

On March 7, 2024, the Company formed a new wholly-owned subsidiary, Spectral IP, Inc., a Delaware corporation ("Spectral IP"), to be utilized to advance artificial intelligent intellectual property with a specific emphasis on healthcare. On March 19, 2024, the Company announced that Spectral IP received a $1.0 million investment from an affiliate of its largest shareholder for the development of its artificial intelligence intellectual property portfolio. The investment is structured as a note payable with a one-year maturity, an interest rate of 8%, and requiring earlier prepayment if the Company spins off Spectral IP to the Company's shareholders or if Spectral IP is sold to a third party.

Yorkville Standby Equity Purchase Agreement

On March 20, 2024, the Company entered into the SEPA with Yorkville pursuant to which the Company has the right to sell to Yorkville up to $30.0 million of its shares of Common Stock, subject to certain limitations and conditions set forth in the SEPA, from time to time during the term of the SEPA. Sales of the shares of Common Stock to Yorkville under the SEPA, and the timing of any such sales, are at the Company's option, and the Company is under no obligation to sell any shares of Common Stock to Yorkville under the SEPA except in connection with notices that may be submitted by Yorkville, as described in the SEPA.

In connection with the SEPA, and subject to the conditions set forth therein, Yorkville has agreed to advance to the Company in the form of Convertible Notes an aggregate principal amount of up to $12.5 million (the "Pre-Paid Advance"), which will be paid in three tranches. The first Pre-Paid Advance was disbursed on March 20, 2024 in the amount of $5.0 million with a fixed conversion price of $3.16, the second Pre-Paid Advance shall be in a principal amount of $5.0 million and advanced after the earlier of the registration statement registering the resale of the shares of Common Stock issuable under the SEPA being declared effective and or shareholder approval to exceed the 19.99% threshold of the aggregate number of shares of Common Stock issued pursuant to the SEPA (the "Exchange Cap") (the "Second Pre-Advance Closing"), and the third Pre-Paid Advance shall be in a principal amount of $2.5 million and advanced sixty days following the Second Pre-Advance Closing. The purchase price for the Pre-Paid Advance is 92.0% of the principal amount of the Pre-Paid Advance. Interest shall accrue on the outstanding balance of any Pre-Paid Advance at an annual rate equal to 0%, subject to an increase to 18% upon an event of default as described in the Convertible Notes. The maturity date of the Convertible Note issue in connection with each Pre-Paid Advance will be 12 months after the issuance date of such Convertible Note.

(b) Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Description
2.1†**	Business Combination Agreement, by and among Rosecliff Acquisition Corp I, Merger Sub I, Merger Sub II and Spectral MD Holdings, Ltd., dated as of April 11, 2023 (incorporated by reference to Annex A of the Registration Statement on Form S-4 (File No. 333-271566)).
3.1**	Second Amended and Restated Certificate of Incorporation of Spectral AI, Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).
3.2**	Amended and Restated Bylaws of Spectral AI, Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).
4.1**	Warrant Agreement, dated February 11, 2021, between Rosecliff Acquisition Corp I and Continental Stock Transfer & Trust Company, as warrant agent (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 17, 2021)
4.2**	Description of the Registrant's Securities (incorporated by reference to the Registrant's Annual Report on Form 10-K filed on March 31, 2022)
4.3**	Amended and Restated Registration Rights & Lock-up Agreement (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).
4.4**	Registration Rights Agreement, dated December 26, 2023, between the Registrant and B. Riley Principal Capital II, LLC (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed with the SEC on December 27, 2023).
10.1**	Form of Indemnification Agreement (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).
10.2**	Sponsor Warrants Purchase Agreement, dated February 11, 2021, between the Registrant and the Sponsor (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 17, 2021)
10.3**	BARDA Award/Contract, July 1, 2019, by and between Spectral MD, Inc. and ASPR-BARDA (incorporated by reference to Exhibit 10.14 of the Registration Statement on Form S-4 (File No. 333-271566)).
10.4**	Amendment of the Solicitation/Modification of the BARDA Contract, dated August 26, 2022, by and between Spectral MD, Inc. and ASPR-BARDA (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form S-4 (File No. 333-271566)).
10.5**	Award/Contract for DHA, dated July 1, 2021, by and between Spectral MD, Inc. and U.S. Army Medical Materiel Development Activity (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form S-4 (File No. 333-271566)).
10.6**	Amendment of the Solicitation/Modification of the DHA Contract, dated July 1, 2021, by and between Spectral MD, Inc. and U.S. Army medical Materiel Development Activity (incorporated by reference to Exhibit 10.17 of the Registration Statement on Form S-4 (File No. 333-271566)).
10.7**	MTEC Research Project Award, dated April 12, 2023, by and between Spectral. MD, Inc. and Advanced Technology International MTEC Consortium Manager (incorporated by reference to Exhibit 10.18 of the Registration Statement on Form S-4 (File No. 333-271566)).

10.8**	Sponsor Letter Agreement, dated April 11, 2023, by and among Rosecliff Acquisition I Sponsor LLC, Spectral MD Holdings, Ltd., and Rosecliff Acquisition Corp I (incorporated by reference to Annex F of the Registration Statement on Form S-4 (File No. 333-271566)).
10.9†**	Common Stock Purchase Agreement, dated December 26, 2023, between the Registrant and B. Riley Principal Capital II, LLC (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on December 27, 2023).
10.10**	Spectral MD, Inc. 2018 Long Term Incentive Plan (incorporated by referenced to Exhibit 99.1 of Registrant's Registration Statement on Form S-8, filed with the SEC on February 9, 2024)
10.10.1**	Form of Stock Option Award Agreement under Spectral MD, Inc. 2018 Long-Term Incentive Plan (incorporated by referenced to Exhibit 99.3 of Registrant's Registration Statement on Form S-8, filed with the SEC on February 9, 2024)
10.10.2**	Form of RSU Award Agreement under Spectral MD, Inc. 2018 Long-Term Incentive Plan (incorporated by referenced to Exhibit 99.4 of Registrant's Registration Statement on Form S-8, filed with the SEC on February 9, 2024)
10.11**	Spectral MD Holdings, Ltd. 2022 Long Term Incentive Plan (incorporated by referenced to Exhibit 99.2 of Registrant's Registration Statement on Form S-8, filed with the SEC on February 9, 2024)
10.11.1**	Form of Stock Option Award Agreement under Spectral MD Holdings, Ltd. 2022 Long-Term Incentive Plan (incorporated by referenced to Exhibit 99.5 of Registrant's Registration Statement on Form S-8, filed with the SEC on February 9, 2024)
10.11.2**	Form of RSU Award Agreement under Spectral MD Holdings, Ltd. 2022 Long-Term Incentive Plan (incorporated by referenced to Exhibit 99.6 of Registrant's Registration Statement on Form S-8, filed with the SEC on February 9, 2024)
10.12	Spectral AI, Inc. 2023 Long Term Incentive Plan
14	Code of Business Conduct and Ethics
19	Insider Trading Policy
21	List of Subsidiaries of the Registrant as of December 31, 2023.
23.1	Consent of KPMG LLP.
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002
32.1	18 U.S.C. Section 1350 Certifications of the Chief Executive Officer and the Chief Financial Officer
97	Policy relating to recovery of erroneously awarded compensation
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File

** Previously filed.

† Certain portions of this Exhibit have been omitted pursuant to Regulation S-K Item 601(a)(5), Item 601(a)(6) or Item 601(b)(10), as applicable, promulgated under the Exchange Act. The Registrant agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Signature	Title	Date
/s/ Peter M. Carlson Peter M. Carlson	Director and Chief Executive Officer (*Principal Executive Officer*)	March 29, 2024
/s/ Vincent Capone Vincent Capone	Chief Financial Officer (*Principal Financial Officer, General Counsel And Principal Accounting Officer*)	March 29, 2024
/s/ Cynthia Cai Cynthia Cai	Director	March 29, 2024
/s/ Richard Cotton Richard Cotton	Chairman of the Board of Directors	March 29, 2024
/s/ Martin Mellish Martin Mellish	Director	March 29, 2024
/s/ Deepak Sadagopan Deepak Sadagopan	Director	March 29, 2024
/s/ Erich Spangenberg Erich Spangenberg	Director	March 29, 2024
/s/ J. Michael DiMaio J. Michael DiMaio	Director	March 29, 2024