Spectral AI, Inc.

6,369,937 Shares of Common Stock

This prospectus relates to the resale of up to 6,369,937 shares of our common stock, par value $0.0001 per share (the "Common Stock") of Spectral AI, Inc. (the "Company"), by YA II PN, LTD, ("Yorkville" or the "Selling Stockholder").

The shares of Common Stock to which this prospectus relates have been or may be issued by us to Yorkville pursuant to a standby equity purchase agreement, dated as of March 20, 2024, by and between the Company and Yorkville (the "SEPA"). Such shares of Common Stock include (i) up to 6,275,000 shares of Common Stock that may be issued to Yorkville pursuant to the SEPA, either in our sole discretion following an Advance Notice (as defined below) or pursuant to an Investor Notice (as defined below) and (ii) 94,937 shares of Common Stock we issued Yorkville, upon our execution of the SEPA on March 20, 2024, as partial consideration for its commitment to purchase shares of our Common Stock in one or more purchases that we may, in our sole discretion, direct them to make, from time to time after the date of this prospectus, pursuant to the SEPA.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of our Common Stock by the Selling Stockholder. However, we may receive up to $30,000,000 aggregate gross proceeds from sales of Common Stock we may elect to make to Yorkville pursuant to the SEPA prior to or after the date of this prospectus. See "*The Standby Equity Facility*" for a description of the SEPA and "*Selling Stockholder*" for additional information regarding Yorkville.

Yorkville may sell or otherwise dispose of the Common Stock described in this prospectus in a number of different ways and at varying prices. See "*Plan of Distribution (Conflict of Interest)*" for more information about how Yorkville may sell or otherwise dispose of the Common Stock pursuant to this prospectus. Yorkville is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended, or the Securities Act.

We will pay the expenses incurred in registering under the Securities Act the offer and sale of the shares of Common Stock to which this prospectus relates by the Selling Stockholder, including legal and accounting fees. See section titled "*Plan of Distribution*" beginning on page 135 of this prospectus.

Shares of our Common Stock are listed on the Nasdaq Stock Market LLC ("Nasdaq") under the symbols "MDAI". On April 18, 2024, the closing price of our Common Stock was $1.89.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described in the section titled "Risk Factors" beginning on page 10 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

Neither the Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of these securities, or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 19, 2024.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC to register the securities described in this prospectus for resale by the Selling Stockholder who may, from time to time, sell the securities described in this prospectus. We will not receive any proceeds from the sale of shares of Common Stock by the Selling Stockholder pursuant to this prospectus.

We may also file a prospectus supplement or post-effective amendment to the registration statement of which this prospectus forms a part that may contain material information relating to these offerings. The prospectus supplement or post-effective amendment may also add, update or change information contained in this prospectus with respect to that offering. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement or post-effective amendment, you should rely on the prospectus supplement or post-effective amendment, as applicable. Before purchasing any securities, you should carefully read this prospectus, any post-effective amendment, and any applicable prospectus supplement, together with the additional information described under the heading "*Where You Can Find More Information*."

Neither we, nor the Selling Stockholder, have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any post-effective amendment, or any applicable prospectus supplement prepared by or on behalf of us or to which we have referred you. We and the Selling Stockholder take no responsibility for and can provide no assurance as to the reliability of any other information that others may give you. We and the Selling Stockholder will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, any post-effective amendment and any applicable prospectus supplement to this prospectus is accurate only as of the date on its respective cover. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus contains, and any post-effective amendment or any prospectus supplement may contain, market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included in this prospectus, any post-effective amendment or any prospectus supplement may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "*Risk Factors*" contained in this prospectus, any post-effective amendment and the applicable prospectus supplement. Accordingly, investors should not place undue reliance on this information.

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").

As used in this prospectus, unless otherwise indicated or the context otherwise requires, references to "we," "us," "our," the "Company," "Registrant," and "Spectral" refer to the consolidated operations of Spectral AI, Inc., formerly known as Rosecliff Acquisition Corp I, and its subsidiaries. References to "RCLF" refer to the Company prior to the consummation of the Business Combination and references to "Legacy Spectral" refer to Spectral MD Holdings, Ltd. prior to the consummation of the Business Combination.

MARKET AND INDUSTRY DATA

This prospectus contains, and any post-effective amendment or any prospectus supplement may contain, information concerning the market and industry in which we conduct our business. Spectral operates in an industry in which it is difficult to obtain precise industry and market information. We have obtained market and industry data in this prospectus from industry publications and from surveys or studies conducted by third parties that it believes to be reliable. We cannot assure you of the accuracy and completeness of such information, and it has not independently verified the market and industry data contained in this prospectus or the underlying assumptions relied on therein. As a result, you should be aware that any such market, industry and other similar data may not be reliable. While we are not aware of any misstatements regarding any industry data presented in this prospectus, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the section entitled "*Risk Factors*" below.

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

We and our subsidiaries own or have rights to trademarks, trade names and service marks that they use in connection with the operation of their business. In addition, their names, logos and website names and addresses are their trademarks or service marks. Other trademarks, trade names and service marks appearing in this prospectus, are the property of their respective owners. Solely for convenience, in some cases, the trademarks, trade names and service marks referred to in this prospectus are listed without the applicable ®, M and SM symbols, but their respective owners will assert, to the fullest extent under applicable law, their rights to these trademarks, trade names and service marks.

BASIS OF PRESENTATION AND GLOSSARY

"*Bylaws*" are to the Amended and Restated Bylaws of Spectral AI, Inc.

"*Closing*" is to the closing of the Business Combination;

"*Closing Date*" is to September 11, 2023;

"*Code*" is to the U.S. Internal Revenue Code of 1986, as amended;

"*Commencement Date*" is to the date that the conditions are met and the first prepaid advance on the SEPA is effected.

"*Commitment Amount*" is to $30,000,000.

"*Common Stock*" are to shares of the Company's common stock, par value $0.0001, after the Business Combination.

"*DGCL*" is to the Delaware General Corporation Law, as may be amended from time to time;

"*Effective Date*" is to March 20, 2024.

"*Equity Incentive Plan*" is to the Spectral AI, Inc. 2023 Equity Incentive Plan;

"*Exchange Act*" is to the Securities Exchange Act of 1934, as amended;

"*Founder Shares*" are to the shares of RCLF Class B common stock initially purchased by the Sponsor and each independent director of RCLF in a private placement prior to the RCLF initial public offering and the shares of Common Stock issued upon conversion of such shares of Class B common stock;

"*GAAP*" is to generally accepted accounting principles in the United States, as applied on a consistent basis;

"*Legacy Spectral*" is to Spectral MD Holdings, Ltd., a Delaware corporation, prior to the consummation of the Business Combination;

"*Merger Sub I*" is to Ghost Merger Sub I Inc., a Delaware corporation and a direct, wholly owned subsidiary of RCLF;

"*Merger Sub II*" is to Ghost Merger Sub II LLC, a Delaware limited liability company and a direct, wholly owned subsidiary of RCLF;

"*Nasdaq*" is to the Nasdaq Stock Market LLC;

"*RCLF*" is to Rosecliff Acquisition Corp I, a Delaware corporation;

"*Original Registration Rights/Lock-Up Agreement*" is to the Amended and Restated Registration Rights Agreement entered into at Closing by RCLF, the Sponsor, the directors and officers of RCLF, Spectral and certain stockholders of Spectral;

"*SEC*" is to the U.S. Securities and Exchange Commission;

"*Securities Act*" is to the Securities Act of 1933, as amended;

"*Selling Stockholder*" is to Yorkville.

"*SEPA*" is to that certain Standby Equity Purchase Agreement, dated March 20, 2024, by and between the Company and Yorkville.

"*SPACs*" are to special purpose acquisition companies;

"*Sponsor*" is to Rosecliff Acquisition Sponsor I LLC, a Delaware limited liability company; and

"Warrants" are to the warrants sold in the IPO, each of which is exercisable for one share of Common Stock, in accordance with its terms.

Unless specified otherwise, amounts in this prospectus are presented in U.S. dollars.

Defined terms in the financial statements contained in this prospectus have the meanings ascribed to them in the financial statements.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995 (the "PSLRA"), including, among other things, statement regarding the plans, strategies and prospects, both business and financial, of the Company. These statements are based on the beliefs and assumptions of the management of the Company. Although the Company believes that its plans, intentions and expectations reflected in or suggested by these forward-looking statements are reasonable, the Company cannot assure you that it will achieve or realize these plans, intentions or expectations. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events or results of operations, and any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These statements may be preceded by, followed by or include the words "anticipate," "believe," "could," "continue," "estimate," "expect," "forecast," "intend" "may," "might," "plan," "possible," "potential," "project," "scheduled," "seek," "should," "will" or similar expressions, but the absence of these words does not mean that a statement is not forward-looking. There are or will be important factors that could cause our actual results to differ materially from those indicated in these forward-looking statements, including, but not limited to, the Company's ability to:

- 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 our 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.
- We incur increased costs as a result of operating as a public company, and the Company's management is required to devote substantial time to 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.

Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements, which speak only as of the date hereof. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise.

You should read this prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus or the documents incorporated by reference herein. Because it is a summary, it may not contain all of the information that may be important to you. To understand this offering fully, you should read this entire prospectus, the registration statement of which this prospectus is a part and the documents incorporated by reference herein carefully, including the information set forth under the heading "Risk Factors" and our financial statements.

Overview of the Company

We are an artificial intelligence ("AI") company focused on medical diagnostics for faster and more accurate treatment decisions in wound care. Anchored by our internally developed DeepView® System, our AI-based digital wound healing assessment in predictive medical diagnostics provides clinicians with an objective and immediate assessment of a wound's healing potential. We have received over $280 million of U.S. Government contracts, including under the U.S. federal mass casualty countermeasures program, which we have used to develop our burn indication and to expand into diabetic foot ulcers ("DFU") and anticipated multiple other clinical indications.

Our DeepView System integrates proprietary imaging technology with AI-enabled algorithms to see deep below the skin surface to provide a healing potential assessment in seconds by clearly defining on day-one healing versus non-healing tissue invisible to the naked eye. Our DeepView System delivers a binary wound healing prediction specifically engineered to allow the physician to make a more accurate, timely and informed decision regarding next step treatment plan for a patient's wounds by informing them on whether the wound is likely to heal over time. The imaging system that makes up part of our DeepView System has received United Kingdom Conformity Assessed ("UKCA") marking for use in the United Kingdom and has Class 1 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.

The Standby Equity Purchase Agreement

On March 20, 2024, Spectral AI, Inc. (the "Company") entered into the Standby Equity Purchase Agreement ("SEPA" and such date the "Effective Date") 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, par value $0.0001 ("Common Stock" and such amount the "Commitment Amount"), 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, in certain circumstances as described below.

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 "Promissory Notes") an aggregate principal amount of up to $12.5 million (each a "Pre-Paid Advance" and collectively, the "Pre-Paid Advances"), which will be paid in three tranches. The first Pre-Paid Advance was disbursed on March 20, 2024 in the principal 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 later of the registration statement registering the resale of the shares of Common Stock issuable under the SEPA being declared effective or upon shareholder approval to exceed 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 each 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 Promissory Notes. The maturity date of the Promissory Note issued in connection with each Pre-Paid Advance will be 12 months after the issuance date of such Promissory Note. Yorkville may convert the Promissory Notes into shares of the Company's Common Stock at any time at a fixed conversion price equal to (i) in respect of the Promissory Note issued in connection with the first Pre-Paid Advance, $3.16, and (ii) in respect of the Promissory Notes issued in connection with the second and third Pre-Paid Advances, a price per share equal to 120% of the average of the daily VWAPs during the three consecutive trading days immediately preceding the issuance date of each Promissory Note (the "Fixed Price").

Beginning on the forty-fifth (45th) day following the issuance date of the Promissory 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) a payment premium of 7% of such Installment Principal Amount, and (iii) accrued and unpaid interest hereunder as of each Installment Date (collectively, the "Installment Amount"). At any time or times on or after any Installment Date, the Investor shall be entitled to convert any portion of any due and unpaid Installment Amount outstanding under a Promissory Note until such amount has been paid into shares at a price per share equal to 85% of the lowest daily VWAP during the 10 consecutive Trading Days immediately preceding the Conversion Date (the "Variable Price" and collectively with the Fixed Price, the "Conversion Price"), but which Variable Price shall not be lower than the $0.47. In addition, upon the occurrence and during the continuation of an event of default, the Promissory Notes shall become immediately due and payable. In no event shall Yorkville be allowed to effect a conversion if such conversion, along with all other shares of Common Stock beneficially owned by Yorkville and its affiliates would exceed 4.99% of the outstanding shares of the Common Stock of the Company.

Upon the satisfaction of the conditions to Yorkville's purchase obligation set forth in the SEPA, including having a registration statement registering the resale of the shares of Common Stock issuable under the SEPA declared effective by the SEC, the Company will have the right, but not the obligation, from time to time at its discretion until the SEPA is terminated to direct Yorkville to purchase a specified number of shares of Common Stock ("Advance") by delivering written notice to Yorkville ("Advance Notice"). While there is no mandatory minimum amount for any Advance, it may not exceed the greater of (i) an amount equal to 100% of the average of the daily traded amount during the five consecutive trading days immediately preceding an Advance Notice, and (ii) 500,000 shares of Common Stock. The Company will not have the right to submit an Advance Notice under the SEPA if a balance remains outstanding under a Promissory Note (as defined below) unless the Company is using the proceeds of such Advance Notice to make payments of an Installment Amount under a Promissory Note.

At any time after the Commencement Date and provided that a balance under a Promissory Note is outstanding, Yorkville may, by providing written notice to the Company (an "Investor Notice"), require the Company to issue and sell shares of Common Stock to Yorkville as set out in the relevant Investor Notice, in accordance with the terms and limitations as set forth in the SEPA. The purchase price of the shares delivered pursuant to an Investor Notice shall be equal to the Conversion Price (as defined below) in effect on the date of delivery of the Investor Notice and shall be paid by offsetting the amount of the aggregate purchase price to be paid by Yorkville against an equal amount outstanding under the Promissory Note.

Otherwise, the shares of Common Stock purchased pursuant to an Advance will be purchased at a price equal to 97% of the lowest daily VWAP of the shares of Common Stock during the three consecutive trading days commencing on the date of the delivery of the Advance Notice, other than the daily VWAP on a day in which the daily VWAP is less than a minimum acceptable price as stated by the Company in the Advance Notice or there is no VWAP on the subject trading day. The Company may establish a minimum acceptable price in each Advance Notice below which the Company will not be obligated to make any sales to Yorkville. "VWAP" is defined as the daily volume weighted average price of the shares of our Common Stock for such trading day on the Nasdaq during regular trading hours as reported by Bloomberg L.P.

Other than as stated above, we will control the timing and amount of any sales of Common Stock to Yorkville that we may elect, in our sole discretion, to effect from time to time during the term of the SEPA. Actual sales of shares of Common Stock to Yorkville under the SEPA will depend on a variety of factors to be determined by us from time to time, including, among other things, market conditions, the trading price of the Common Stock and determinations by us as to the appropriate sources of funding for our business and our operations.

Under the applicable Nasdaq rules, in no event may we issue to Yorkville under the SEPA more than 3,475,907 shares of Common Stock, which number of shares is equal to 19.99% of the shares of Common Stock outstanding immediately prior to the execution of the SEPA (the "Exchange Cap"), unless (i) we obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap in accordance with applicable Nasdaq

rules, or (ii) the average price per share paid by Yorkville for all of the shares of Common Stock that we direct Yorkville to purchase from us pursuant to the SEPA, if any, equals or exceeds $2.37 per share (representing the lower of (a) the official closing price of our Common Stock on Nasdaq immediately preceding the execution of the SEPA and (b) the average official closing price of our Common Stock on Nasdaq for the five consecutive Trading Days immediately preceding the execution of the SEPA, adjusted as required by Nasdaq to take into account our issuance of the Commitment Shares (as defined below), to Yorkville as consideration), so that the Exchange Cap limitation will not apply to issuances and sales of Common Stock pursuant to the SEPA.

Moreover, we may not issue or sell any shares of Common Stock to Yorkville under the SEPA which, when aggregated with all other shares of Common Stock then beneficially owned by Yorkville and its affiliates (as calculated pursuant to Section 13(d) of the Exchange Act, would result in Yorkville beneficially owning more than 4.99% of the outstanding shares of our Common Stock (the "Beneficial Ownership Limitation").

The net proceeds to us from sales that we elect to make to Yorkville under the SEPA, if any, will depend on the frequency and prices at which we sell shares of our Common Stock to Yorkville. We expect that any proceeds received by us from such sales to Yorkville will be used for working capital and general corporate purposes.

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the SEPA or Registration Rights Agreement, other than a prohibition on repaying any loans to any executives or employees of the Company or payments in respect of any related party debt, and a prohibition on effecting or entering into an agreement to effect an "equity line of credit" or other substantially similar continuous offering with a third party, in which we may offer, issue or sell Common Stock or any securities exercisable, exchangeable or convertible into Common Stock at a future determined price. Notwithstanding the foregoing, the Company is permitted to effect issuances and sales of its Common Stock pursuant the common stock purchase agreement, dated December 26, 2023, entered into between the Company and B. Riley Principal Capital II, resulting in gross proceeds not to exceed $3,000,000 from and after the Effective Date.

Yorkville has agreed that none of Yorkville, its sole member, any of their respective officers, or any entity managed or controlled by Yorkville or its sole member will engage in or effect, directly or indirectly, for its own account or for the account of any other of such persons or entities, any short sales of the Common Stock or hedging transaction that establishes a net short position in the Common Stock during the term of the SEPA.

The SEPA will automatically terminate on the earlier to occur of (i) the 36-month anniversary of the Effective Date, provided that if a Promissory Note is then outstanding, such termination shall be delayed until such date that the Promissory Note that was outstanding has been repaid, or (ii) the date on which Yorkville shall have made payment of Advances pursuant to the SEPA for Common Shares equal to the Commitment Amount.

We have the right to terminate the SEPA at any time after Effective Date, at no cost or penalty, upon five Trading Days' prior written notice to Yorkville, provided that (i) there are no outstanding Advance Notices under which Common Shares have yet to be issued, (ii) there is not an outstanding Promissory Note and (iii) the Company has paid all amounts owed to Yorkville pursuant to the SEPA. We and Yorkville may also agree to terminate the SEPA by mutual written consent. Neither we nor Yorkville may assign or transfer our respective rights and obligations under the SEPA or the Registration Rights Agreement, and no provision of the SEPA or the Registration Rights Agreement may be modified or waived by us or Yorkville.

As consideration for Yorkville's commitment to purchase shares of Common Stock at our direction upon the terms and subject to the conditions set forth in the SEPA, upon our execution of the SEPA, we (i) issued 94,937 shares of Common Stock to Yorkville (the "Commitment Shares"), which Commitment Shares have a total aggregate value equal to 0.75% of Yorkville's $30,000,000 total aggregate purchase commitment under the SEPA (each Commitment Share valued at $2.37 per share, representing the official closing price of the Common Stock on Nasdaq immediately preceding the execution of the SEPA) and (ii) agreed to pay Yorkville a cash commitment fee in the amount of $75,000, which is equal to 0.25% of Yorkville's $30,000,000 total aggregate purchase commitment under the SEPA, upon the six month anniversary of the SEPA (the "Cash Commitment Fee"). In addition, we paid Yorkville a diligence fee in the amount of $25,000, which was paid prior to the Effective Date.

The SEPA and the Registration Rights Agreement contain customary representations, warranties, conditions, and indemnification obligations of the parties. Copies of the agreements have been filed as exhibits to the registration statement that includes this prospectus and are available electronically on the SEC's website at *www.sec.gov.*

Because the per share purchase price that Yorkville will pay for shares of Common Stock ("Purchase Shares") pursuant to any Advance that we may elect to effect pursuant to the SEPA will be determined by reference to the VWAP during the applicable period for such Advance on the applicable purchase date for such Advance ("Purchase Date"), as of the date of this prospectus, we cannot determine the actual purchase price per share that Yorkville will be required to pay for any Purchase Shares that we may elect to sell to Yorkville under the SEPA from and after Commencement Date and, therefore, we cannot be certain how many Purchase Shares, in the aggregate, we may issue and sell to Yorkville under the SEPA from and after the Commencement Date. As of April 8, 2024, there were 17,561,808 shares of our Common Stock outstanding, of which 9,446,957 shares were held by non-affiliates of our company. If all of the 6,275,000 shares offered for resale by Yorkville under this prospectus were issued and outstanding as of the date hereof, such shares would represent approximately 26.3% of the total number of outstanding shares of Common Stock and approximately 39.9% of the total number of outstanding shares of Common Stock held by non-affiliates of our company, in each case as of April 8, 2024.

Although the SEPA provides that we may sell up to $30.0 million of our Common Stock to Yorkville, only 6,275,000 Purchase Shares (in addition to the 94,937 Commitment Shares, for which we have not and will not receive any cash consideration) are being registered under the Securities Act for resale by Yorkville under the registration statement that includes this prospectus. If we were to issue and sell all of such 6,275,000 Purchase Shares to Yorkville at an assumed purchase price per share of $2.24 (without taking into account the 19.99% Exchange Cap limitation), representing the closing sale price of our Common Stock on Nasdaq on April 8, 2024, we would only receive approximately $14,056,000 in aggregate gross proceeds from the sale of such Purchase Shares to Yorkville under the SEPA. Depending on the market prices of our Common Stock on the purchase dates on which we elect to sell such Purchase Shares to Yorkville under the SEPA, we may need to register under the Securities Act additional shares of our Common Stock for resale by Yorkville which, together with the 6,275,000 Purchase Shares included in this prospectus, will enable us to issue and sell to Yorkville such aggregate number of shares of Common Stock under the SEPA as will be necessary in order for us to receive aggregate proceeds equal to Yorkville's $30.0 million maximum aggregate purchase commitment available to us under the SEPA.

If we elect to issue and sell to Yorkville more than the 6,275,000 shares of Common Stock being registered under the Securities Act for resale by Yorkville under the registration statement that includes this prospectus (94,937 of which shares represent the Commitment Shares that we issued to Yorkville upon execution of the SEPA on March 20, 2024, for which we have not and will not receive any cash consideration), which we have the right, but not the obligation, to do, we must first (i) obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap under the SEPA in accordance with applicable Nasdaq rules and (ii) file with the SEC one or more additional registration statements to register under the Securities Act for the offer and resale by Yorkville of any such additional shares of our Common Stock we wish to sell from time to time under the SEPA, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our Common Stock to Yorkville under the SEPA. Any issuance and sale by us under the SEPA of a substantial amount of shares of Common Stock in addition to the 6,275,000 shares of Common Stock being registered for resale by Yorkville under the registration statement that includes this prospectus could cause additional substantial dilution to our stockholders.

The number of shares of Common Stock ultimately offered for resale by Yorkville through this prospectus is dependent upon the number of shares of Common Stock, if any, we elect to sell to Yorkville under the SEPA from and after the Commencement Date. The issuance of our Common Stock to Yorkville pursuant to the SEPA will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted. Although the number of shares of our Common Stock that our existing stockholders own will not decrease, the shares of our Common Stock owned by our existing stockholders will represent a smaller percentage of our total outstanding shares of our Common Stock after any such issuance.

Summary Risk Factors

Investments in our securities involve substantial risk. The occurrence of one or more of the events or circumstances described in the section of this prospectus entitled "*Risk Factors*," alone or in combination with other events or circumstances, may have a material adverse effect on our business, cash flows, financial condition and results of operations. Important factors and risks that could cause actual results to differ materially from those in the forward-looking statements include, among others, the following:

- *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 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 "Risk Factors," elsewhere in this Registration Statement on Form S-1 and in our other filings with the Securities and Exchange Commission.*

Emerging Growth Company and Smaller Reporting Company

As a company with less than $1.235 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- the option to present only two years of audited financial statements and only two years of related "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act");
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote of stockholders on executive compensation, stockholder approval of any golden parachute payments not previously approved and having to disclose the ratio of the compensation of our chief executive officer to the median compensation of our employees.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of the initial public offering of Rosecliff's securities. However, if (i) our annual gross revenue exceeds $1.235 billion, (ii) we issue more than $1.0 billion of non-convertible debt in any three-year period or (iii) we become a "large accelerated filer" (as defined in Rule 12b-2 under the Exchange Act) prior to the end of such five-year period, we will cease to be an emerging growth company. We will be deemed to be a "large accelerated filer" at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of $700.0 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act, for a period of at least 12 months and (c) have filed at least one annual report pursuant to the Exchange Act.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period to comply with new or revised accounting standards. We have elected to use the extended transition period to comply with new or revised accounting standards. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are also a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting Common Stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting Common Stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Corporate Information

We were incorporated in Delaware on November 17, 2020, under the name Rosecliff Acquisition Corp I, in order to effectuate a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses. RCLF completed its initial public offering on February 11, 2021. On September 11, 2023, RCLF and Legacy Spectral consummated the transactions contemplated by the Business Combination Agreement. On the Closing Date, RCLF changed its name to Spectral AI, Inc.

The mailing address of our principal executive office is 2515 McKinney Avenue, Suite 1000, Dallas, Texas 75201, and our telephone number is (972) 499-4934.

THE OFFERING

Shares of Common Stock offered by the Selling Stockholder	Up to 6,369,937 shares of Common Stock consisting of: • 94,937 Commitment Shares that we issued to Yorkville in connection with the execution of the SEPA on March 20, 2024, as partial consideration for its commitment to purchase shares of Common Stock at our direction under the SEPA, for which we have not and will not receive any cash consideration; and • Up to 6,275,000 Purchase Shares that may be issued to Yorkville from time to time from and after the Commencement Date pursuant to the SEPA.
Shares of Common Stock outstanding prior to this offering	17,561,808 shares of Common Stock (as of April 8, 2024 and includes the Commitment Shares).
Shares of Common Stock outstanding immediately after giving effect to the issuance of the shares registered hereunder	23,836,808 shares of Common Stock
Use of proceeds	We will not receive any proceeds from the resale of shares of Common Stock included in this prospectus by Yorkville. However, we may receive up to $30.0 million in aggregate gross proceeds under the SEPA (of which the Pre-Paid Advances are a part) from sales of Common Stock that we may elect to make to Yorkville pursuant to the SEPA, if any, from time to time in our sole discretion, from and after the Commencement Date. We expect to use the net proceeds that we receive from sales of our Common Stock to Yorkville, if any, under the SEPA for investment in growth and general corporate purposes. We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, we retain broad discretion over the use of the net proceeds from the sale of our Common Stock under the SEPA. The precise amount and timing of the application of such proceeds will depend upon our liquidity needs and the availability and cost of other capital over which we have little or no control. As of the date hereof, we cannot specify with certainty the particular uses for the net proceeds. See the section titled "*Use of Proceeds*."
Risk factors	You should carefully read the section titled "*Risk Factors*" beginning on page 10 of this prospectus and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our Common Stock.
Nasdaq symbol for our Common Stock	"MDAI"

The number of shares of Common Stock outstanding is based on 17,561,808 shares of Common Stock as of April 8, 2024 and excludes the following, in each case as of April 8, 2024, except as otherwise noted:

- 3,614,949 shares of our Common Stock issuable upon the exercise of outstanding options under the 2018 Long Term Incentive Plan and the 2022 Long Term Incentive Plan, with a weighted average exercise price of $2.22 per share;
- 58,197 shares of our Common Stock issuable upon the exercise of outstanding restricted stock units under the 2022 Long Term Incentive Plan, with an exercise price of $4.48 per share;
- 73,978 shares of our Common Stock issuable upon the exercise of 73,978 Warrants, with an exercise price of $7.60 per share; and
- 193,889 shares of our Common Stock reserved for future issuance under the 2018 Long Term Incentive Plan and 1,792,918 shares of our Common Stock reserved for future issuance under the 2022 Long Term Incentive Plan.

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.

Unless the context otherwise requires, all references in this section to "we," "us," or "our" refers to the Company and its subsidiaries.

Risks Related to the Offering

It is not possible to predict the actual number of shares we will sell under the SEPA to Yorkville, or the actual gross proceeds resulting from those sales.

On March 20, 2024, we entered into the SEPA with Yorkville, pursuant to which Yorkville has committed to purchase up to $30.0 million of shares of our Common Stock, subject to certain limitations and conditions set forth in the SEPA. The shares of our Common Stock that may be issued under the SEPA may be sold by us to Yorkville at our discretion from time to time for a period of up to 36 months, unless the SEPA is earlier terminated, beginning on the Effective Date.

We generally have the right to control the timing and amount of any sales of our shares of Common Stock to Yorkville under the SEPA. Sales of our Common Stock, if any, to Yorkville under the SEPA will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Yorkville all, some or none of the shares of our Common Stock that may be available for us to sell to Yorkville pursuant to the SEPA.

Because the per share purchase price that Yorkville will pay for Purchase Shares in any transaction that we may elect to effect pursuant to the SEPA will be determined by reference to the VWAP during the applicable period, respectively, on the applicable Purchase Date, as of the date of this prospectus, it is not possible for us to predict the number of shares of Common Stock that we will sell to Yorkville under the SEPA, the purchase price per share that Yorkville will pay for shares purchased from us under the SEPA, or the aggregate gross proceeds that we will receive from those purchases by Yorkville under the SEPA.

Although the SEPA provides that we may sell up to an aggregate of $30.0 million of our Common Stock to Yorkville, only 6,369,937 shares of our Common Stock are being registered under the Securities Act for resale by Yorkville under the registration statement that includes this prospectus, which include the 94,937 Commitment Shares that we issued to Yorkville upon our execution of the SEPA on March 20, 2024, as partial consideration for its commitment to purchase shares of our Common Stock at our direction from time to time under the SEPA. If it becomes necessary for us to issue and sell to Yorkville under the SEPA more than the 6,275,000 Purchase Shares being registered under the Securities Act for resale by Yorkville under the registration statement that includes this prospectus in order to receive aggregate gross proceeds equal to $30.0 million under the SEPA, we must first (i) obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap under the SEPA in accordance with applicable Nasdaq rules and (ii) file with the SEC one or more additional registration statements to register under the Securities Act the resale by Yorkville of any such additional shares of our Common Stock we wish to sell from time to time under the SEPA, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our Common Stock to Yorkville under the SEPA. Any issuance and sale by us under the SEPA of a substantial amount of shares of Common Stock in addition to the 6,369,937 shares of Common Stock being registered for resale by Yorkville under this prospectus could cause additional substantial dilution to our stockholders. The number of shares of our Common Stock ultimately offered for sale by Yorkville is dependent upon the number of shares of Common Stock, if any, we ultimately elect to sell to Yorkville under the SEPA.

Investors who buy shares at different times will likely pay different prices.

Pursuant to the SEPA, we will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold to Yorkville. If and when we do elect to sell shares of our Common Stock to Yorkville pursuant to the SEPA, after Yorkville has acquired such shares, Yorkville may resell all, some or none of such shares at any time or from time to time in its discretion and at different prices. As a result, investors who purchase shares from Yorkville in this offering at different times will likely pay different prices for those shares, and so may experience different levels of dilution, and in some cases substantial dilution, and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Yorkville in this offering as a result of future sales made by us to Yorkville at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares to Yorkville under the SEPA, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Yorkville may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

Sales of a substantial number of our securities in the public market by our existing stockholders could cause the price of our shares of Common Stock to fall.

Yorkville can resell, under this prospectus, up to 6,369,937 shares of Common Stock, consisting of (i) up to 6,275,000 Purchase Shares that we may, in our sole discretion, elect to sell to Yorkville, from time to time from and after the Commencement Date pursuant to the SEPA and (ii) the 94,937 Commitment Shares we issued to Yorkville upon our execution of the SEPA on March 20, 2024, as partial consideration for its commitment to purchase shares of our Common Stock that we may, in our sole discretion, direct Yorkville to purchase from us pursuant to the SEPA, from time to time after the date of this prospectus and during the term of the SEPA. If all of the 6,369,937 shares offered for resale by Yorkville under this prospectus were issued and outstanding as of the date hereof (without taking into account the 19.99% Exchange Cap limitation), such shares would represent approximately 26% of the total number of outstanding shares of Common Stock and approximately 39% of the total number of outstanding shares of Common Stock held by non-affiliates of our company, in each case as of April 8, 2024.

Sales of a substantial number of our shares of Common Stock in the public market by Yorkville and/or by our other existing stockholders, or the perception that those sales might occur, could depress the market price of our shares of Common Stock and could impair our ability to raise capital through the sale of additional equity securities.

Our management team will have broad discretion over the use of the net proceeds from our sale of shares of Common Stock to Yorkville, if any, and you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management team will have broad discretion as to the use of the net proceeds from our sale of shares of Common Stock to Yorkville, if any, and we could use such proceeds for purposes other than those contemplated at the time of commencement of this offering. Accordingly, you will be relying on the judgment of our management team with regard to the use of those net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest those net proceeds in a way that does not yield a favorable, or any, return for us. The failure of our management team to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flows.

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 substantially all 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 half of 2025. 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.

Under the terms of our current contract with DHA, the Company is required to provide monthly reports and one final technical report at the end of the contract term. The Company is allowed to advance the development of the research from this contract with the FDA, provided the Company shares all communication, both formal and informal, to or from FDA regarding the technology being developed under this contract with the DHA and its representatives are permitted to participate in any sponsor meetings both formal and informal with the FDA upon request. In addition, the Company is entitled to maintain ownership of the inventions generated from the contract in accordance with the terms contained in the DHA award.

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.

As part of the BARDA contract, we represented that we are a small business concern under NAICS Code 541714 ("Research and Development in Biotechnology"). We are also registered with the FDA as a small business, based on self-assessment. For this representation to continue to be accurate, we would have to continue to comply with the small business size standards published by the U.S. Small Business Association for NAICS Code 541714. If we were to grow beyond 1,000 employees as a result of an expansion or any acquisition, we would no longer qualify as a small business concern; this could threaten our ability to maintain the BARDA contract.

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 has the right to sell to B. Riley up to $10.0 million 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 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. 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 Promissory Notes an aggregate principal amount of up to $12,500,000 (the "Pre-Paid Advance"), which will be paid in three tranches. The SEPA provides that the Company may draw an additional $3.0 million under the Purchase Agreement prior to any utilization of the SEPA to satisfy the repayment of any Pre-Paid Advance. There can be no assurance that the variable conversion price per share of our Common Stock at the time of any such conversion will be at or above the fixed conversion price as established for the first Pre-Paid Advance which may result in significant dilution to our existing shareholders.

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 SEPA financing will be sufficient to meet our capital requirements and fund our operations through at least March 31, 2025. 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. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. The De Novo classification process is available for novel devices of low to moderate risk, for which there are no legally marketed devices on which to base the substantial equivalence determination, or after the applicant receives a not-substantially-equivalent decision from FDA in response to a 510(k) application. This petition requests the FDA down-classify a new device from a Class III to a Class II regulation. Should the De Novo classification request be declined, the device, as a Class III device, would require pursuit of a PMA under Section 515 of the FDCA, requiring additional time and expense. 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.

To demonstrate compliance with the general safety and performance requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its risk classification. Except for low-risk medical devices (Class I), where the manufacturer can self-assess to the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. See "*Business — Government Regulation — Regulation of Medical Devices in the European Union*."

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 or 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 regulatory clearance, approval, De Novo classification, or certification to revise the process for market authorization, De Novo classification, certification, manufacture and marketing of regulated products or the reimbursement thereof. 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, over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. In November 2018, FDA officials announced forthcoming steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, 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.

In September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the "safety and performance based" pathway and announced that it intends to continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain 510(k) clearance or otherwise create competition that may negatively affect our business.

In October 2021, the FDA issued a final rule on the De Novo classification process, which became effective on January 3, 2022. The rule explains when the De Novo classification route may be available to applicants, and what information should be included in the request so that the FDA can determine whether to grant the De Novo classification request. This includes, for example, the device's regulatory history, proposed indications for use, device description, labeling, advertisements, and information demonstrating that when subject to general controls, or general and special controls, the probable benefit to health outweighs any probable injury or illness from such use. The FDA will grant the De Novo classification request if none of the reasons in the regulations for declining a De Novo request applies to the product at issue, including that the request includes false information or omits

material information, the device has already been classified under a PMA, or an inspection of the device facility results in a determination that general or general and special controls would not provide reasonable assurance of safety and effectiveness.

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 clearance, approval, or De Novo classification for, or to manufacture, market or distribute 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 clearance, approval, or De Novo classification; 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. On May 25, 2017, the EU Medical Devices Regulation entered into force, which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

The EU Medical Devices Regulation entered into application on May 26, 2021. The new regulation among other things:

- strengthens the rules on placing devices on the market (*e.g.*, reclassification of certain devices and wider scope than the EU Medical Devices Directive) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow up of the quality, performance and safety of devices placed on the market;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improves the traceability of medical devices throughout the supply chain to the end user or patient through the introduction of a unique device identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (Eudamed) to provide the European Commission, competent authorities, economic operators, notified bodies, sponsors, patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens the rules for the assessment of certain high risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

These modifications may have an effect on the way we develop our business in the EU and EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed or canceled, which could adversely affect our ability to grow our business.

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. Separately, in response to the global COVID-19 pandemic, in March 2020, the FDA temporarily postponed all domestic and foreign routine surveillance facility inspections. Subsequently, in July 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system and in May 2021, the FDA issued a new report outlining the agency's plan to move toward a more consistent state of inspectional capacity and priorities for domestic and foreign inspections that were not performed during the pandemic. In July 2021, the FDA stated that it had largely returned to standard operations for domestic inspections; however, the agency's foreign inspectional activities were still hampered by the pandemic. In January 2022, the FDA again put certain inspectional activities on hold because of the spread of the Omicron variant of COVID-19. In February of the same year, the FDA announced that it had resumed domestic inspection activities and certain foreign inspections. However, it is possible that new 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, it 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 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 510(k) clearances, or other 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. Devices authorized for marketing pursuant to a 510(k) clearance cannot be marketed for any intended use beyond the cleared indications. 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, or De Novo classification for commercialization. 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.

By way of example, in the United States, the Affordable Care Act ("ACA") was enacted in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which have impacted existing government healthcare programs and will result in the development of new programs. Since its enactment, there have been numerous amendments to the ACA and revisions to implementing regulations, along with judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the Supreme Court ruled that states and individuals lacked standing to challenge the constitutionality of the ACA's individual mandate, post-repeal of its associated tax penalty. Additionally, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and ended August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Under Republican leadership, the House of Representatives has yet to release its budget proposals for 2023. Nevertheless, virtually every Republican budget or fiscal plan over the last decade has included a repeal of the ACA and deep cuts to Medicaid. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain likely. We cannot predict what effect further changes related to the ACA, including under the Republican congress or Biden administration, will have on our business.

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 and cost of additional 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. For example, California enacted the California Consumer Privacy Act (the "CCPA"), which creates individual privacy rights for California consumers (as defined in the law), including the right to opt out of certain disclosures of their information, and places increased privacy and security obligations on entities handling certain personal data of consumers or households and may apply to us in the future. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the California Privacy Rights Act (the "CPRA"), recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Enforcement of CPRA is scheduled to begin on July 1, 2023. The CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States, as other states or the federal government follow California's lead and increase protections for U.S. residents. For example, on March 2, 2021, the Virginia Consumer Data Protection Act, which took effect on January 1, 2023, was signed into law. Privacy initiatives have also been signed into law in Colorado (the Colorado Privacy Act, effective July 1, 2023), Connecticut (the Connecticut Personal Data Privacy and Online Monitoring Act, effective July 1, 2023), and Utah (the Utah Consumer Privacy Act, effective December 31, 2023).

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. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the EU (the "CJEU"). While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission has published revised standard contractual clauses for data transfers from the EEA: the revised clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. If necessary, we will be required to implement the 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 AID 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 faster 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. Spectral has enrolled subjects in its DFU studies in clinical and academic sites across the US and the EU with approximately 430 subjects across well-known medical facilities. Spectral has also signed with international partners such as the Royal College of Surgeons in Ireland, a well-respected institution 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 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, especially as we transition to operating as a U.S. public company. 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 Corporate Development Officer and the 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 April 8, 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 faster 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 prospectus, we have 11 issued and allowed U.S. patents with six U.S. patent applications pending. We have 12 issued and allowed international patents with 26 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 will be 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. In recent months, there has been significant volatility and instability among banks and financial institutions. 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, you may not be able to sell your securities at or above the price at which it was 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, the 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 the 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 the 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 have a sufficient complement of personnel with appropriate technical expertise to perform an effective risk assessment related to determining the appropriate balances to record for material legal and tax expenses and related accruals

and unbilled revenue; 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 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, including those registered in this registration statement, 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 the lock-ups described above, 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 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 of our Common Stock 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. 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.

USE OF PROCEEDS

Any sales of Common Stock by Yorkville pursuant to this prospectus will be solely for Yorkville's accounts. The Company will not receive any proceeds from any such sales.

We may receive up to $30.0 million aggregate gross proceeds under the SEPA from any sales we make to Yorkville pursuant to the SEPA. The net proceeds from sales, if any, under the SEPA, will depend on the frequency and prices at which we sell our Common Stock to Yorkville after the date of this prospectus. See the section titled "*Plan of Distribution*" in this prospectus for more information.

We expect to use any proceeds that we receive under the SEPA for working capital and general corporate purposes. As of the date of this prospectus, we cannot specify with certainty all of the particular uses, and the respective amounts we may allocate to those uses, for any net proceeds we receive. Accordingly, we will retain broad discretion over the use of these proceeds.

The holders will pay any underwriting discounts, selling commissions and stock transfer taxes and fees incurred by such holders in connection with any sale of their shares of Common Stock. The Company will generally bear all other costs, fees and expenses incurred in effecting the registration of the shares of Common Stock covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq listing fees and fees and expenses of Company counsel and independent registered public accountants.

DETERMINATION OF OFFERING PRICE

We cannot currently determine the price or prices at which shares of Common Stock may be sold by Yorkville under this prospectus.

THE STANDBY EQUITY PURCHASE AGREEMENT

On March 20, 2024, we entered into the SEPA and the Registration Rights Agreement with Yorkville. Upon the terms and subject to the satisfaction of the conditions contained in the SEPA, from and after the Commencement Date, we will have the right, in our sold discretion, to sell to Yorkville up to $30.0 million of shares of our Common Stock, subject to certain limitations set forth in the SEPA, from time to time after the date of this prospectus and during the term of the SEPA. Sales of Common Stock by us to Yorkville under the SEPA, and the timing of any such sales, are solely at our option, and we are under no obligation to sell any securities to Yorkville under the SEPA. In accordance with our obligations under the Registration Rights Agreement, we have filed the registration statement that includes this prospectus with the SEC to register under the Securities Act the resale by Yorkville of up to 6,369,937 shares of Common Stock, consisting of (i) up to 6,275,000 Purchase Shares that we may, in our sole discretion, elect to sell to Yorkville, from time to time from and after the Commencement Date pursuant to the SEPA and (ii) the 94,937 Commitment Shares we issued to Yorkville upon our execution of the SEPA on March 20, 2024, together with our payment of the Cash Commitment Fee to Yorkville, as consideration for its commitment to purchase shares of our Common Stock that we may, in our sole discretion, direct Yorkville to purchase from us pursuant to the SEPA, from time to time after the date of this prospectus and during the term of the SEPA.

Upon the satisfaction of the conditions to Yorkville's purchase obligation set forth in the SEPA, including having a registration statement registering the resale of the shares of Common Stock issuable under the SEPA declared effective by the Securities and Exchange Commission, the Company will have the right, but not the obligation, from time to time at its discretion until the SEPA is terminated to direct Yorkville to purchase an Advance by delivering an Advance Notice. While there is no mandatory minimum amount for any Advance, it may not exceed the greater of (i) an amount equal to 100% of the average of the daily traded amount during the five consecutive trading days immediately preceding an Advance Notice, and (ii) 500,000 shares of Common Stock.

The shares of Common Stock purchased pursuant to an Advance delivered by the Company will be purchased at a price equal to 97% of the lowest daily VWAP of the shares of common stock during the three consecutive trading days commencing on the date of the delivery of the Advance Notice, other than the daily VWAP on a day in which the daily VWAP is less than a minimum acceptable price as stated by the Company in the Advance Notice or there is no VWAP on the subject trading day. The Company may establish a minimum acceptable price in each Advance Notice below which the Company will not be obligated to make any sales to Yorkville. "VWAP" is defined as the daily volume weighted average price of the shares of our Common Stock for such trading day on the Nasdaq during regular trading hours as reported by Bloomberg L.P.

Under the applicable Nasdaq rules, in no event may we issue to Yorkville under the SEPA more than 3,475,907 shares of Common Stock, which number of shares is equal to the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap in accordance with applicable Nasdaq rules, or (ii) the average price per share paid by Yorkville for all of the shares of Common Stock that we direct Yorkville to purchase from us pursuant to the SEPA, if any, equals or exceeds $2.37 per share (representing the lower of (a) the official closing price of our Common Stock on Nasdaq immediately preceding the execution of the SEPA and (b) the average official closing price of our Common Stock on Nasdaq for the five consecutive Trading Days immediately preceding the execution of the SEPA, adjusted as required by Nasdaq to take into account our issuance of the Commitment Shares, to Yorkville as consideration), so that the Exchange Cap limitation will not apply to issuances and sales of Common Stock pursuant to the SEPA.

Moreover, we may not issue or sell any shares of Common Stock to Yorkville under the SEPA which, when aggregated with all other shares of Common Stock then beneficially owned by Yorkville and its affiliates (as calculated pursuant to Section 13(d) of the Exchange Act, would result in Yorkville beneficially owning more than 4.99% of the outstanding shares of our Common Stock).

The net proceeds to us from sales that we elect to make to Yorkville under the SEPA, if any, will depend on the frequency and prices at which we sell shares of our Common Stock to Yorkville. We expect that any proceeds received by us from such sales to Yorkville will be used for working capital and general corporate purposes.

Neither we nor Yorkville may assign or transfer our respective rights and obligations under the SEPA or the Registration Rights Agreement, and no provision of the SEPA or the Registration Rights Agreement may be modified or waived by us or Yorkville.

As consideration for Yorkville's commitment to purchase shares of Common Stock at our direction upon the terms and subject to the conditions set forth in the SEPA, upon our execution of the SEPA, we (i) issued the Commitment Shares, which have a total aggregate value equal to 0.75% of Yorkville's $30.0 million total aggregate purchase commitment under the SEPA (each Commitment Share valued at $2.37 per share, representing the official closing price of the Common Stock on Nasdaq immediately preceding the execution of the SEPA) and (ii) agreed to pay Yorkville a Cash Commitment Fee in the amount of $75,000, which is equal to 0.25% of Yorkville's $30.0 million total aggregate purchase commitment under the SEPA, upon the six month anniversary of the SEPA. In addition, we paid Yorkville a diligence fee in the amount of $25,000, which has been paid prior to the Effective Date.

The SEPA and the Registration Rights Agreement contain customary representations, warranties, conditions and indemnification obligations of the parties. Copies of the agreements have been filed as exhibits to the registration statement that includes this prospectus and are available electronically on the SEC's website at *www.sec.gov*.

Pre-Paid Advances

In connection with the SEPA, and subject to the conditions set forth therein, Yorkville has agreed to advance to the Company the Promissory Notes for an aggregate principal amount of up to $12.5 million, 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 later of the registration statement registering the resale of the shares of Common Stock issuable under the SEPA being declared effective or shareholder approval to exceed the Exchange Cap, 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 Promissory Notes. The maturity date of the Promissory Note issued in connection with each Pre-Paid Advance will be 12 months after the issuance date of such Promissory Note. Yorkville may convert the Promissory Notes into shares of the Company's Common Stock at any time at a fixed conversion price equal to (i) in respect of the Promissory Note issued in connection with the first Pre-Paid Advance, $3.16, and (ii) in respect of the Promissory Notes issued in connection with the second and third Pre-Paid Advances, a price per share equal to the Fixed Price.

Beginning on the forty-fifth (45th) day following the issuance date of the Promissory Note issued in connection with the first Pre-Paid Advance, and continuing on each Installment Date thereafter, the Company shall repay a portion of the outstanding balance of the Pre-Paid Advance in an amount equal to (i) the Installment Principal Amount, plus (ii) a payment premium of 7% of such Installment Principal Amount, and (iii) accrued and unpaid interest hereunder as of each Installment Date. At any time or times on or after any Installment Date, the Investor shall be entitled to convert any portion of any due and unpaid Installment Amount outstanding under a Promissory Note until such amount has been paid into shares at a price per share equal to the Variable Price, but which Variable Price shall not be lower than the $0.47 . In addition, upon the occurrence and during the continuation of an event of default, the Promissory Notes shall become immediately due and payable. In no event shall Yorkville be allowed to effect a conversion if such conversion, along with all other shares of Common Stock beneficially owned by Yorkville and its affiliates would exceed 4.99% of the outstanding shares of the Common Stock of the Company.

Purchases of Common Stock Under the SEPA

Advance Notice

From and after the Commencement Date, we will have the right, but not the obligation, from time to time at our sole discretion for a period of up to 36 months, unless the SEPA is earlier terminated, beginning on the Effective Date, to direct Yorkville to purchase a specified number of shares of Common Stock, not to exceed the Maximum Advance Amount (as defined below), by timely delivering an Advance Notice to Yorkville by 9:00 a.m. New York City time on any Trading Day we select as the purchase date (the "Purchase Date") for such purchase.

The Maximum Advance Amount applicable to such Advance will be equal to the greater of:

- 500,000 shares of Common Stock; and
- an amount equal to one hundred percent (100%) of the average of the daily trading volume of the Company's Common Stock during regular trading hours as reported by Bloomberg L.P. ("Daily Traded Amount") during the five consecutive Trading Days immediately preceding the date of such Advance Notice.

The actual number of shares of Common Stock that Yorkville will be required to purchase in an Advance, which we refer to as the Advance Amount, will be equal to the number of shares that we specify in the applicable Advance Notice, subject to adjustment to the extent necessary to give effect to the applicable Maximum Advance Amount and other applicable limitations set forth in the SEPA, including the Beneficial Ownership Limitation and, if then applicable, the Exchange Cap.

The per share purchase price that Yorkville will be required to pay for the Advance Amount in an Advance effected by us pursuant to the SEPA, if any, will be equal to the VWAP of our Common Stock for the applicable Pricing Period, less a fixed 3% discount to the VWAP for such Pricing Period. The "Pricing Period" for an Advance is defined in the SEPA as the three consecutive Trading Days commencing on the Advance Notice Date.

Investor Notice

In addition to the Advances described above, from and after the Commencement Date, provided there is a balance remaining outstanding under a Promissory Note, Yorkville may, by delivering an Investor Notice to the Company, cause an Advance Notice to be deemed delivered to Yorkville and the issuance and sale of shares of Common Stock to Yorkville pursuant to an Advance, in accordance with the following provisions:

- Yorkville shall, in its sole discretion, select the amount of the Advance up to the Maximum Advance Amount applicable to Yorkville, and the time it desires to deliver each Investor Notice; provided that the amount of the Advance selected shall not exceed the balance owed under all Promissory Notes outstanding on the date of delivery of the Investor Notice.
- The purchase price of the shares of Common Stock in respect of any Advance Notice deemed delivered pursuant to an Investor Notice shall be equal to the Conversion Price (as defined in the respective Promissory Note) in effect on the date of delivery of the Investor Notice (the "Purchase Price"). The Investor shall pay the Purchase Price for shares of Common Stock to be issued pursuant to the Investor Notice by offsetting the amount of the Purchase Price to be paid by Yorkville against an equal amount outstanding under a Promissory Note (first towards accrued and unpaid interest, if any, then towards principal).
- Each Investor Notice shall set forth the amount of the Advance requested, the purchase price (which shall be equal to the Conversion Price) along with a report by Bloomberg, L.P. indicating the relevant VWAP used in calculating the Conversion Price, the number of shares of Common Stock to be issued by the Company and purchased by Yorkville, the aggregate amount of accrued and unpaid interest under the subject Promissory Note (if any) that shall be offset by the issuance of shares of Common Stock, the aggregate amount of principal of the Promissory Note that shall be offset by the issuance of shares of Common Stock, and the total amount of the Promissory Note that shall be outstanding following the closing of the Advance.

In the case of an Advance Notice or Investor Notice effected under the SEPA, if any, all share and dollar amounts used in determining the purchase price per share of Common Stock to be purchased by Yorkville in an Advance, or in determining the applicable maximum purchase share amounts or applicable volume or price amounts in connection with any such Advance, in each case, will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during any period used to calculate such per share purchase price, maximum purchase share amounts or applicable volume or price amounts.

At or prior to each Advance Date, Yorkville shall deliver to the Company a Settlement Document setting forth the number of shares requested and Minimum Acceptable Price, among other items. Promptly after the Company causes its transfer agent to electronically transfer the Advance Shares to Yorkville, Yorkville shall pay to the Company the aggregate purchase price of the shares of Common Stock not later than one Trading Day after such receipt.

Conditions Precedent to the Right of the Company to Deliver an Advance Notice

Yorkville's obligation to accept Advance Notices that are timely delivered by us under the SEPA and to purchase shares of our Common Stock in Advances under the SEPA, are subject to satisfaction of the conditions precedent thereto set forth in the SEPA, all of which are entirely outside of Yorkville's control, which conditions include the following:

- the accuracy in all material respects of the representations and warranties of the Company included in the SEPA as of the Advance Notice Date;
- the Company having paid the Cash Commitment Fee or issued the Commitment Shares to an account designated by Yorkville;
- the registration statement that includes this prospectus (and any one or more additional registration statements filed with the SEC that include shares of Common Stock that may be issued and sold by the Company to Yorkville under the SEPA) having been declared effective under the Securities Act by the SEC, and Yorkville being able to utilize this prospectus (and the prospectus included in any one or more additional registration statements filed with the SEC under the Registration Rights Agreement) to resell all of the shares of Common Stock included in this prospectus (and included in any such additional prospectuses);
- the Company obtaining all permits and qualifications required by any applicable state for the offer and sale of all shares of Common Stock issuable pursuant to such Advance Notice, or shall have the availability of exemptions therefrom;
- the Board of Directors approving the transactions contemplated by the SEPA and Registration Rights Agreement, which approval shall remain in full force;
- there shall not have occurred any event and there shall not exist any condition or state of facts, which makes any statement of a material fact made in the registration statement that includes this prospectus (or in any one or more additional registration statements filed with the SEC that include shares of Common Stock that may be issued and sold by the Company to Yorkville under the SEPA) untrue or which requires the making of any additions to or changes to the statements contained;

  therein in order to state a material fact required by the Securities Act to be stated therein or necessary in order to make the statements then made therein (in the case of this prospectus or the prospectus included in any one or more additional registration statements filed with the SEC under the Registration Rights Agreement, in the light of the circumstances under which they were made) not misleading;
- the Company performing, satisfying and complying in all material respects with all covenants, agreements and conditions required by the SEPA;
- trading in the Common Stock shall not have been suspended by the SEC, Nasdaq or FINRA, the Company shall not have received any final and non-appealable notice that the listing or quotation of the Common Stock on Nasdaq, shall be terminated on a date certain (unless, prior to such date, the Common Stock is listed or quoted on any other Principal Market, as such term is defined in the SEPA), and there shall be no suspension of, or restriction on, accepting additional deposits of the Common Stock, electronic trading or book-entry services by The Depository Trust Company with respect to the Common Stock;
- the Company shall have authorized all of the shares of Common Stock issuable pursuant to the applicable Advance Notice by all necessary corporate action of the Company;
- the absence of any statute, regulation, order, decree, writ, ruling or injunction by any court or governmental authority of competent jurisdiction which prohibits the consummation of or that would materially modify or delay any of the transactions contemplated by the SEPA or the Registration Rights Agreement;

- the absence of any action, suit or proceeding before any arbitrator or any court or governmental authority seeking to restrain, prevent or change the transactions contemplated by the SEPA or the Registration Rights Agreement, or seeking material damages in connection with such transactions; and

- no condition, occurrence, state of facts or event constituting a Material Adverse Effect (as such term is defined in the SEPA) shall have occurred and be continuing.

Termination of the SEPA

Unless earlier terminated as provided in the SEPA, the SEPA will terminate automatically on the earliest to occur of:

- the 36-month anniversary of the Effective Date, provided that if a Promissory Note is then outstanding, such termination shall be delayed until such date that the Promissory Note that was outstanding has been repaid; or

- the date on which Yorkville shall have purchased shares of Common Stock under the SEPA for an aggregate gross purchase price equal to $30.0 million;

We have the right to terminate the SEPA at any time after the Effective Date, at no cost or penalty, upon five Trading Days' prior written notice to Yorkville; provided that (i) there are no outstanding Advance Notices under which shares of Common Stock have yet to be issued, (ii) there is not an outstanding Promissory Note, and (iii) the Company has paid all amounts owed to Yorkville pursuant to the SEPA. We and Yorkville may also terminate the SEPA at any time by mutual written consent.

No Short-Selling or Hedging by Yorkville

Yorkville has agreed that none of Yorkville, its sole member, any of their respective officers, or any entity managed or controlled by Yorkville or its sole member will engage in or effect, directly or indirectly, for its own account or for the account of any other of such persons or entities, any short sales of the Common Stock or hedging transaction that establishes a net short position in the Common Stock during the term of the SEPA.

Prohibition on Dilutive Issuances and Similar Transactions

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the SEPA or Registration Rights Agreement, other than a prohibition on repaying any loans to any executives or employees of the Company or payments in respect of any related party debt, and a prohibition on effecting or entering into an agreement to effect an "equity line of credit" or other substantially similar continuous offering with a third party, in which we may offer, issue or sell Common Stock or any securities exercisable, exchangeable or convertible into Common Stock at a future determined price. Notwithstanding the foregoing, the Company shall be permitted to effect issuances and sales pursuant the common stock purchase agreement, dated December 26, 2023, entered into between the Company and B. Riley Principal Capital II, resulting in gross proceeds not to exceed $3,000,000 from and after the Effective Date.

Effect of Sales of our Common Stock under the SEPA on our Stockholders

The Commitment Shares that we issued, and the Purchase Shares to be issued or sold by us, to Yorkville under the SEPA that are being registered under the Securities Act for resale by Yorkville in this offering are expected to be freely tradable. The 6,396,937 shares of Common Stock being registered for resale in this offering may be issued and sold by us to Yorkville from time to time over a period of up to 36 months, unless the SEPA is earlier terminated, commencing on the Effective Date. The resale by Yorkville of a significant amount of shares registered for resale in this offering at any given time, or the perception that these sales may occur, could cause the market price of our Common Stock to decline and to be highly volatile. Sales of our Common Stock, if any, to Yorkville under the SEPA will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Yorkville all, some or none of the shares of our Common Stock that may be available for us to sell to Yorkville pursuant to the SEPA.

If and when we do sell shares of our Common Stock to Yorkville pursuant to the SEPA, after Yorkville has acquired such shares, Yorkville may resell all, some or none of such shares at any time or from time to time in its discretion and at different prices. As a result, investors who purchase shares from Yorkville in this offering at different

times will likely pay different prices for those shares, and so may experience different levels of dilution, and in some cases substantial dilution, and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Yorkville in this offering as a result of future sales made by us to Yorkville at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares of our Common Stock to Yorkville under the SEPA, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Yorkville may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

Because the per share purchase price that Yorkville will pay for Purchase Shares in any Advance that we may elect to effect pursuant to the SEPA will be determined by reference to the VWAP during the applicable Pricing Period on the applicable Purchase Date for such Advance, as of the date of this prospectus, it is not possible for us to predict the number of shares of Common Stock that we will sell to Yorkville under the SEPA, the actual purchase price per share to be paid by Yorkville for those shares, or the actual gross proceeds to be raised by us from those sales, if any.

As of April 8, 2024, there were 17,561,808 shares of our Common Stock outstanding. If all of the 6,396,937 shares offered for resale by Yorkville under this prospectus were issued and outstanding as of the date hereof, such shares would represent approximately 26% of the total number of outstanding shares of Common Stock and approximately 39% of the total number of outstanding shares of Common Stock held by non-affiliates of our company, in each case as of April 8, 2024.

Although the SEPA provides that we may sell up to $30.0 million of our Common Stock to Yorkville, only 6,275,000 shares (in addition to the 94,937 Commitment Shares, for which we have not and will not receive any cash consideration) are being registered under the Securities Act for resale by Yorkville under the registration statement that includes this prospectus. If we were to issue and sell all of such 6,275,000 shares to Yorkville at an assumed purchase price per share of $2.24 (without taking into account the 19.99% Exchange Cap limitation), representing the closing sale price of our Common Stock on Nasdaq on April 8, 2024, we would only receive approximately $14,056,000 in aggregate gross proceeds from the sale of such Purchase Shares to Yorkville under the SEPA. Depending on the market prices of our Common Stock on the Purchase Dates on which we elect to sell such Purchase Shares to Yorkville under the SEPA, we may need to register under the Securities Act additional shares of our Common Stock for resale by Yorkville which, together with the 6,275,000 Purchase Shares included in this prospectus, will enable us to issue and sell to Yorkville such aggregate number of shares of Common Stock under the SEPA as will be necessary in order for us to receive aggregate proceeds equal to Yorkville's $30.0 million maximum aggregate purchase commitment available to us under the SEPA.

If we elect to issue and sell to Yorkville more than the 6,396,937 shares of Common Stock being registered under the Securities Act for resale by Yorkville under the registration statement that includes this prospectus (94,937 of which shares represent the Commitment Shares that we issued to Yorkville upon execution of the SEPA on March 20, 2024, for which we have not and will not receive any cash consideration), which we have the right, but not the obligation, to do, we must first (i) obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap under the SEPA in accordance with applicable Nasdaq rules and (ii) file with the SEC one or more additional registration statements to register under the Securities Act the resale by Yorkville of any such additional shares of our Common Stock we wish to sell from time to time under the SEPA, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our Common Stock to Yorkville under the SEPA. Any issuance and sale by us under the SEPA of a substantial amount of shares of Common Stock in addition to the 6,396,937 shares of Common Stock being registered for resale by Yorkville under the registration statement that includes this prospectus could cause additional substantial dilution to our stockholders.

The number of shares of Common Stock ultimately offered for resale by Yorkville through this prospectus is dependent upon the number of shares of Common Stock, if any, we elect to sell to Yorkville under the SEPA from and after the Commencement Date. The issuance of our Common Stock to Yorkville pursuant to the SEPA will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted. Although the number of shares of our Common Stock that our existing stockholders own will not decrease, the shares of our Common Stock owned by our existing stockholders will represent a smaller percentage of our total outstanding shares of our Common Stock after any such issuance.

The following table sets forth the amount of gross proceeds we would receive from Yorkville from our sale of shares of Common Stock to Yorkville under the SEPA at varying purchase prices:

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if Full Purchase[1]	Percentage of Outstanding Shares After Giving Effect to the Issuance to Yorkville[2]	Gross Proceeds from the Sale of Shares to Yorkville Under the SEPA
$1.00	3,380,970	19.3%	$ 3,380,970
$2.00	3,380,970	19.3%	$ 6,761,940
$2.24[3]	3,380,970	19.3%	$ 7,573,373
$3.00	3,380,970	19.3%	$ 10,142,910
$4.00	3,380,970	19.3%	$ 13,523,880
$5.00	3,380,970	19.3%	$ 16,904,850

(1) Excluding the 94,937 Commitment Shares that we issued to Yorkville upon the execution of the SEPA on March 20, 2024. Although the SEPA provides that we may sell up to $30,000,000 of our Common Stock to Yorkville, we are only registering 6,396,937 shares under the registration statement that includes this prospectus, including the 94,937 Commitment Shares, which may or may not cover all of the shares we ultimately sell to Yorkville under the SEPA. We will not issue more than an aggregate of 3,475,907 shares of our Common Stock (the Exchange Cap), unless otherwise approved by our stockholders or if the average price per share paid by Yorkville for all of the shares of Common Stock that we direct Yorkville to purchase from us pursuant to the SEPA, if any, equals or exceeds $2.37 per share. The number of shares to be issued as set forth in this column (i) gives effect to the Exchange Cap and (ii) is without regard for the Beneficial Ownership Limitation.

(2) The denominator is based on 17,561,808 shares of Common Stock outstanding as of April 8, 2024 (which, for these purposes, includes the 94,937 Commitment Shares we issued to Yorkville on March 20, 2024), adjusted to include the issuance of the number of shares set forth in the adjacent column that we would have sold to Yorkville, assuming the average purchase price in the first column. The numerator is based on the number of shares issuable under the SEPA (that are the subject of this offering) at the corresponding assumed average purchase price set forth in the first column.

(3) The closing sale price of our Common Stock on Nasdaq on April 8, 2024.

MARKET INFORMATION FOR COMMON STOCK AND DIVIDEND POLICY

Market Information

Our Common Stock and Public Warrants are currently listed on Nasdaq under the symbols "MDAI" and "MDAIW," respectively. As of April 8, 2024, there were 4,893 holders of record of our Common Stock and 25 holders of record of our Public Warrants. The actual number of stockholders of our Common Stock and the actual number of holders of our Warrants is greater than the number of record holders and includes holders of our Common Stock or Warrants whose shares of Common Stock or Warrants are held in street name by brokers and other nominees.

Dividend Policy

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 of directors deems relevant.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless otherwise indicated or the context otherwise requires, references in this section to "we," "our," "us" or other similar terms refer to the business and operations of Spectral AI, Inc., and its subsidiaries or Legacy Spectral, prior to its business combination with Spectral MD Holdings, Ltd. 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 here and in our Annual Report on Form 10-K. In addition to historical data, this discussion contains forward-looking statements about our business, results of operations, cash flows, financial condition and prospects based on current expectations that involve risks, uncertainties and assumptions. Our actual results could differ materially from such forward-looking statements. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed in the sections titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements". Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future.

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

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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*.

"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. 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.

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.

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 later of the registration statement registering the resale of the shares of Common Stock issuable under the SEPA being declared effective 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 the Company's Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies for the years ended December 31, 2023 and 2022 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 Prospectus. 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 Prospectus 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 S-1 for recently adopted accounting standards and recently issued accounting standards as of the dates of the statement of financial position included in this Form S-1.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in 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; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

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.

BUSINESS

Company 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.

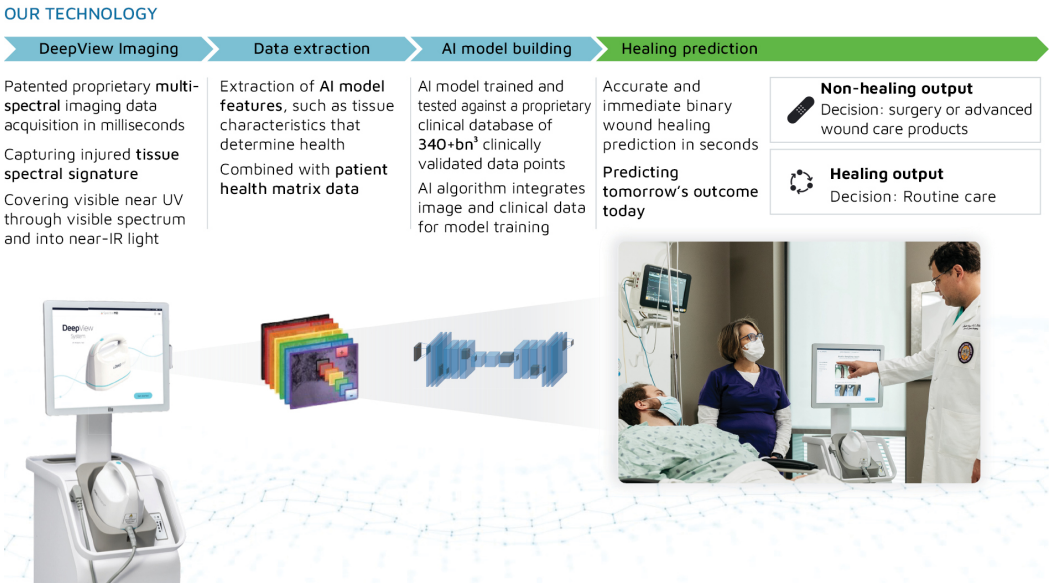

Figure 1 — DeepView Imaging technology

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 Breakthrough Device ("BDD") status for its burn indication. The FDA's designation as a 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 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.

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 unable to identify a predicate, or if the new indication for use is classified as a Class III significant risk device. There can be no assurance, however, that we will be able to achieve any regulatory clearance for any future indications or that we will be able to obtain any such clearance on our projected timelines.

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 System with AI on our projected timeline, or at all.

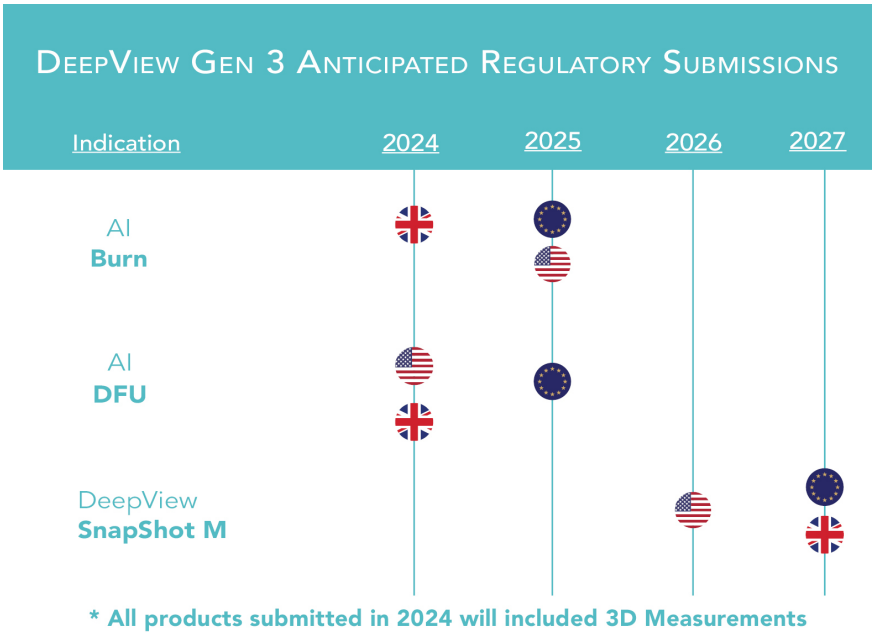

Figure 2 — Summary of key regulatory submissions

Strategic Partnerships

We have developed strategic partnerships with multiple clinical and academic partners. In the United States, we entered into clinical trial agreements with leading research hospitals across 13 sites that enrolled subjects in our Burn AI Training Study. The agreements are substantially similar by study and include a detailed listing of the clinical trial services for which we will pay, how much will be paid for each service, a start-up fee (if any), Investigational Review Board fees, monitoring fees, close-out fees, the contractual term, and other provisions. The clinical trial services provided by each site generally include the screening of prospective patients and, for those patients to be enrolled in the study, imaging using our device according to the trial protocol, truthing sessions, and subject monitoring. Further, each agreement requires us to indemnify each respective clinical site for any losses, costs, expenses, or damages finally awarded by court order or finally paid in settlement or judgment incurred as a result of third party claims, suits, demands, actions or proceedings, which arise out of: (i) the site's performance of its obligations under the agreement in accordance with the protocol; (ii) our use of the study results; (iii) the design or manufacture of the device; (iv) our negligent acts or omissions or intentional misconduct; or (v) our violation of any applicable law, rule, or regulation. We maintain insurance in conjunction with this indemnification. The agreements *may* be terminated upon *30* days' written notice, subject to conditions of paying all liabilities incurred through the date of termination. We will be adding to these sites as we begin our Validation Study.

In the EU and UK, we have engaged in a clinical partnership with the Royal College of Surgeons Ireland, as well as key opinion leaders to provide us greater knowledge in the wound care sector. Our partnerships with these institutions provide us the opportunity to collaborate with leading wound care providers to develop effective early stage wound assessment technology. These arrangements support the ongoing clinical validation studies we utilize in developing our algorithmic model through patient enrollment.

We continually look to expand our clinical support partnerships to provide a diverse population of subjects with which to complete our clinical studies. In addition, we have developed key development and manufacturing relationships for the production and delivery of our DeepView System. Below at Figure 3 is a summary of our current key clinical, developmental and manufacturing relationships.

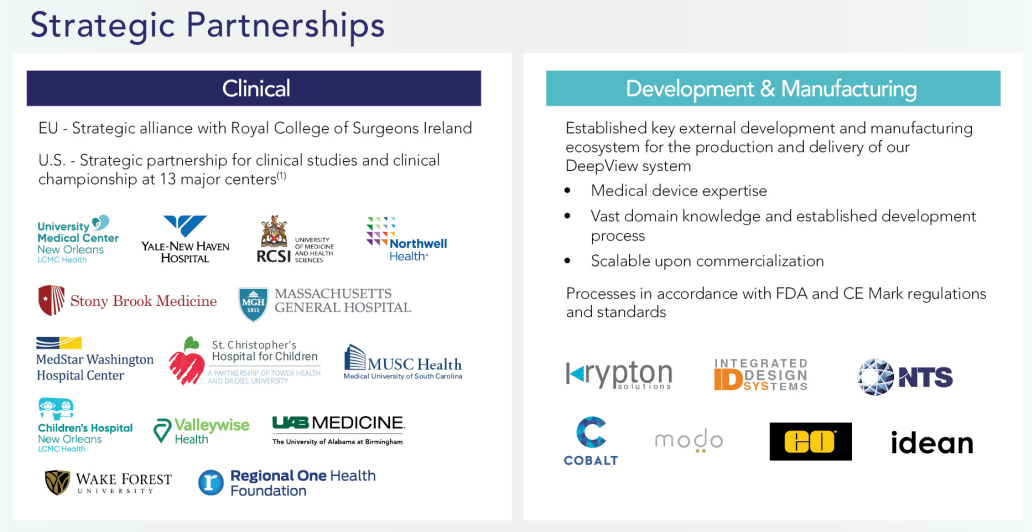

Figure 3 — Summary of key relationships

Diabetic Foot Ulcers (DFU)

Diabetes (type 1 and type 2) affects over 34 million people in the United States alone and more than 460 million people worldwide. A further 88 million adults are affected by pre-diabetes in the United States. Twenty percent of the 30.2 million American adults with diabetes will develop a DFU in their lifetime. DFU is a severe chronic diabetic complication that consists of lesions in the deep tissues associated with neurological disorders and peripheral vascular disease in the lower limbs. It is the most frequently recognized, complex and costly symptom of diabetes and can lead to limb amputation if left undiagnosed, misdiagnosed or untreated. DFU-related mortality is as high as 5% during the first year and 42% within five years.

There is a large and growing number of diabetic patients who suffer from DFU, with over 4,000,000, 200,000 and 1,000,000 receiving treatment in the United States, UK and EU4, respectively, every year. However, there is currently no effective diagnostic pathway for DFU patients in the United States, UK or EU4.

For example, in the United States, patients may undergo standard wound care therapy for 30 days to determine if the ulcer has healed by 50%, before receiving more advanced wound care therapy (*i.e.*, negative pressure wound therapy, synthetic skin substitute grafts, growth factors and biologic wound products, and hyperbaric oxygen therapy).

In major European markets there are also significant delays in both initial diagnosis of DFUs and referral to specialist treatment programs. In France, England, Spain, and Germany, 54%, 50%, 59%, and 46% of DFU patients, respectively, are diagnosed by Week 4, while 65%, 48%, 51%, and 46% of the patients, respectively, are referred by Week 4.

Many of these chronic wounds will not respond to standard wound care therapy and would have benefited from advanced wound care therapy on "Day One." Further complicating this clinical issue, we have identified that clinicians' wound healing predictions have only a 50% accuracy rate. Unfortunately, diagnostic tools to assess the healing potential of DFUs, such as trans-cutaneous oxygen measurement, ankle-brachial index, and doppler ultrasounds do not provide a wound healing prediction. These systems are often inaccurate and only provide a range of values that indirectly correlate to wound healing.

All current systems claiming to be effective in determining DFU healing potential measure only one physiologic parameter, and none applies AI from multiple sources of information, such as photoplethysmography and MSI, to determine potential viability of the tissue. We believe that a single parameter cannot effectively discriminate healing from non-healing DFUs. The American Heart Association concurred noting in a 2019 scientific summary that "No single vascular test has been identified as the most important predictor of wound healing or major amputation for the threatened limb."

In the United States, DFU patients have an annual cost of up to $63,100 per patient and see an outpatient provider, on average, 15.5 times per year. Non-healing DFUs in the United Kingdom are reported as being four times more expensive than DFUs that heal. Our primary objective is to provide physicians with a healing prediction that enables them to therapeutically intervene earlier in the patient's care pathway. Our DeepView technology aims to reduce waiting times, minimize patient costs and lower the probability of infections by offering advanced wound care therapy on "Day One."

Burn Injuries

In the United States and the UK there are over 490,000 and 87,000 burn victims, respectively, who receive emergency medical treatment each year. According to the Institute for Health Metrics and Evaluation, approximately nine million people worldwide seek medical treatment annually for burns, of which approximately 120,000 result in death. In the United States, there are only 134 specialized hospital departments that treat burn patients and about 250 burn surgeons in the country, and of recent medical graduates, only 1% or less train to become a burn specialist.

Burn victims have varying degrees of tissue damage upon initial admission to the emergency room and burn surgeons must evaluate tissue viability, based on their subjective views and experience, as either healing or non-healing to determine what areas of the burn wound must be surgically excised for grafting. The diagnostic accuracy rate of burn surgeons assessing the viability of burned tissues is estimated to be between 50% to 75%, which can result in unnecessary surgeries for burn patients.

In addition, the period of assessment is quite lengthy. Physicians typically admit the patient for a period of up to 21 days to wait for the viable tissue to present itself as healing or non-healing before taking the patient to surgery. This "wait and see" period comes at an above average cost for the facility and duress for the burn victim. Currently, the average hospital stay is 8.1 days with an average cost of approximately $24,000. Our DeepView System aims to provide the physician with a "Day One" assessment of whether the burn wound will heal over time and to enable the physician to triage the patient to the appropriate setting sooner. In addition, our technology aims to assist the physician in accurately determining which areas of the burn wound are appropriate for excision and grafting.

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).

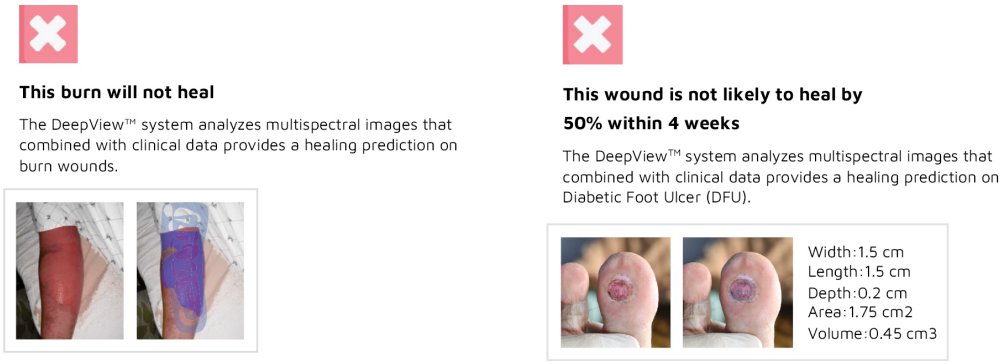

Figure 4 — Illustration of DeepView's binary decision assist output where the colored region marks the predicted non-healing portion of the wound.

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

Artificial Intelligence and Data Repository

We are developing what we believe to be the only AI enabled predictive wound healing imaging technology that translates raw physiological data/images into an output to provide "Day One" healing assessments for wound care. 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.

As with many developing technologies, AI presents risks and challenges that could affect its further development, adoption, and use, and therefore our business. See "*Risk Factors — Issues in the use of artificial intelligence, including machine learning, in our analytics platforms may result in reputational harm or liability*" for further details.

Technical Characterization

There are a number of non-contact, non-invasive, non-radiation optical modalities available for the assessment of burn wound severity such as near infrared spectroscopy, terahertz spectroscopy, laser Doppler imaging, optical coherence tomography, laser speckle imaging, special frequency domain imaging. There are several imaging tools already available commercially, some of which involve invasive procedures — NOVADAQ, Moore Instruments, Tissue Analytics, HITACHI. However, none of these devices are indicated for the prediction of wound-healing potential.

AI Applications

Spectral is developing two applications for wound healing prediction that will be available on the DeepView System. They include the assessment of burn wound depth and the assessment of DFU healing potential. The purpose of the burn wound AI algorithm is to automatically segment (or highlight) the regions of deep burn tissue within a DeepView image. Deeply burned tissue is typically treated by excision and grafting with skin harvested from a healthy region elsewhere on the body. Therefore, the accurate identification and differentiation of severely burned skin from less severely burn skin has the potential to improve treatment decisions regarding surgical excision as well as in upstream burn care where burn depth effects resuscitation efforts for the patient.

In the development of these applications, the availability of MSI images and the true physiology of the burn or DFU in the image are required. In our clinical studies where data is collected for AI development, we follow standardized protocols designed for accurate wound assessment. For burn wounds, a group of burn surgeons and dermatopathologists are involved in the independent "ground truth" classification of the true depth of burn wounds for AI training. Punch biopsies taken immediately prior to surgical excision are interpreted by a derma-pathologist for viable epidermis, dermis and other tissue structures such as hair follicles and sweat glands. In addition, when burn patients are not sent for surgery, the true burn physiology is determined by a standardized healing assessment of the burn tissue at 21-days post-burn. Using either punch biopsies or healing assessment data, a panel of three expert burn surgeons evaluates every DeepView GEN3 image collected in the study to obtain a consensus label of the burn's "ground truth" physiology. Only these rigorously evaluated labels from expert panels are used for DL algorithm development and training.

Below are sample images from our proof-of-concept clinical study conducted at Wake Forest Baptist Medical Center Burn Center in Winston-Salem, North Carolina showing color images of clinical burns (left column), the DeepView System's prediction of deep and non-viable burn tissue superimposed on color images where the algorithm identifies non-healing burns as purple (center column), and histologically determined depth of tissue damage, Ground

Truth, for color images (right column) where white areas indicate the true regions of non-healing burns determined by histology result (Figure 5). These wounds include both light and dark pigmented patients, and the burn in the middle row is a healing burn as indicated by the lack of a white region in its Ground Truth image.

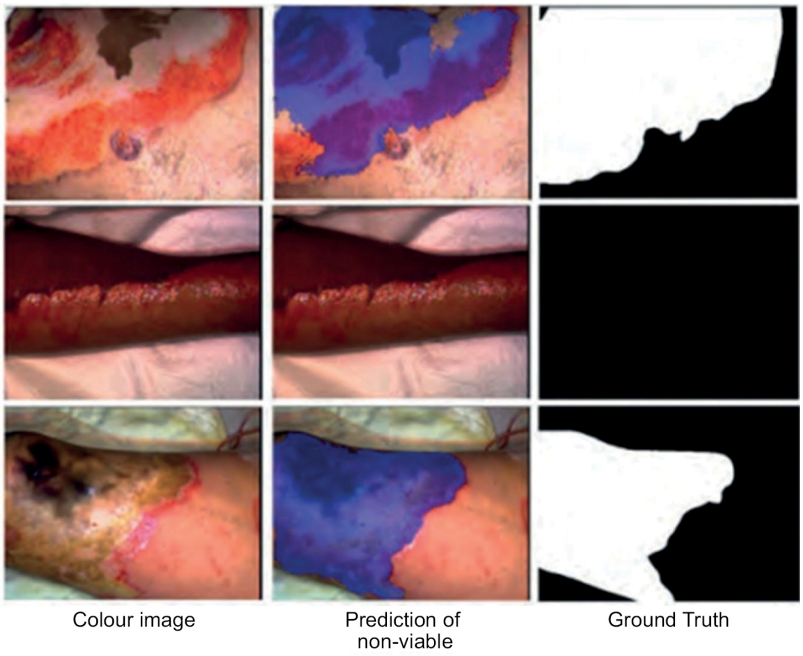

Figure 5 — Illustration of DeepView's highlighted region that marks the predicted non-healing portion of the wound

We have the largest (over 1,000 biopsies) proprietary burn biopsy tissue bank known to date, resulting from our successful completion of three multicenter burn imaging studies. The tissue collected and stored in this bank is a valuable resource for scientific advancement in wound research including drug development, gene expression, proteomics, and immunology.

The aim of the DFU AI application is to classify DFUs that will not respond to standard wound care therapy so that wound care doctors can rapidly transition these patient's wounds to advanced therapies that accelerate healing. This is importance to wound care doctors because current standard of care involves a wait-and-see approach where treatment is first given, and only if the wound does not shows a measurable response after four weeks is the therapy changed to a more advanced method. This technology has the potential to expedite the use of advanced treatment, saving patients up to a month of unnecessary care.

The DFU algorithm relies on MSI data within and around the wound. To capture this data, the borders of the wound must be known. Below are sample images of three sets of results from the DeepView GEN 3 System for automated segmentation of DFU tissue, a part of the DFU assessment application, showing color photographs

representative of the input DeepView data to the trained AI (left column), AI predicted locations of the callous (yellow) and wound (cyan) (center column) and Ground Truth masks indicating the true location of the callous (yellow) and wound (cyan) (right column) (See Figure 6).

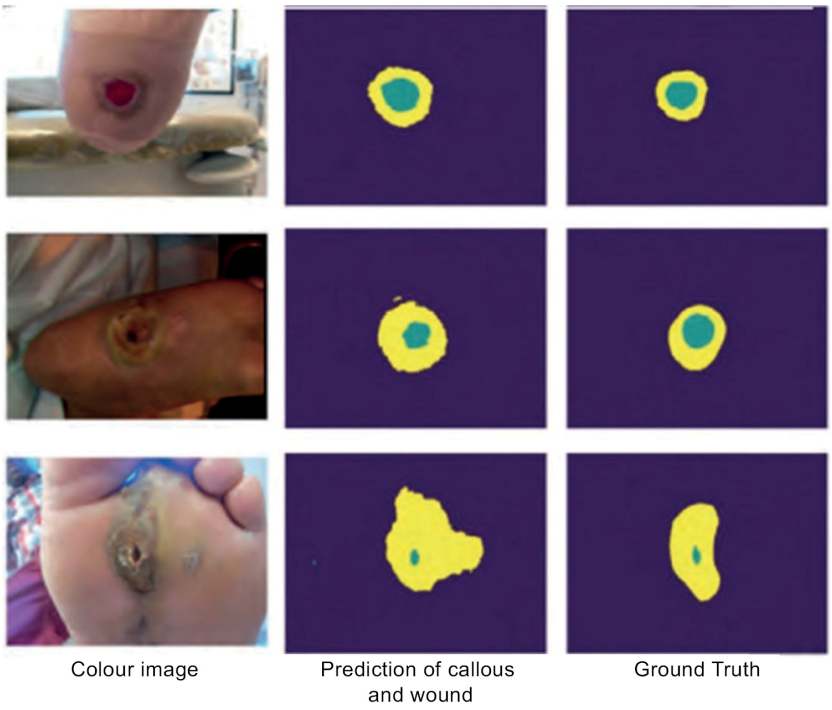

Figure 6 — Sample images of three sets of results from the DeepView GEN 3 System for automated segmentation of wound tissue

Following wound segmentation, an algorithm is used to predict the DFU's potential to respond to treatment. Input multispectral patient data processed by DL algorithm (center, grey box) to yield the probability output of positive for responsive or negative for non-responsive (right, Figures 5 and 6, center column). DL is a subset of Machine Learning ("ML"), which in turn is a subset of AI. Using multi-layer artificial neural network (center, grey box) comprised of convolution layers (slabs) and fully connected layers (dots), DL algorithm can learn directly from raw image data input to help make intelligent decisions and can increase its predictive accuracy for non-healing tissue when provided more data for algorithm training. Furthermore, while not shown explicitly in this figure, we have explored the use of combining patient medical data with images for classification of ulcer healing potential. Additionally, the process of algorithm training for DFU is different to that of burn since the input data for the two are mutually exclusive.

Medical Imaging Solutions

Central to the DeepView System is the proprietary AI predictive analytics for the assessment of wound healing potential applicable to both burns and DFUs. The AI analytics is driven by DL and ML algorithms that are being trained and optimized exclusively to the unique and proprietary MSI datasets acquired from clinical studies. Our in-house expertise has made possible the necessary technology platform to integrate the information contained in the rich multidisciplinary datasets of images and patient health data.

It is important to recognize that, to avoid costly and time-consuming clinical trials, many companies specializing in medical imaging analytics that are supported by AI utilize purchased or publicly available clinical datasets. When an AI device intended for use with a specific clinical protocol has been trained using data obtained from an external source, such as data acquired through a different clinical protocol, the resulting device output could be compromised. This is a result of external data not adequately representing the same patient population or collection methods to which

the algorithm will be applied in the real world. To meet the high standards necessary for the development of predictive algorithms, the algorithm is developed using data that was collected with the same imaging technology, under the same clinical circumstances, and on the same population for which it is intended.

As of December 31, 2023, approximately 340 billion pixels of proprietary DFU and burn data have been acquired and utilized for the DL algorithms training. Plans are in place to store anonymized patient data on a reputable cloud platform that incorporate administrative, technical, and physical safeguards consistent with the security regulations promulgated pursuant to HIPAA.

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 7.

Figure 7 — DeepView 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 will provide us with external, industry-specific perspectives and technical support. Brief biographical details of our Advisory Board are summarized below.

Toby Cosgrove

Dr. Toby Cosgrove M.D. is the former President and Chief Executive Officer of Cleveland Clinic and currently serves as an Executive Advisor to the $5 billion healthcare system. Dr. Cosgrove is a sought-after speaker worldwide. He has addressed the World Economic Forum Annual Meeting at Davos, Switzerland, and the Senate Health, Education, Labor and Pensions Committee, in Washington, D.C. He is regularly quoted and featured in national magazines and newspapers, including a cover story in Time, and major articles in Newsweek, the New York Times, and the Washington Post. He has appeared on CNN, Fox, MSNBC, NBC, CBS, “The Charlie Rose Show” on PBS, and other national media outlets.

The recipient of Cleveland Clinic’s Master Clinician Award, Innovator of the Year Award and Lerner Humanitarian Award, Dr. Cosgrove is also a member of Cleveland Medical Hall of Fame and Cleveland Business Hall of Fame. In 2007, he was named Cleveland Business Executive of the Year by the Sales and Marketing Executives of Cleveland, and Castle Connolly’s National Physician of the Year. He also received the Woodrow Wilson Center Award for Public Service as well as Harvard Business School’s Award from HBS Alumni, Cleveland, and the Humanitarian Award of the Diversity Center of Northeast Ohio. Dr. Cosgrove topped Inside Business’s “Power 100” listing for Northeast Ohio and is highly ranked among Modern Healthcare’s “100 most powerful people in healthcare” and “most powerful physician executives.”

John Botts, CBE

Mr. Botts is a Senior Advisor to Allen & Company, Chairman of The Ink Factory, and Advisor/Director to several early-stage tech platform companies. He is a former career banker with Citi running its investment banking division in Europe, including CVC. He is also a former Chairman of UBM plc, Euromoney plc, former Advisor of Corsair Capital, Director of Songbird (Canary Wharf), and currently serves as Director of Glyndebourne Productions (former Chair) and the Tate Foundation and as a Member of the Council on Foreign Relations.

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 System, there can be no assurance that we will be able to obtain market authorization in the US or EU.

Clinical Studies

DFU Clinical Studies

In November 2021, we completed enrollment for our IRB approved multi-center training study to support the development of our DFU application for the DeepView System. The study enrolled a total of 100 adult subjects and was executed successfully and on schedule across five clinical sites in the United States. We followed up on this study with another training study with an additional enrollment of another 100 adult subjects, which was executed successfully and on schedule across five clinical sites in the United States, and concluded in January 2023. The DFU images and clinical data collected are currently being incorporated into the database for the development of DeepView's DFU algorithm. The data informs on key datapoints that are captured in additional newly developed features of the DeepView System.

In February 2023, we commenced our validation study with a planned enrollment of another 100 adult subjects across 10 clinical sites in the United States and EU. The data collected throughout the study will support our applications for FDA and CE mark approval for DeepView's DFU indication — one of the necessary milestones required to commercialize DeepView's DFU application. The completion of enrollment for the multi-center study is an important milestone and illustrates how we are delivering on the expected milestones since our initial public offering on the AIM market in June 2021. The development of the DeepView System for the DFU application and the user interface software have seen substantial progress.

Burn Wound Clinical Studies

Following the successful completion of the ePOC multi-center clinical study in the first quarter of 2021, we received two additional grants, $20.6 million in March 2021 and $18.8 million in September 2021, to bolster our existing clinical database to train the AI algorithm, and to improve the DeepView® technology in early burn wound healing assessment. The $20.6 million contract awarded under Option 1A was exercised by BARDA in March 2021 to execute the first stage of the clinical training study to train the DeepView AI algorithm at five sites. The contract option funding of $18.8 million under Option 1B of our prior contract with BARDA was granted six months ahead of schedule, which enabled us to accelerate the initiation of the second stage of our clinical training study with confidence. Funding from Option 1B was used to expand the study to 10 clinical sites, and from 100 to a total of 250 clinical subjects. This study was completed in the second quarter of 2023 and included 190 adult and 60 pediatric clinical subjects across 12 clinical sites; resulting in one of the largest prospective multi-center burn studies ever conducted. In adult participants, the DeepView GEN 3 System showed 92% accuracy, with cross-validation from the AI model for identification of non-healing burn regions. 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 will advance our validation study in 2023 in order to complete the AI algorithm's development.

We began conducting a clinical validation study in the fourth quarter of 2023 with the objective of completing the development of the ML algorithm, the results from which will be used in submission to the FDA. We plan to enroll an additional 250 subjects (both adult and pediatric) across at least 20 clinical sites in the United States.

We were granted BDD status by the FDA in 2018 for the MSI combined with AI device technology applied to burn wound assessment. The BDD Program is a program issued to certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Our BDD status gives us prioritized reviews and a dedicated line of communication with reviewing members of the FDA. We regularly engage with the reviewers and meet them on average twice a year to share development progress and future directions for feedback, which includes clinical study design and the image data acquisition protocol for burn wounds. As a result of this continuing and transparent interaction with the FDA, we have gained

a deeper understanding of the regulatory pathway for the DeepView GEN 3 System and have already established that a component of the marketing submission will involve an AI algorithm performance upgrade plan applicable at appropriate stages of the life span of the device.

In April 2023, we held a pre-submission meeting with the FDA to ensure that the design of the validation study will meet the evidentiary requirements of the FDA. Our goal is for the Burn application to follow a similar clinical and regulatory framework with a forecasted De Novo submission to the FDA in 2025.

Clinical Validation and Regulatory Pathway

Based on the evaluated risk of the technology, we believe that DeepView may achieve Class II classification in the US via a De Novo application. We have received a recommendation from HPRA for a Class IIa designation for CE Mark certification in the EU.

We intend to present the AI-DFU application as the first indication for regulatory marketing authorization in the United States and UK. The burn indication for use may follow as a 510(k), subject to review and agreement by the FDA, supported by clinical data evaluated by a methodology similar to AI-DFU.

We recognize that establishing the clinical foundation is key to the successful commercialization of our technology. We plan to establish this foundation by:

- obtaining the input and clinical buy-in of physician key opinion leaders in wound care and burn surgery;
- attending trade shows to showcase the Group's technology (American Burn Association, Southern Burn Association, American College of Cardiology, and Society for Advanced Wound Care); and
- publishing results in peer-reviewed journals (Journal of Wound Care, Journal of Vascular Surgery, Journal of Burn Care & Research).

The BARDA Contract

Since 2013, we have received approximately $279.6 million in government contracts, primarily from BARDA, which accounts for $272.9 million. This has allowed us to develop our technology and further our clinical trials. From 2013 through 2019 our BARDA "Burn I" contract we received $26.0 million and have been awarded an additional $96.9 million under our BARDA "Burn II" contract which was awarded in multiple tranches. 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 $22.0 million. This will include the distribution of up to 30 DeepView Systems in various emergency rooms and burn centers to support the clinical validation study and to transition the use of our DeepView System to being used routinely upon FDA clearance. The contract also includes options, similar to our prior BARDA contracts, with an additional total value of approximately $95.0 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. However, marketing authorization from the FDA or other regulatory agencies, foreign or domestic, cannot be guaranteed and may take longer than planned. This grant funding is non-dilutive to our stockholders, and we believe it validates the important nature of its mission and technology.

The scope of work for the BARDA contract includes preclinical, clinical and manufacturing development activities that fall into the following areas: non-clinical efficacy studies; clinical activities; manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities. Under the terms of the contract, we must complete specific tasks required in three discrete work segments: (i) expanded proof-of-concept (POC) clinical study; (ii) algorithm training clinical study; and (iii) device validation clinical study.

The BARDA contract is a cost-plus-fixed fee contract. That is, we are entitled to receive reimbursement for all costs incurred in accordance with the contract provisions that advance the development of DeepView System portable optical imaging device and machine learning algorithm to classify burn would healing potential in mass casualty and conventional burn injuries, plus a fixed fee. The BARDA contract requires us to provide reporting deliverables that include monthly technical and annual reports and a final report. BARDA will make periodic assessments of progress

and the continuation of the contract is based on our performance, the timeliness and quality of deliverables, and other factors. 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.

We own the intellectual property rights to inventions made in the performance of work under the BARDA contract, provided that we disclose such inventions to the U.S. government and notify the U.S. government of our election to retain title. The U.S. government will have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, such inventions throughout the world, in addition to other rights customarily reserved by the U.S. government for intellectual property generated using government funds.

Defense Health Agency (DHA)

On June 23, 2021, we were 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 on a monthly basis. This funding enables us to research and develop a fully portable, handheld version of our DeepView solution and has been extended through the end of 2023. We were previously awarded a STTR Phase I and initial Phase II contract from the DHA. We have made considerable progress in the development of the miniaturized DeepView technology. We have developed an early scientific prototype of the DeepView technology with key optical and computing capabilities in a fully handheld, portable form.

On March 12, 2024, the Company announced a new contract with the DHA that provides significant additional support for the development of the handheld version of DeepView Snapshot® M. The newly secured contract is valued at approximately $500,000.

Under the terms of our current contract with DHA, the Company is required to provide monthly reports and one final technical report at the end of the contract term. The Company is allowed to advance the development of the research from this contract with the FDA, provided the Company shares all communication, both formal and informal, to or from FDA regarding the technology being developed under this contract with the DHA and its representatives are permitted to participate in any sponsor meetings both formal and informal with the FDA upon request. In addition, the Company is entitled to maintain ownership of the inventions generated from the contract in accordance with the terms contained in the DHA award.

We own the intellectual property rights to inventions made in the performance of work under the DHA contract, provided that we disclose such inventions to the U.S. government and notify the U.S. government of our election to retain title. The U.S. government will have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, such inventions throughout the world, in addition to other rights customarily reserved by the U.S. government for intellectual property generated using government funds.

MTEC Grant

On June 15, 2020, we entered into a Research Project Award agreement (the “MTEC Agreement”) with the Advanced Technology International as Consortium Manager for MTEC, a 501(c)(3) biomedical technology consortium working in partnership with the Department of Defense. In April 2023, we received a grant of approximately $4.0 million for the purpose of designing and developing a handheld device that will be capable of performing digital burn assessment in military and combat environments. The MTEC Agreement extends the DHA Sequential Phase II STTR contract for the development of the handheld device of the DeepView System. Under the terms of the MTEC Agreement, MTEC will pay us a firm fixed fee based upon our achievement of certain milestones described in the agreement through April 5, 2025. The milestone payment schedule is based on a three phased approach to the development of our handheld device. Phase 1 of the MTEC Agreement began in April 2023 and was extended through the third quarter of 2023 and focused on the planning, design and testing of the handheld device for its intended applications. Phase 1 had a funding budget of $1,170,000. We are now in Phase 2, which is intended to run through October 2024 and encompasses the development, design modification and build-out of the handheld device to the U.S. government standards as identified in the design and commercialization plans for the device. Phase 2 has a funding budget of $1,558,000. Phase 3 of the MTEC Agreement addresses the complete manufacturing of the device, the process validation of the production and completion of up to thirty handheld devices. Phase 3 begins following completion of Phase 2 and is intended to run through April 2024 with a funding budget of approximately $1,272,000.

The MTEC Agreement includes general provisions regarding the provision of "government purpose rights" and "unlimited data rights" to the US Government relating to the results and intellectual property of the materials included in the contract award in which the Company has explicitly retained all of the intellectual property rights relating to the ownership of the intellectual property associated with the contract.

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. See "Risk Factors — *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"* for further details.

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® 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 11 issued and allowed U.S. patents with six U.S. patent applications pending. We have 12 issued and allowed international patents with 26 foreign and international patent applications pending.

Our material owned and pending patent applications, their identification number, a description, the type of patent protection, jurisdiction, and expiration date are included in the table below.

Issued U.S. Patents

Patent No.	Description	Type of Patent Protection	Jurisdiction	Expiration
11,304,604	Burn/wound classification based on combined MSI and (PPG)	Utility	United States	February 23, 2039
9,717,417	Tissue classification based on combined MSI and PPG	Utility	United States	October 28, 2035
9,962,090	Tissue classification based on combined MSI and PPG	Utility	United States	October 28, 2035
10,750,992	Amputation site analysis and tissue classification based on MSI, machine learning, and healthcare metrics	Utility	United States	March 2, 2038
11,337,643	Amputation site analysis and tissue classification based on MSI, machine learning, and healthcare metrics	Utility	United States	March 2, 2038
10,740,884	High-precision, multi-aperture, MSI snapshot imaging	Utility	United States	December 11, 2039

Patent No.	Description	Type of Patent Protection	Jurisdiction	Expiration
11,182,888	High-precision, multi-aperture, MSI snapshot imaging	Utility	United States	December 11, 2039
11,631,164	High-precision, multi-aperture, MSI snapshot imaging	Utility	United States	December 11, 2039
10,783,632	DFU healing potential prediction and wound assessment based on MSI, machine learning, and healthcare metrics	Utility	United States	December 11, 2039
11,599,998	DFU healing potential prediction and wound assessment based on MSI, machine learning, and healthcare metrics	Utility	United States	December 11, 2039
11,948,300	DFU healing potential prediction and wound assessment based on MSI, machine learning, and healthcare metrics	Utility	United States	December 11, 2039

Pending U.S. Patent Applications

Application No.	Description	Type of Patent Protection	Jurisdiction
17/585,346	Tissue classification based on combined MSI and PPG	Utility	United States
18/178,875	High-precision, multi-aperture, MSI snapshot imaging	Utility	United States
18/620,830	DFU healing potential prediction and wound assessment based on MSI, machine learning, and healthcare metrics	Utility	United States
17/820,837	Wound assessment based on MSI, optical biomarkers, and machine learning	Utility	United States
18/152,654	Burn/histology assessment based on MSI and machine learning	Utility	United States
18/470,318	High-precision, single-aperture, MSI snapshot imaging with multiplexed illumination		

Issued Foreign Patents

Patent No.	Description	Type of Patent Protection	Jurisdiction	Expiration
ZL201580070907.8	Burn/wound classification based on combined multi-spectral imaging (MSI) and photoplethysmography (PPG)	Utility	China	October 28, 2035
3212057	Burn/wound classification based on combined multi-spectral imaging (MSI) and photoplethysmography (PPG)	Utility	Europe	October 28, 2035
3212057	Burn/wound classification based on combined multi-spectral imaging (MSI) and photoplethysmography (PPG)	Utility	Belgium	October 28, 2035
3212057	Burn/wound classification based on combined multi-spectral imaging (MSI) and photoplethysmography (PPG)	Utility	Germany	October 28, 2035
3212057	Burn/wound classification based on combined multi-spectral imaging (MSI) and photoplethysmography (PPG)	Utility	France	October 28, 2035

Patent No.	Description	Type of Patent Protection	Jurisdiction	Expiration
3212057	Burn/wound classification based on combined multi-spectral imaging (MSI) and photoplethysmography (PPG)	Utility	United Kingdom	October 28, 2035
6893877	Burn/wound classification based on combined multi-spectral imaging (MSI) and photoplethysmography (PPG)	Utility	Japan	October 28, 2035
ZL201680076887.X	Tissue classification based on combined MSI and PPG	Utility	China	April 28, 2036
6785307	Tissue classification based on combined MSI and PPG	Utility	Japan	April 28, 2036
10-2634161	Tissue classification based on combined MSI and PPG	Utility	South Korea	April 28, 2036
7186298	High-precision, multi-aperture, MSI snapshot imaging	Utility	Japan	December 11, 2039

Pending Foreign Patent Applications

Application No.	Description	Type of Patent Protection	Jurisdiction
16860418.9	Tissue classification based on combined MSI and PPG	Utility	Europe
19120058.3	Tissue classification based on combined MSI and PPG	Utility	Hong Kong
201880028365.1	Amputation site analysis and tissue classification based on MSI, machine learning, and healthcare metrics	Utility	China
18760531.6	Amputation site analysis and tissue classification based on MSI, machine learning, and healthcare metrics	Utility	Europe
62020010555.4	Amputation site analysis and tissue classification based on MSI, machine learning, and healthcare metrics	Utility	Hong Kong
11 2021 0111131	High-precision, multi-aperture, MSI snapshot imaging	Utility	Brazil
201980087508.0	High-precision, multi-aperture, MSI snapshot imaging	Utility	China
19895125.3	High-precision, multi-aperture, MSI snapshot imaging	Utility	Europe
202117023312	High-precision, multi-aperture, MSI snapshot imaging	Utility	India
2022-188817	High-precision, multi-aperture, MSI snapshot imaging	Utility	Japan
2022-188833	High-precision, multi-aperture, MSI snapshot imaging	Utility	Japan
10-2021-7021579	High-precision, multi-aperture, MSI snapshot imaging	Utility	South Korea
11 2021 0111328	DFU healing potential prediction and wound assessment based on MSI, machine learning, healthcare metrics	Utility	Brazil
201980087443.X	DFU healing potential prediction and wound assessment based on MSI, machine learning, healthcare metrics	Utility	China

Application No.	Description	Type of Patent Protection	Jurisdiction
19894740.0	DFU healing potential prediction and wound assessment based on MSI, machine learning, healthcare metrics	Utility	Europe
202117023888	DFU healing potential prediction and wound assessment based on MSI, machine learning, healthcare metrics	Utility	India
2023-063250	DFU healing potential prediction and wound assessment based on MSI, machine learning, healthcare metrics	Utility	Japan
10-2021-7021623	DFU healing potential prediction and wound assessment based on MSI, machine learning, healthcare metrics	Utility	South Korea
202180030012.7	Wound assessment based on MSI, optical biomarkers, and machine learning	Utility	China
21759766.5	Wound assessment based on MSI, optical biomarkers, and machine learning	Utility	Europe
202217054022	Wound assessment based on MSI, optical biomarkers, and machine learning	Utility	India
21842496.8	Burn/histology assessment based on MSI and machine learning	Utility	China
21842496.8	Burn/histology assessment based on MSI and machine learning	Utility	Europe
202317002043	Burn/histology assessment based on MSI and machine learning	Utility	India
2023-502581	Burn/histology assessment based on MSI and machine learning	Utility	Japan
PCT/US2023/011157	Topological characterization and assessment of tissue including wounds, using MSI and machine learning	Utility	International PCT Application

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.

The duration of trademark registrations varies from country to country; however, trademark are generally valid and may be renewed indefinitely as long as they are in use and/or their registrations are properly maintained. We have an active program designed to ensure that our trademarks are registered, renewed, protected and maintained. We plan to continue to use all of our core trademarks and plan to renew the registrations for such trademarks as needed.

We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into confidentiality agreements with parties who have access to them. We also enter into confidentiality and invention assignment agreements with our employees and our agreements with consultants include invention assignment obligations.

Government Regulation

Regulation of Medical Devices in the United States

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event

reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires market authorization by the FDA via clearance through a premarket notification submitted under Section 510(k) of the FDCA, De Novo application request, or approval of a PMA. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II, or Class III — depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of the QSR; facility registration and product listing; reporting of adverse medical events; and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's general controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries, and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. A *De Novo* petition is required when a new intended use is requested for a technology that is established to be of moderate risk to the patient. This petition requests the FDA down-classify a new device from a Class III to a Class II regulation. Some pre-amendment devices are unclassified but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. We have obtained 510(k) clearance for the first two generations of our DeepView System. However, there can be no assurance that we will be able to obtain FDA market authorization via 510(k) clearance or granted Class II classification via De Novo application process for our current DeepView System.

510(k) Clearance Marketing Pathway

Our previously approved products are subject to requirements for pre-market notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we submitted to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to premarket approval (*i.e.*, a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process).

The FDA's 510(k) clearance process usually takes from three to 12 months but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements or can request a risk-based classification determination for the device in accordance with the "De Novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's

determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until such marketing approval or clearance has been granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k)-clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k)-clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the 510(k) pathway. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k)-clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-marketing surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Regulatory Pathway

We have had multiple interactions with the FDA since 2013 and have obtained 510(k) clearance for the first two generations of our DeepView technology. DeepView GEN 1 employed photoplethysmography and was 510(k) cleared in 2013 and DeepView GEN 2, which employed PPG and MSI was FDA cleared in 2017. With the ongoing support of

BARDA, these two previous iterations were not commercialized due to the integration of AI algorithms and improved optics throughout 2018 and 2019 in order to further enhance the utility of the system. The development of this improved technology enabled us to achieve BDD status for the technology's burn application (AI®-Burn). The FDA's designation as a Breakthrough Device allows for expedited regulatory approval pathways and a dedicated line of communication with reviewing members of the FDA. We have engaged in pre-submission meetings with the FDA to ensure that our regulatory pathway and data collection for the technology to meet the FDA's requirements. In addition to burn, we plan to pursue an FDA De Novo application for the AI®-DFU in 2024.

We plan to submit for FDA marketing application of the burn application in 2025 in accordance with the projected timeline for the BARDA contract. We are in the process of selecting a notified body to schedule the QMS certification audit in compliance with ISO 13485:2016 MDSAP under the U.S. and Canadian jurisdictions. We anticipate certification in 2025. In parallel, we are 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. On July 14, 2023, we completed our UKCA Mark registration for the imaging components of the DeepView System. There can be no assurance, however, that we will be able to obtain market authorization in the US (FDA), UK (MHRA) or EU for our DeepView System (with AI technology).

Clinical Trials

Clinical trials are almost always required to support a PMA and De Novo classification and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE") regulations, which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted; used in supporting or sustaining human life; substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health; or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies involving human subjects must be approved by, and conducted under the oversight of an IRB for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and complying with labeling and record-keeping requirements. In some cases, an IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness; study plan; or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA, or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Manufacturing processes for medical devices and accessories are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled and unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with any marketed products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval, or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers and manufacturers. If the FDA determines that a manufacturer or supplier has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying requests for 510(k) clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

Regulation of Medical Devices in the European Union

In the EU, until May 25, 2021, medical devices were regulated by the Council Directive 93/42/EEC (the "EU Medical Devices Directive"), which has been repealed and replaced by Regulation (EU) No 2017/745 (the "EU Medical Devices Regulation"). Unlike directives, regulations are directly applicable in all EU member states without the need for member states to implement into national law.

All medical devices placed on the EU market must meet the general safety and performance requirements of 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.

Compliance with the general safety and performance requirements is a prerequisite for European Conformity Marking, or CE-Mark, without which medical devices cannot be marketed or sold in the EU. To demonstrate compliance with the general safety and performance requirements medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low-risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality management system. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a CE marking certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply a CE Mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the CE Mark, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it renews the relevant CE marking certificate(s).

All manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions ("FSCAs") must be reported to the relevant authorities of the EU member states. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.

The aforementioned EU rules are generally applicable in the EEA, which consists of the 27 EU member states *plus* Norway, Liechtenstein and Iceland.

U.S. Healthcare Fraud and Abuse Laws

In the United States, if our products become reimbursable by the federal and state government health care programs, we will become subject to a number of federal and state health care regulatory laws that constrain or restrict certain business practices in the health care industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, transparency laws governing, or requiring disclosure of, payments and other transfers of value made to physicians and other health care providers, and other health care fraud and abuse laws.

The federal Anti-Kickback Statute is a criminal law that prohibits, among other things, the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in cash or kind, to induce or reward patient referrals or the generation of business involving any item or service payable by federal health care programs such as Medicare and Medicaid. Federal courts have held that the Anti-Kickback Statute can be violated if just "one purpose" of a payment is to induce referral, and a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Given the breadth of the law, the federal Anti-Kickback Statute includes statutory exceptions and regulatory safe harbors that protect certain arrangements. Failure to meet the requirements of an exception or safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances, including the parties' intent and the arrangement's potential for abuse, and may be subject to greater scrutiny by enforcement agencies. Violations of the Anti-Kickback Statute can result in exclusion from federal and state government health care programs as well as civil and criminal penalties.

The Federal False Claims Act (the "FCA") prohibits a person from knowingly presenting, or causing to be presented, a false or fraudulent request for payment from the federal government, or from making a false statement or using a false record material to a false claim or an obligation to pay the government. The federal FCA further provides that a lawsuit thereunder may be initiated not only by the government, but in the name of the United States by private parties through *qui tam* (or "whistleblower") lawsuits. Moreover, the law defines a claim that includes items or service resulting from a violation of the Anti-Kickback Statute to be "false." Penalties for a violation of the FCA include fines for each false claim, *plus* up to three times the amount of damage caused by each false claim. Violations can also result in exclusion from participation in federal and state government health care programs.

Further, the Civil Monetary Penalties Statute authorizes the imposition of civil monetary penalties and sometimes exclusion against an individual or entity based on a variety of prohibited conduct, including, but not limited to, violating the Anti-Kickback Statute, submitting false claims in violation of the FCA, or offering remuneration to a federal health care program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive health care items or services from a particular provider.

HIPAA also established federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals beginning in 2022, and teaching hospitals. Applicable manufacturers and applicable group purchasing organizations must also report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Several states have also adopted similar fraud and abuse laws as described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any payor, including patients and commercial insurers, not just those reimbursed by a federally funded healthcare program.

Violation of any of these laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement, fines, additional reporting requirements and compliance oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/or imprisonment.

U.S. Coverage and Reimbursement

In the United States, federal and state government healthcare programs, including Medicare and Medicaid, provide coverage for certain medical products and procedures. Where third-party payor coverage is not available, patients would be responsible for all of the costs associated with treatment using our products, once commercialized.

Thus, availability of third-party payor reimbursement for our product will be important for our commercial success if the product is cleared by the FDA. No uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor. As a result, the coverage determination process can be a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. To contain costs of new technologies, third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Providers may not ultimately purchase our products once commercialized if the providers do not receive sufficient reimbursement from payors for the cost of the product or procedures using our product. If third-party payors do not provide coverage or adequate reimbursement levels for procedures using our products, the demand for our products will not increase and/or there may be significant pricing pressure, either of which could adversely impact our business and financial condition.

U.S. Healthcare Reform

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the health care system, many of which are intended to contain or reduce healthcare costs. By way of example, the ACA substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through May 15, 2021 (and later extended to August 15, 2021) for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once commercialized or additional pricing pressure.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related personal information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act (the "FTCA")) that govern the collection, 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 imposes privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, 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. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the FTC, misleading consumers about what is happening with their health information or failing to take appropriate steps to keep consumers' personal information secure may constitute deceptive or unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA. The FTC also 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.

In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act, the California Privacy Rights Act and the General Data Protection Regulation, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

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 has been extended through May 30, 2028.

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. As of April 8, 2024, we had 80 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.

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.

MANAGEMENT

Executive Officers and Directors

The following table lists the names, ages and positions of the individuals who currently serve as our executive officers and directors.

Name	Age	Position
Executive Officers		
Peter M. Carlson	59	Chief Executive Officer and Director
Vincent Capone	57	Chief Financial Officer and General Counsel
Non-Employee Directors		
Cynthia Cai	59	Director
Richard Cotton	63	Director
Martin Mellish	66	Director
J. Michael DiMaio	68	Director
Deepak Sadagopan	50	Director
Erich Spangenberg	64	Director

Executive Officers

Peter M. Carlson

Mr. Carlson was appointed as the Company's Chief Executive Officer effective February 29, 2024. Mr. Carlson most recently served as the Company's Chief Financial Officer. Prior to his role as CFO at the Company, Mr. Carlson served as CFO at MiMedx Group, Inc., a pioneer and leader in the advanced wound care space. Prior to joining MiMedx, Mr. Carlson was with Brighthouse Financial, and played an essential role in establishing Brighthouse as a separate public company after its spin-off from MetLife, Inc., where he worked for eight years. At MetLife, as Chief Accounting Officer, he led accounting, tax and financial reporting activities, along with budgeting and financial planning. Prior to MetLife, Pete was the Controller at Wachovia Corporation and an audit partner for a Big Four accounting firm. Mr. Carlson currently serves as a Board Member at White Mountains Insurance Group and as a trustee for Wake Forest University. He is a certified public accountant in New York and North Carolina, and he received a Bachelor of Science from Wake Forest University.

Vincent Capone

Prior to his joint role as Chief Financial Officer and General Counsel, Mr. Capone has served as General Counsel and Corporate Secretary of the Company since March 2022. Prior to joining the Company, Mr. Capone most recently served as President of a New York-based private equity fund investing in technology companies. Mr. Capone has an extensive background in representing life science and technology companies and he has a proven track record as a business-focused and results-oriented leader in driving corporate growth and development. He began his career at KPMG, LLP before practicing corporate and securities law. He has more than 20 years of broad legal experience, first at Morgan Lewis LLP, then as a Partner at Reed Smith LLP. Mr. Capone serves as a senior advisor to Alexet Capital Associates, LLC and is a Board Member of the Ryan Lesher Foundation, a non-profit organization assisting families in Bucks County, Pennsylvania. Additionally, while currently inactive, he was a certified public accountant in Pennsylvania. Mr. Capone earned both his J.D. and M.B.A. degrees from Temple University and his B.S. degree in Accounting from The Pennsylvania State University.

Non-Employee Directors

Cynthia Cai

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

and president of Tharton Consulting, which provides investment and management consulting services. She is also a venture partner of Viva BioInnovator, an equity investor in biotech innovation with novel solutions to cross multiple therapeutic areas. Before that, she served as senior advisor to Northern Light Venture Capital, led its healthcare investment effort in the United States. Previously Dr. Cai had progressive leadership roles with Agilent Technologies, as global associate vice president of marketing, she was responsible for its billion-dollar Chromatography, Automation, and Mass Spec. business. Dr. Cai serves on the board of directors for Spectral (London: SMD), Arthrosi Therapeutics, F5 Therapeutics, AceLink Therapeutics, Exarta Therapeutics, and Amberstone Biosciences. She is also a member of the board for the Science History Institute in Philadelphia. Dr. Cai earned a B.A. and M. Eng. from Tsinghua University in Beijing, received her Ph.D. in Chemistry from the University of Massachusetts, and an MBA from The Wharton Business School of the University of Pennsylvania.

Richard Cotton

Richard Cotton is the current Chairman of the Company's Board of Directors. Richard Cotton has a wealth of experience in non-executive director, advisory and senior financial roles in life sciences and other industrial sectors. His extensive experience covers all the value creation activities from R&D, to manufacturing and commercial in international organizations. He has significant experience in the development and successful execution of strategy, corporate finance and M&A, capital markets and governance. Currently Richard is Chair at Nasdaq listed AI predictive diagnostics company Spectral AI, and is also a Financial Adviser at Novumgen Ltd., a Specialty Pharmaceuticals company. His prior executive roles include highly successful tenures as Chief Financial Officer at Dechra Pharmaceuticals plc, an FTSE 250 animal health company, and as Chief Financial Officer at Consort Medical plc., a medical device and drug formulation business. Mr. Cotton is a fellow of the Chartered Institute of Management Accountants and holds a BA (Hons) in Business Studies from Kingston University.

Martin Mellish

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

John Michael DiMaio

Dr. Michael DiMaio is one of the Company's founders and previously served as the Company's Chief Executive Officer and Chairman of the Board of Directors from 2011 to 2020. He is the Chief of Staff and a practicing board-certified general, cardiac and thoracic surgeon at Baylor Scott & White-The Heart Hospitals. He has been elected or served as a member on many distinguished medical organizations including the American Surgical Association, Society of Thoracic Surgeons, American College of Surgeons, American Association of Thoracic Surgery, American Heart Association, American Burn Association, International Society of Heart and Lung Transplantation, American Society of Transplant Surgeons, and the Southern Thoracic Surgical Association. He has authored nearly 500 peer-reviewed publications and directs a research group that has produced over 1,000 publications in medical journals that include JAMA, New England Journal of Medicine, Lancet, Science, and Circulation. Dr. DiMaio has served as an editorial board member or reviewer for some the most prestigious medical journals in the world and has served as a grant reviewer for the National Institutes of Health (NIH), the American Heart Association, and the U.S. Department of Defense in an addition to serving on international medical guideline committees. Dr. DiMaio earned his medical degree from the University of Miami and completed his internal medicine, general surgery, and cardiothoracic surgery residencies at Duke University Medical Center.

Deepak Sadagopan

Deepak Sadagopan currently serves as Chief Operating Officer of Population Health at Providence St. Joseph Health, where he leads population health initiatives across the system to transform care. Mr. Sadagopan has more than 22 years of experience in health care, serving in leadership roles at Siemens PLM Solutions, Quest Diagnostics, McKesson, and Edifecs. Over the past eight years, he has focused on working closely with payers and providers on the use of technology to drive business decisions making the transition from volume to value-based delivery models. Mr. Sadagopan is a leading voice in ensuring value-based care and Health IT policy initiatives enable equitable access to health care. He serves on the steering committee for HL7's DaVinci Accelerator to guide value-based care collaboration between payers and providers, and on the Department of Health and Human Services' ONC FAST National Steering Committee to accelerate interoperability data standards. He serves on the faculty of the School of Public Health at the University of Washington as Clinical Assistant Professor, teaching MHA courses in Value-Based Care and economics. Mr. Sadagopan earned his master's degree in healthcare delivery and economics from Dartmouth College. He also has a master's degree in engineering, specializing in data science, from the University of Connecticut and has completed an executive management program with the MIT Sloan School of Management.

Erich Spangenberg

Erich Spangenberg accepted his appointment to the Board on November 27, 2023. Erich Spangenberg is a serial entrepreneur and industry luminary in the patent business. Mr. Spangenberg is currently the Managing Partner at Sauvegarder Investment Management, a multi-strategy investment firm dedicated to IP-related financing and investment opportunities. Mr. Spangenberg started his career as a corporate lawyer (working for Jones Day), then as an investment banker (having held positions at Donaldson, Lufkin, and Jenrette) and, before launching his entrepreneurial endeavours, worked in telecommunications and distressed debt industries. Mr. Spangenberg was a Periclean Scholar at Skidmore College, a Distinguished Graduate with an M.Sc. from The London School of Economics and was on Law Review at Case Western Reserve University, where he earned his Juris Doctorate. Mr. Spangenberg was the first outside investor in the Company in 2011, previously served on the Company's Board of Directors from 2011-2022 and is the Company's largest outside stockholder.

Limitations on Liability and Indemnification of Officers and Directors

The Company entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements require the Company to indemnify its directors and executive officers to the fullest extent permitted by Delaware law.

The Company maintains a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe these provisions in the Charter, Bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

For more details regarding the related party transactions between the Company and its other anticipated executive officers and directors, see the sections entitled "*Certain Relationships and Related Party Transactions.*"

Corporate Governance

We have structured our corporate governance in a manner we believe closely aligns our interest with those of our stockholders. Notable features of our corporate governance include:

- we have independent director representation on our audit, compensation and nominating and corporate governance committees, and our independent directors will meet regularly in executive sessions without the presence of our corporate officers or non-independent directors; and
- at least one of our directors will qualify as an "audit committee financial expert" as defined by the SEC.

Election of Officers

Each executive officer serves at the discretion of our Board and holds office until his or her successor is duly appointed or until his or her earlier resignation or removal. There are no family relationships among any of our directors and executive officers.

Board Composition

Our Board consists of seven directors. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor or until his or her earlier death, resignation or removal. The authorized number of directors may be changed by resolution of our Board. Vacancies on our Board may be filled by resolution of the Board.

Our Board consists of (i) Cynthia Cai, (ii) Peter M. Carlson, (iii) Richard Cotton, (iv) J. Michael DiMaio, (v) Martin Mellish, (vi) Deepak Sadagopan and (vii) Erich Spangenberg. Our Board is chaired by Mr. Cotton.

Four directors qualify as "independent directors" under Nasdaq listing rules, namely, Cynthia Cai, Richard Cotton, Martin Mellish, and Deepak Sadagopan. For more details, see the section entitled "*Independence of our Board of Directors*."

At any meeting of stockholders at which directors are to be elected, the number of directors elected may not exceed the greatest number of directors then in office in any class of directors. Beginning with the Company's first annual meeting of stockholders, the directors shall be elected to hold office for a term expiring at the next annual meeting of stockholders of the Company and until his or her successor shall be elected and qualified, or until his or her earlier death, resignation, retirement, disqualification or removal from office. Subject to the rights, if any, of the holders of any series of preferred stock to elect additional directors under circumstances specified in a preferred stock designation, directors may be elected by the stockholders only at an annual meeting of stockholders.

Our Board is chaired by Mr. Cotton, a non-executive director. The Chairperson is responsible for the management, development and effective performance of the Board of Directors and provides leadership to the Board of Directors and the management team.

Independence of our Board of Directors

Based on information provided by each director concerning his or her background, employment, and affiliations, our Board has determined that the Board meets independence standards under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. In making these determinations, our Board considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "*Certain Relationships and Related Party Transactions.*"

Board Committees

Our Board has four standing committees: an executive committee; an audit committee; a compensation committee; and a nominating and governance committee. Each of the committees reports to the Board as it deems appropriate and as the Board may request. The composition, duties and responsibilities of these committees are set forth below. In the future, our Board may establish other committees, as it deems appropriate, to assist it with its responsibilities.

Executive Committee

The Executive Committee currently consists of Erich Spangenberg (Chair), Richard Cotton, Peter Carlson and Martin Mellish. The Executive Committee shall, during the intervals between meetings of the Board, have all delegable power and authority of the Board regarding the management of the business and affairs of the Company that are not separately delegated to other committees of the Board. In addition, the Executive Committee shall assist the Company in discussing and reviewing all manner of significant financial transactions and related opportunities prior to review and approval or denial by the Board. The Executive Committee operates under a written charter adopted by the Board, which is available on our website.

Audit Committee

The Audit Committee currently consists of Martin Mellish (Chair), Richard Cotton and Deepak Sadagopan. Our Board of Directors has determined that each member of the Audit Committee satisfies the independence and financial literacy requirements as defined by applicable Nasdaq Stock Market listing standards governing the qualifications of Audit Committee members. Martin Mellish qualifies as an "audit committee financial expert" under the rules of the SEC and satisfies the financial sophistication requirements under applicable Nasdaq Stock Market listing qualifications. The Audit Committee assists our Board of Directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting and legal compliance functions by approving the services performed by our independent registered public accounting firm and reviewing their reports regarding our accounting practices and systems of internal accounting controls. The Audit Committee also oversees the audit efforts of our independent registered public accounting firm and takes those actions as it deems necessary to satisfy itself that the independent registered public accounting firm is independent of management. The Board has delegated to the Audit Committee the responsibility of monitoring the Company's financial risks. Any material financial risks identified by the Audit Committee are reported to the full Board.

Our Board adopted a new written charter for the audit committee, which is available on our website. The information on our website is not intended to form a part of or be incorporated by reference into this registration statement.

Compensation Committee

The Compensation Committee currently consists of Cynthia Cai (Chair) and Martin Mellish, both of whom our Board has determined are independent directors under the listing standards of the Nasdaq Stock Market governing the independence of directors. The Compensation Committee's determines our general compensation policies and the compensation provided to our officers. The Compensation Committee also makes recommendations to our Board regarding director compensation. In addition, the Compensation Committee reviews and determines security-based compensation for our directors, officers, employees and consultants and will administer our equity incentive plans. Our Compensation Committee also oversees our corporate compensation programs. The Compensation Committee operates under a written charter adopted by the Board.

Our Board has adopted a new written charter for the compensation committee, which is available on our website.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee currently consists of Erich Spangenberg (Chair), Richard Cotton and Cynthia Cai. Our Board has determined that Mr. Cotton and Dr. Cai are independent directors under the listing standards of the Nasdaq Stock Market governing the independence of directors. The Nominating and Corporate Governance Committee's responsibilities include identifying individuals qualified to become Board members and recommending to the Board the director nominees for the next Annual Meeting of Stockholders, as well as candidates to fill vacancies on the Board. Additionally, the Nominating and Corporate Governance Committee recommends to the Board the directors to be appointed to Board committees. The Nominating and Corporate Governance Committee also developed and recommended to the Board a set of corporate governance guidelines and oversees the effectiveness of our corporate governance in accordance with those guidelines. The Nominating and Corporate Governance Committee operates under a written charter adopted by the Board, which is available on our website.

Role of Our Board of Directors in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. Our Board administers this oversight function directly through our Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight.

In particular, our Board is responsible for monitoring and assessing strategic risk exposure, and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also has the responsibility to review with management the process by which risk assessment and management is undertaken, monitor compliance with legal and regulatory requirements, and review the adequacy and effectiveness of our internal controls over financial

reporting. Our nominating and corporate governance committee is responsible for periodically evaluating our corporate governance policies and systems in light of the governance risks that we face and the adequacy of our policies and procedures designed to address such risks. Our compensation committee assesses and monitors whether any of our compensation plans, policies and programs comply with applicable legal and regulatory requirements.

Code of Business Conduct and Ethics for Employees, Executive Officers, and Directors

Our Board has adopted a Code of Business Conduct and Ethics (the "Code of Conduct"), applicable to all of our employees, executive officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The Code of Conduct is available on our website. Any amendments to the Code of Conduct, or any waivers of its requirements, are expected to be disclosed on its website to the extent required by applicable rules and exchange requirements.

Corporate Governance Guidelines

We have adopted a set of corporate governance guidelines to provide the framework for the governance of our Board and to assist our Board in the exercise of its responsibilities. These guidelines reflect our Board's commitment to monitoring the effectiveness of policy and decision-making both at the board and management levels, with a view to enhancing stockholder value over the long term. The corporate governance guidelines are available on our website.

Compensation of the Company's Executive Officers and Directors

Employment Agreements

We entered into employment agreements (the "Executive Employment Agreements") with each of Wensheng Fan, Peter Carlson, Nils Windler, Vincent Capone and Dr. Niko Pagoulatos, that govern certain terms and conditions of such executive officers' employment with us. The Executive Employment Agreements provide for base salary, eligibility to receive an annual bonus, eligibility to receive certain severance benefits upon involuntary terminations of employment, as well as customary confidentiality, assignment of intellectual property provisions, and certain restrictive covenants, including post-employment non-solicitation provisions.

Overview of Anticipated Executive Compensation Program

Decisions with respect to the compensation of the Company's executive officers, including our named executive officers, are made by the compensation committee of our Board. The following discussion is based on the current and expected compensation of our named executive officers and directors. The actual compensation of our named executive officers will depend on the judgment of the members of the compensation committee and may differ from that set forth in the following discussion. Such compensation will also generally be governed by our executive officers' employment agreements, as in effect from time to time, including as described above.

Compensation for our executive officers has the following components: base salary, cash bonus opportunities, equity compensation, employee benefits, executive perquisites and severance benefits. Base salaries, employee benefits, executive perquisites and severance benefits are designed to attract and retain senior management talent. We also use annual cash bonuses and equity awards to promote performance-based pay that aligns the interests of our named executive officers with the long-term interests of its equity-owners and to enhance executive retention.

Annual Bonuses

We expect to use annual cash incentive bonuses for the named executive officers to motivate their achievement of short-term performance goals and tie a portion of their cash compensation to performance. We expect that, near the beginning of each year, the compensation committee will select the performance targets, target amounts, target award opportunities and other terms and conditions of annual cash bonuses for the named executive officers, subject to the terms of their employment agreements. Following the end of each year, the compensation committee will determine the extent to which the performance targets were achieved and the amount of the award that is payable to the named executive officers.

Equity-Based Awards

We expect to use equity-based awards in future years to promote our interest by providing these executives with the opportunity to acquire equity interests as an incentive for their remaining in our service and aligning the executives' interests with those of its equity holders.

Other Compensation

We offer various employee benefit plans to employees and other benefits to named executive officers of the Company, which are the same or similar to those currently offered by the Company. For more information, see "*Executive Officer and Director Compensation — Narrative Disclosure to Summary Compensation Table*." We may also provide our named executive officers with perquisites and personal benefits that are not generally available to all employees.

Director Compensation

The Company's Board expects to review director compensation periodically to ensure that director compensation remains competitive such that we are able to recruit and retain qualified directors. The Company has adopted a director compensation program that is designed to align compensation with its business objectives and the creation of stockholder value, while enabling the Company to attract, retain, incentivize and reward directors who contribute to the long-term success of the Company. We believe director compensation is in accordance with industry practice and standards.

EXECUTIVE OFFICER AND DIRECTOR COMPENSATION

Throughout this section, unless otherwise noted, "the Company," "we," "us," "our," "Spectral" and similar terms refer to Legacy Spectral prior to the Business Combination and Spectral after the consummation of the Business Combination. Upon the consummation of the Business Combination, the executive officers of Legacy Spectral became the executive officers of Spectral.

Overview

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 named executive officer and director compensation described in this section discusses our 2023 compensation programs. This discussion may contain forward-looking statements that are based on the Company's current plans, considerations, expectations and determinations regarding future compensation programs.

Executive and Director Compensation

The Spectral Board of Directors, with input from our Chief Executive Officer, has historically determined the compensation for our named executive officers. Our named executive officers for the fiscal year ended December 31, 2023, which consist of our principal executive officer, principal financial officer and the next three most highly compensated executive officers who were serving as executive officers as of December 31, 2023, are:

- Wensheng Fan, Chief Executive Officer;
- Nils Windler, Chief Financial Officer;
- Niko Pagoulatos;
- Vincent Capone; and
- Christine Marks.

Summary Compensation Table

The following table summarizes the compensation earned by each of our named executive officers for the fiscal year ended December 31, 2023.

Name and Principal Position	Year	Salary ($)	Bonus[1] ($)	Stock Awards ($)	Option Awards[2] ($)	All Other Compensation[3] ($)	Total ($)
Wensheng Fan[4]	2023	523,958	385,000		370,806	88,757	1,368,521
Former Chief Executive Officer	2022	496,875	265,000		232,000	92,804	1,086,679
Nils Windler[5]	2023	350,000	60,000		117,056	33,122	560,177
Former Chief Financial Officer	2022	350,000	50,000		103,982	19,814	523,796
Niko Pagoulatos, Ph.D.[6]	2023	350,000	—		78,611	33,423	462,035
Former Chief Operating Officer	2022	38,447	20,000		11,792	1,873	72,112
Vincent Capone[7]	2023	331,250	65,000		97,010	34,616	527,876
General Counsel and Chief Financial Officer	2022	162,500			45,600	11,837	219,937
Christine Marks	2023	286,500	40,000		23,354	22,818	372,672
Vice President, Marketing & Commercialization	2022	193,750			11,400	12,017	217,167

(1) The amounts shown in this column represent the payments of bonuses earned during fiscal year 2022.

(2) The amounts shown in this column represent the grant date fair values of option awards granted in 2023 as computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification Topic 718. See Note 12 to the consolidated financial statements for a discussion of the assumptions used in the calculation of these amounts.

(3) For Mr. Fan, in 2023, the amount included in this column consists of $51,777 for his participation as an executive member of our board of directors; $17,893 representing matching contributions to Mr. Fan's 401(K) plan and $19,088 for health benefits provided to him.
For Mr. Fan, in 2022, the amount included in this column consists of $48,392 for his participation as an executive member of our board of directors; $25,896 representing matching contributions to Mr. Fan's 401(K) plan and $18,516 for health benefits provided to him.
For Mr. Windler, in 2023, the amount included in this column consists of $15,272 representing matching contributions to Mr. Windler's 401(K) plan and $17,850 for health benefits provided to him.
For Mr. Windler, in 2022, the amount included in this column consists of $19,814 for health benefits provided to him.
For Dr. Pagoulatos in 2023, the amount in this column consists of $15,563 in matching contributions to Dr. Pagoulatos' 401(K) plan and $17,860 for health benefits provided to him.
For Dr. Pagoulatos in 2022, the amount in this column consists of $1,873 for health benefits provided to him.
For Mr. Capone in 2023, the amount in this column consists of $20,275 in matching contributions to Mr. Capone's 401(K) plan and $14,341 for health benefits provided to him.
For Mr. Capone in 2022, the amount in this column consists of $5,250 in matching contributions to Mr. Capone's 401(K) plan and $6,587 for health benefits provided to him.
For Ms. Marks in 2023, the amount in this column consists of $17,062 in matching contributions to Ms. Marks' 401(K) plan and $5,756 for health benefits provided to her.
For Ms. Marks in 2022, the amount in this column consists of $6,875 in matching contributions to Ms. Marks' 401(K) plan and $5,142 for health benefits provided to her.

(4) Mr. Fan resigned as our Chief Executive Officer effective February 29, 2024.

(5) Mr. Windler resigned as our Chief Financial Officer effective January 3, 2024.

(6) Dr. Pagoulatos was hired effective as of November 7, 2022 and resigned as our Chief Operating Officer on March 29, 2024.

(7) Mr. Capone was appointed as our Chief Financial Officer effective February 29, 2024, in addition to his position as General Counsel.

Narrative Disclosure to Summary Compensation Table

Base Salary

We provide each named executive officer with a base salary for the services that the executive officer performs for us. This compensation component constitutes a stable element of compensation while other compensation elements are variable. Base salaries are reviewed annually and may be increased based on the individual performance of the named executive officer, company performance, any change in the executive's position within our business, the scope of their responsibilities and market data.

Equity Incentive Awards

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.

In September 2022, we adopted 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.

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. For information on the grant dates, vesting terms and expiration terms, as applicable, of these equity awards, as well as other outstanding stock options under the 2018 Plan and 2022 Plan. See the Outstanding Equity Awards at 2023 Fiscal Year-End Table.

Health and Retirement Benefits

We provide medical, dental, vision, life insurance and disability benefits to all eligible employees. Our named executive officers are eligible to participate in these benefits on the same basis as all other employees. We maintain a 401(k) savings plan that allows participants, including our named executive officers, to defer cash compensation

into the plan up to the maximum annual deferral limit under applicable IRS guidelines. Eligible employees begin to receive benefits on their first day of employment and are fully vested in their salary deferrals. We provide fully vested safe-harbor employer matching contributions equal to 100% of the first 6% of cash compensation deferred into the 401(k) plan by participants for each year.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table provides information regarding outstanding equity awards held by each of our named executive officers as of December 31, 2023.

	Option Awards[1]				
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Wensheng Fan[2][3]	5/1/2019	872,939	—	1.03	5/1/2029
	6/25/2020	261,882	—	2.17	6/25/2030
	6/25/2020	87,294	—	2.17	6/25/2030
	11/20/2020	—	—	2.06	11/20/2023
	1/15/2021	342,192	—	2.17	1/15/2031
	10/8/2021	6,466	3,233	5.46	10/8/2031
	2/3/2022	51,730	25,865	4.95	2/3/2032
	4/13/2023	—	22,044	4.54	4/13/2033
	4/13/2023	—	66,705	4.54	4/13/2033
Nils Windler[4][5]	12/17/2021	70,050	26,943	5.26	12/17/2031
	4/13/2023	—	12,932	4.48	4/13/2033
	4/13/2023	—	6,466	4.48	4/13/2033
Dr. Niko Pagoulatos, Ph.D.[6][7]	11/07/2022	28,913	49,730	3.81	11/07/2032
	11/07/2022	8,810	9,540	3.81	11/07/2032
Vincent Capone[8][9]	5/06/2022	16,165	44,790	4.47	5/06/2032
	5/06/2022	—	6,939	4.47	5/06/2032
	4/13/2023	—	6,014	4.48	4/13/2033
	4/13/2023	—	12,027	4.48	4/13/2033
	6/29/2023	—	6,466	5.54	6/01/2033
	6/29/2023	—	12,932	5.54	6/01/2033
Christine Marks[10]	5/06/2022	4,210	12,933	4.47	5/06/2032
	4/13/2023	—	7,274	4.48	5/06/2032
Peter Carlson[11]	—	—	—	—	—

(1) Each of the options granted were incentive stock options and were issued at their then current fair market value.
(2) The options awarded to Mr. Fan vest in three equal annual installments beginning on the grant date, subject to his continued provision of service to us on each vesting date.
(3) Mr. Fan resigned as our Chief Executive Officer effective February 29, 2024.
(4) The options awarded to Mr. Windler vest in three equal annual installments beginning on the grant date, subject to his continued provision of service to us on each vesting date.
(5) Mr. Windler resigned as our Chief Financial Officer effective January 3, 2024.
(6) The options awarded to Dr. Pagoulatos vest in three equal annual installments beginning on the grant date, subject to his continued provision of service to us on each vesting date.
(7) Dr. Pagoulatos resigned as our Chief Operating Officer on March 29, 2024.

(8) The options awarded to Mr. Capone vest in three equal annual installments beginning on the grant date, subject to his continued provision of service to us on each vesting date.

(9) Mr. Capone was appointed as Chief Financial Officer effective February 29, 2024, in addition to his role as General Counsel.

(10) The options awarded to Ms. Marks vest in three equal annual installments beginning on the grant date, subject to his continued provision of service to us on each vesting date.

(11) Mr. Carlson was not issued an equity award until January 3, 2024, when he joined the Company.

Retirement Benefits, Termination and Change in Control Provisions at December 31, 2023

During fiscal year 2023, our executive officers (including our named executive officers) were eligible to participate in our 401(k) plan, as described above under "*Executive Officer and Director Compensation — Health and Retirement Benefits*." There were no other pension or retirement benefits pursuant to any existing plan provided or contributed to by us.

Each of the 2018 Plan and 2022 Plan provide that upon a "Change in Control" (as defined therein), our Compensation Committee may accelerate the vesting of options granted pursuant to the 2018 Plan or the 2022 Plan or make such adjustments to the existing grants as the committee deems appropriate to reflect such Change in Control transaction. Upon a termination of employment of our executive officers, all options granted under the 2018 Plan or the 2022 Plan are required to be exercised within 90 days of termination of such executive's employment with us or such options will be forfeited and included back in the 2018 Plan and 2022 Plan.

Non-Employee Director Compensation

In 2023, we paid our non-executive and executive directors cash compensation for their contributions to the operations of the business. The following table provides the compensation amounts for each non-executive member of the Board of Directors for 2023. Mr. Fan received $51,777 for his participation as an executive member of our board of directors:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Richard Cotton	88,983	32,270		121,253
Gerry Beaney[1]	58,985	—		58,985
Cynthia Cai	73,445	32,270		105,715
Martin Mellish	93,509	32,270		125,779
Deepak Sadagopan[2]	10,000	—		10,000
Erich Spangenberg[3]	10,000	6,525		16,525
Michael Murphy[4]	—	—		—

(1) Mr. Beaney resigned from the Board on September 8, 2023 in connection with the closing of the Business Combination.

(2) Mr. Sadagopan joined the Board on September 11, 2023 in connection with the closing of the Business Combination.

(3) Mr. Spangenberg joined the Board on November 27, 2023.

(4) Mr. Murphy joined the Board on September 11, 2023 in connection with the closing of the Business Combination. Mr. Murphy resigned from the Board on January 30, 2024.

Executive Officer and Director Compensation Arrangements

Equity

In connection with the Business Combination, the equity-based awards for Spectral's named executive officers were treated in accordance with the terms of the Business Combination Agreement and converted into equity-based awards that settle in shares of the Company's Common Stock.

RCLF and Spectral waived the requirement in the Business Combination Agreement that RCLF approve and adopt the Equity Incentive Plan to be effective in connection with the Business Combination. Instead, the Company will seek to approve and adopt a new equity incentive plan at its first annual meeting following the Business Combination, pursuant to the terms of the Business Combination Agreement, which shall provide for an aggregate share reserve

thereunder equal to (a) such number of shares of Common Stock sufficient to satisfy all Legacy Spectral Options plus (b) no more than 15% of RCLF's fully-diluted outstanding stock immediately after the Business Combination. The Equity Incentive Plan shall also include a customary 5% evergreen provision.

Employment Arrangements

We entered into employment agreements (the "Executive Employment Agreements") with each of Wensheng Fan, Peter Carlson, Nils Windler, Vincent Capone and Dr. Niko Pagoulatos, that govern certain terms and conditions of such executive officers' employment with us. The Executive Employment Agreements provide for base salary, eligibility to receive an annual bonus, eligibility to receive certain severance benefits upon involuntary terminations of employment, as well as customary confidentiality, assignment of intellectual property provisions, and certain restrictive covenants, including post-employment non-solicitation provisions.

Non-Employee Director Compensation

The Company's Board expects to review director compensation periodically to ensure that director compensation remains competitive such that we are able to recruit and retain qualified directors. The Company has adopted a director compensation program that is designed to align compensation with its business objectives and the creation of stockholder value, while enabling the Company to attract, retain, incentivize and reward directors who contribute to the long-term success of the Company.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Related Person Transactions

Other than the investment in our new intellectual property subsidiary and the Registration Rights listed below, there has been no transaction, and no transaction is currently proposed, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any related person had or will have a direct or indirect material interest.

Investment in Spectral IP, Inc.

On March 7, 2024, the Company formed a new wholly-owned subsidiary, Spectral IP, Inc. ("Spectral IP"), to advance intellectual property relevant to the broader Artificial Intelligence ecosystem, with a specific emphasis on healthcare. On March 19, 2024, the Company received a $1.0 million investment into Spectral IP from an affiliate of the Company's largest stockholder. The investment is structured as a one-year note payable with interest accruing at an annual rate of 8.00% and requiring earlier prepayment if Spectral IP is spun-off to the Company's shareholders or is sold.

Registration Rights

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").

Pursuant to the Business Combination agreement, at the closing of the Business Combination (the "Closing"), RCLF, RCLF's Sponsor (the "Sponsor") and certain stockholders of the Company entered into the Registration Rights/Lock-Up Agreement (the "Registration Rights/Lock-Up Agreement"), pursuant to which, among other things, the Company agreed to register for resale, pursuant to Rule 415 under the Securities Act, certain shares of Common Stock and other equity securities of the Company that are held by the parties thereto from time to time. Legacy Spectral stockholders party to the agreement also agreed, among other things and subject to limited exceptions, that their shares received as consideration in connection with the Business Combination may not be transferred until the date that is six months following Closing, and the Sponsor and other holders of Founder Shares agreed, among other things, that the shares of Common Stock held by the Sponsor (other than shares acquired in any potential Private Placement or shares acquired in the public market) may not be transferred until the date that is six months following the Closing. On February 7, 2024, Dr. J. Michael DiMaio and Erich Spangenberg, who together hold approximately 45% of the Company's outstanding shares, each agreed to an additional six-month extension of the current lock-up of their outstanding shares under the Registration Rights/Lock-Up Agreement through a new agreement.

Policies and Procedures for Related Party Transactions

The Company adopted a written related person transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

A "Related Person Transaction" is a transaction, arrangement or relationship in which the Company or any of its subsidiaries was, is or will be a participant, the amount of which involved exceeds $120,000, and in which any related person had, has or will have a direct or indirect material interest.

A “Related Person” means:

- any person who is or was (since the beginning of the last fiscal year for which the Company has filed an Annual Report on Form 10-K and proxy statement, even if such person does not presently serve in that role) an executive officer, director or nominee for director of the Company;
- any person who is known by the Company to be the beneficial owner of more than 5% of any class of its voting stock; and
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law of a person, and any person (other than a tenant or an employee) sharing the household of such person.

It is also anticipated that the Company will have policies and procedures designed to minimize potential conflicts of interest arising from any dealings it may have with its affiliates and to provide appropriate procedures for the disclosure of any real or potential conflicts of interest that may exist from time to time.

BENEFICIAL OWNERSHIP OF SECURITIES

Common Stock

The following table sets forth certain information known to us as of April 8, 2024 with respect to the shares of our Common Stock beneficially owned as of that date by: (i) each of our directors and each of our nominees for director; (ii) each of our executive officers named in the 2023 Summary Compensation Table contained in this prospectus; (iii) all of our directors and executive officers as a group; and (iv) each person known by us to beneficially own more than 5% of our Common Stock. Except as otherwise indicated, we believe each beneficial owner named below has sole voting and sole investment power with respect to all shares of Common Stock beneficially owned by that holder. Except as otherwise indicated, the address for each stockholder is 2515 McKinney Avenue, Suite 1000, Dallas, TX 75201. Percentage calculations of beneficial ownership are based on 17,561,808 Shares of Common Stock outstanding on April 8, 2024.

Name and Address of Beneficial Owner[1][2]	Number of Shares Beneficially Owned	%
Directors and Named Executive Officers of the Company		
Wensheng Fan[5]	1,686,865	9.61%
Cynthia Cai	—	
Richard Cotton	47,529	*
Martin Mellish	—	
Michael P. Murphy[3][4]	848,333	4.83%
Deepak Sadagopan	—	*
Niko Pagoulatos, Ph.D.[6]	40,417	*
Nils Windler[7]	72,744	*
Peter M. Carlson	—	
Vincent Capone[8]	57,743	*
Erich Spangenberg[9]	4,736,131	26.97%
John Michael DiMaio, M.D.[10]	2,485,908	14.16%
All Directors and Executive Officers of the Company as a Group (13 Individuals)[11]	9,975,670	56.80%
Five Percent Holders		
Erich Spangenberg[12]	4,736,131	26.97%
John Michael DiMaio[13]	2,485,908	14.16%
Wensheng Fan	1,686,865	9.61%
Octopus Investments plc[15]	960,211	5.47%
Jeffrey Thatcher, Ph.D.[16]	820,723	4.67%

* Less than one percent.

(1) Unless otherwise noted, the business address of each of the following individuals is c/o Spectral AI, Inc., 2515 McKinney Avenue, Suite 1000, Dallas, Texas 75201.

(2) Excludes Shares issuable pursuant to warrants issued in connection with the Rosecliff Initial Public Offering.

(3) Shares of Common Stock following the conversion of Class B common stock upon the Closing on a one-for-one basis, subject to adjustment, as described in the section entitled "Description of Securities" in our prospectus filed with the SEC pursuant to Rule 424(b)(4) (File No. 333-252478).

(4) Rosecliff Acquisition Sponsor I LLC, the Sponsor, is the record holder of 848,333 shares of Common Stock following the conversion of Class B common stock upon the Closing of the Business Combination and has a principal place of business in New York. Michael P. Murphy is the managing member of Rosecliff Credit Opportunity Fund I GP, LLC, a Delaware limited liability company, which is the general partner of Rosecliff Credit Opportunity Fund I, L.P., a Delaware limited partnership, which is the managing member of the Sponsor. Each of Rosecliff Credit Opportunity Fund I GP, LLC and Rosecliff Credit Opportunity Fund I, L.P. has a principal place of business in New York. Mr. Murphy is a U.S. person living in New York.

(5) Includes 1,652,086 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the date hereof.

(6) Consists of 40,417 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the date hereof.

(7) Consists of 72,744 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the date hereof.

(8) Includes 48,043 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the date hereof.

(9) Mr. Spangenberg joined our Board on November 10, 2023.

(10) Dr. DiMaio joined our Board on February 7, 2024.

(11) Includes 1,813,290 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the date hereof.

(12) Includes 577,574 shares held by Erich Spangenberg and 4,158,557 owned by ELS 1960 Family, L.P. The business address of ELS 1960 Family, L.P. is 241 Navajo Street, Miami, Florida 33166. ELS 1960 Family, L.P. is a limited partnership that was established in 2017 for the benefit of Mr. Erich Spangenberg and his heirs. Mr. Spangenberg is currently the majority limited partner of ELS 1960 Family, L.P. and the co-managing partner of ELS 1960 Family GP, LLC which also holds an interest in ELS 1960 Family, L.P.

(13) The business address for Dr. DiMaio is 4708 Alliance Blvd., Pavilion I, Suite 540, Plano, Texas 75093.

(14) The business address for Board of Regents of the University of Texas System for the Benefit of the University of Texas Southwestern Medical Center is UT Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, Texas 75390

(15) The business address for Octopus Investments plc is PO Box 10847, Chelmsford CM99 2BU. Octopus Investments is a United Kingdom based financial services company managing more than £12.9 billion on behalf of over 63,000 investors while employing over 750 employees. It is the United Kingdom’s largest provider of venture capital trust (VCT), Enterprise Investment Scheme (EIS) and Business Property Relief (BPR)-qualified investments. VCT, EIS and BPR programs are large UK government-sponsored programs to provide tax and other incentives for institutional and individual investments in areas such as venture capital and commercial real estate transactions.

(16) Includes 820,723 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the date hereof.

SELLING STOCKHOLDER

This prospectus relates to the offer and sale by Yorkville, or the Selling Stockholder, of up to 6,369,937 shares of our Common Stock that have been and may be issued by us to the Selling Stockholder under the SEPA. For additional information regarding the shares of our Common Stock included in this prospectus, see the section titled "*Standby Equity Purchase Agreement*" above. We are registering the shares of our Common Stock included in this prospectus pursuant to the provisions of the Registration Rights Agreement we entered into with Yorkville on March 20, 2024, in order to permit the Selling Stockholder to offer the shares included in this prospectus for resale from time to time. Except for the transactions contemplated by the SEPA and the Registration Rights Agreement and as set forth in the section titled "*Plan of Distribution*" in this prospectus, Yorkville has not had any material relationship with us within the past three years. As used in this prospectus, the term "Selling Stockholder" means Yorkville.

The table below presents information regarding the Selling Stockholder and the shares of our Common Stock that may be resold by the Selling Stockholder from time to time under this prospectus. This table is prepared based on information supplied to us by the Selling Stockholder, and reflects holdings as of April 8, 2024. The number of shares in the column "Maximum Number of Shares of Common Stock to be Offered Pursuant to this Prospectus" represents all of the shares of our Common Stock being offered for resale by the Selling Stockholder under this prospectus. The Selling Stockholder may sell some, all or none of the shares being offered for resale in this offering. We do not know how long the Selling Stockholder will hold the shares before selling them and, except as set forth in the section titled "*Plan of Distribution*" in this prospectus, we are not aware of any existing arrangements between the Selling Stockholder and any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares of our Common Stock being offered for resale by this prospectus.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act, and includes shares of our Common Stock with respect to which the Selling Stockholder has sole or shared voting and investment power. The percentage of shares of our Common Stock beneficially owned by the Selling Stockholder prior to the offering shown in the table below is based on an aggregate of 17,561,808 shares of our Common Stock outstanding on April 8, 2024. Because the purchase price to be paid by the Selling Stockholder for shares of our Common Stock, if any, that we may elect to sell to the Selling Stockholder in one or more transactions from time to time under the SEPA will be determined on the applicable purchase dates therefor, the actual number of shares of our Common Stock that we may sell to the Selling Stockholder under the SEPA may be fewer than the number of shares being offered for resale under this prospectus. The fourth column assumes the resale by the Selling Stockholder of all of the shares of our Common Stock being offered for resale pursuant to this prospectus.

	Number of Shares of Common Stock Beneficially Owned Prior to Offering		Maximum Number of Shares of Common Stock to be Offered Pursuant to this Prospectus	Number of Shares of Common Stock Beneficially Owned After Offering[3]	
Name of Selling Stockholder	Number[1]	Percent[2]		Number	Percent
YA II PN, Ltd.[4]	94,937	*	6,369,937	0	—

* Represents beneficial ownership of less than 1.0% of the outstanding shares of our Common Stock.

(1) Represents the 94,937 shares of our Common Stock we issued to Yorkville on March 20, 2024 as Commitment Shares in partial consideration for entering into the SEPA with us. Yorkville is prohibited from acquiring shares of our Common Stock pursuant to the SEPA or upon conversion of the Promissory Notes to the extent such shares, when aggregated with all other shares of our Common Stock then beneficially owned by Yorkville, would cause Yorkville's beneficial ownership of our Common Stock to exceed the 4.99% Beneficial Ownership Limitation would exceed the 19.99% Exchange Cap, unless we obtain stockholder approval to do so, or unless the average price for all shares of our Common Stock purchased by Yorkville under the SEPA equals or exceeds $2.37 per share, such that the Exchange Cap limitation would not apply under applicable Nasdaq rules. Therefore, for the purposes hereof, we have excluded from the number of shares beneficially owned prior to the offering all of the shares that Yorkville may be acquire under the SEPA or the Promissory Notes.

(2) Applicable percentage ownership is based on 17,561,808 shares of our Common Stock outstanding as of April 8, 2024.

(3) Assumes the sale of all shares of our Common Stock being offered for resale pursuant to this prospectus.

(4) YA II PN, Ltd. is a fund managed by Yorkville Advisors Global, LP ("***Yorkville LP***"). Yorkville Advisors Global II, LLC ("***Yorkville LLC***") is the general partner of Yorkville LP. All investment decisions for Yorkville are made by Yorkville LLC's President and managing member, Mr. Mark Angelo. The business address of Yorkville is 1012 Springfield Avenue, Mountainside, NJ 07092.

DESCRIPTION OF SECURITIES

The following description summarizes certain important terms of our capital stock, including the provisions included in our Charter, Bylaws and the Warrant Agreement. This description is not complete and is qualified by reference to the full text of our Charter, Bylaws and the Warrant Agreement, which are included as exhibits to the registration statement of which this prospectus is a part, as well as the applicable provisions of the DGCL.

Authorized and Outstanding Capital Stock

The Charter authorizes the issuance of 81,000,000 shares of capital stock of the Company, consisting of (i) 80,000,000 shares of common stock, par value $0.0001 per share (the "Common Stock"), and (ii) 1,000,000 shares of preferred stock, par value $0.0001 per share (the "Preferred Stock").

Common Stock

Voting Rights

Holders of Common Stock are entitled to cast one vote per share of Common Stock on all matters to be voted on by stockholders. Holders of Common Stock will vote together as a single class, and an action will be approved by stockholders if the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, while directors will be elected by a plurality of the votes cast. Holders of Common Stock are not entitled to cumulate their votes in the election of directors.

When a quorum is present at any meeting, any matter other than the election of directors to be voted upon by the stockholders at such meeting will be decided by a majority vote of the holders of shares of capital stock present or represented at the meeting and voting affirmatively or negatively on such matter. At all meetings of stockholders for the election of directors at which a quorum is present, a plurality of the votes cast will be sufficient to elect such directors.

Dividend Rights

Subject to preferences that may apply to any Preferred Stock, holders of Common Stock will be entitled to the payment of dividends at the times and in the amounts as the Board in its discretion may determine.

Liquidation, Dissolution and Winding Up

On the liquidation, dissolution, distribution of assets or winding up of the Company, each holder of Common Stock will be entitled, pro rata on a per share basis, to all assets of the Company of whatever kind available for distribution to the holders of Common Stock, subject to the designations, preferences, limitations, restrictions and relative rights of any Preferred Stock then outstanding.

Other Matters

The holders of Common Stock will not have redemption, conversion, preemptive or other subscription rights and there will be no sinking fund provisions applicable to Common Stock. All of the outstanding shares of Common Stock are validly issued, fully paid and non-assessable.

Preferred Stock

General

The Charter provides that the Board has the authority, without action by the stockholders, to designate and issue shares of Preferred Stock in one or more series, and the number of shares constituting any such series, and to fix the voting powers, designations, preferences, limitations, restrictions and relative rights of each series of Preferred Stock, including, without limitation, dividend rights, conversion rights, rights and terms of redemption, and liquidation preferences, which rights may be greater than the rights of the holders of Common Stock.

The purpose of authorizing the Board to issue Preferred Stock and determine the rights and preferences of any series of Preferred Stock is to eliminate delays associated with a stockholder vote on specific issuances. The simplified issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions, future financings

and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Additionally, the issuance of Preferred Stock may adversely affect the holders of Common Stock by restricting dividends on Common Stock, diluting the voting power of Common Stock or subordinating the dividend or liquidation rights of Common Stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of Common Stock.

Warrants

Each whole Warrant entitles the registered holder to purchase one share of our Common Stock at a price of $11.50 per share, subject to adjustment as discussed below, at any time commencing 30 days after the completion of the Business Combination. Pursuant to the Warrant Agreement, a Warrant holder may exercise its Warrants only for a whole number of shares of Common Stock. This means that only a whole Warrant may be exercised at any given time by a warrant holder. No fractional Warrants will be issued upon separation of the units and only whole Warrants will trade on Nasdaq.

No Warrant will be exercisable for cash unless we have an effective and current registration statement covering the shares of Common Stock issuable upon exercise of the Warrants and a current prospectus relating to such shares of Common Stock. Notwithstanding the foregoing, if the registration statement covering the shares of Common Stock issuable upon exercise of the Warrants is not effective within 60 days from the Closing, warrant holders may, until such time as there is an effective registration statement and during any period when we shall have failed to maintain an effective registration statement, exercise Warrants on a cashless basis pursuant to an available exemption from registration under the Securities Act. In such event, each holder would pay the exercise price by surrendering the whole Warrant for that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the Warrants, *multiplied by* the difference between the exercise price of the Warrant and the "fair market value" by (y) the fair market value. The "fair market value" shall mean the average reported trading price of the shares of Common Stock for the ten (10) trading days ending on the trading day prior to the date of exercise. The Warrants will expire five years from the Closing at 5:00 p.m., New York City time.

The outstanding Warrants (excluding the Warrants issued in the private placements contemporaneously with the IPO) may be called for redemption, in whole and not in part, at a price of $0.01 per warrant:

- at any time after the Warrants become exercisable;
- upon not less than 30 days' prior written notice of redemption to each warrant holder;
- if, and only if, the reported last sale price of the shares of Common Stock equals or exceeds $18.00 per share, for any 20 trading days within a 30-day trading period commencing after the Warrants become exercisable and ending on the third business day prior to the notice of redemption to Warrant holders; and
- if, and only if, there is a current registration statement in effect with respect to the shares of Common Stock underlying such Warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption.

The right to exercise will be forfeited unless the Warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of a Warrant will have no further rights except to receive the redemption price for such holder's Warrants upon surrender of such Warrants.

The redemption criteria for the Warrants have been established at a price which is intended to provide Warrant holders a reasonable premium to the initial exercise price and provide a sufficient differential between the then-prevailing share price and the Warrant exercise price so that if the share price declines as a result of a redemption call, the redemption will not cause the share price to drop below the exercise price of the Warrant.

If the Warrants are called for redemption as described above, management will have the option to require all holders that wish to exercise Warrants to do so on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the Warrants for that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the Warrants, *multiplied by* the difference between the exercise price of the Warrant and the "fair market value" by (y) the fair market value. The "fair market value" for this purpose shall mean the average reported closing price of the shares of Common Stock for

the ten (10) trading days ending on the third trading day prior to the date on which the notice of redemption is sent to holders of the Warrants. Whether we will exercise our option to require all holders to exercise their Warrants on a "cashless basis" will depend on a variety of factors including the price of the Common Stock at the time the Warrants are called for redemption, our cash needs at such time and concerns regarding dilutive share issuances.

The Warrants have been issued in registered form under a Warrant Agreement between Continental Stock Transfer & Trust Company, as warrant agent, and RCLF. The Warrant Agreement provides that the terms of the Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval, by written consent or vote, of the holders of 65% of the then outstanding Warrants in order to make any change that adversely affects the interests of the registered holders.

The exercise price and number of shares of Common Stock issuable on exercise of the Warrants may be adjusted in certain circumstances including in the event of a share dividend, extraordinary dividend or our recapitalization, reorganization, merger or consolidation. However, the Warrants will not be adjusted for issuances of shares of Common Stock at a price below their respective exercise prices.

The Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the Warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of Warrants being exercised. The Warrant holders do not have the rights or privileges of holders of shares of Common Stock and any voting rights until they exercise their Warrants and receive shares of Common Stock. After the issuance of shares of Common Stock upon exercise of the Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Except as described above, no Warrants will be exercisable for cash and we will not be obligated to issue shares of Common Stock unless at the time a holder seeks to exercise such warrants, a prospectus relating to the shares of Common Stock issuable upon exercise of the Warrants is current and the shares of Common Stock have been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the Warrants. Under the terms of the Warrant Agreement, we have agreed to use commercially reasonable efforts to meet these conditions and to maintain a current prospectus relating to the shares of Common Stock issuable upon exercise of the Warrants until the expiration of the Warrants. However, we cannot assure you that we will be able to do so and, if we do not maintain a current prospectus relating to the shares of Common Stock issuable upon exercise of the Warrants, holders will be unable to exercise their Warrants, and we will not be required to settle any such warrant exercise. If the prospectus relating to the shares of Common Stock issuable upon the exercise of the Warrants is not current or if the Common Stock is not qualified or exempt from qualification in the jurisdictions in which the holders of the Warrants reside, we will not be required to net cash settle or cash settle the warrant exercise, the Warrants may have no value, the market for the Warrants may be limited and the Warrants may expire worthless.

Warrant holders may elect to be subject to a restriction on the exercise of their Warrants such that an electing Warrant holder would not be able to exercise their Warrants to the extent that, after giving effect to such exercise, such holder would beneficially own in excess of 9.8% of the shares of Common Stock outstanding.

No fractional shares will be issued upon exercise of the Warrants. If, upon exercise of the Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of shares of Common Stock to be issued to the Warrant holder.

The Warrant Agreement provides that, subject to applicable law, any action, proceeding or claim against us arising out of or relating in any way to the Warrant Agreement will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and we irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim. Notwithstanding the foregoing, these provisions of the Warrant Agreement will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act (or the rules and regulations thereunder) or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum.

Original Registration Rights and Lock-up Agreement

At the Closing, the Company, the Sponsor and certain stockholders of Legacy Spectral and RCLF entered into the Original Registration Rights/Lock-Up Agreement, pursuant to which, among other things, the Company agreed to register for resale, pursuant to Rule 415 under the Securities Act, shares of Common Stock that are held by the parties

thereto from time to time. Pursuant to the Original Registration Rights/Lock-Up Agreement, the Company will agree to file a shelf registration statement registering the resale of the Common Stock within 45 days of the Closing. Up to twice in any 12-month period, certain Legacy Spectral stockholders and the Sponsor may request to sell all or any portion of their Registrable Securities (as defined in the Original Registration Rights/Lock-Up Agreement) in an underwritten offering so long as the total offering price is reasonably expected to exceed $10 million. The Company also agreed to provide customary "piggyback" registration rights, subject to certain requirements and customary conditions. The Original Registration Rights/Lock-Up Agreement provides that the Company will pay certain expenses relating to such registrations and indemnify the stockholders against certain liabilities.

In addition, pursuant to the Original Registration Rights/Lock-up Agreements, Legacy Spectral stockholders party to the agreement agreed, among other things and subject to limited exceptions, that their shares received as consideration in the First Merger (including New Awards and shares issuable upon exercise or conversion of New Awards) may not be transferred until the date that is six months following Closing, and the Sponsor and other holders of Founder Shares agreed, among other things, that the shares of Common Stock held by the Sponsor (other than shares acquired in any potential Private Placement or shares acquired in the public market) may not be transferred until the date that is six months following the Closing. Certain stockholders of Legacy Spectral, representing approximately 45% of the Company's outstanding Common Stock have entered into a contractual agreement to extend their respective restrictions on transfer until the date that is one year following the Closing.

Exclusive Forum

The Charter provides that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (the "Chancery Court") shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring: (i) any derivative action or proceeding brought on the Company's behalf; (ii) any action, suit or proceeding asserting a claim of breach of fiduciary duty owed by any current or former director, officer or other employee, agent or stockholder of the Company to the Company or its 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, the Charter or the 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, and, if such action is filed in a court other than the Chancery Court (a "Foreign Action") by any stockholder (including any beneficial owner), to the fullest extent permitted by law, such stockholder shall be deemed to have consented to (a) the personal jurisdiction of the Chancery Court in connection with any action brought in any such court; and (b) having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

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.

Certain Anti-Takeover Effects of Provisions of the Proposed Charter, Proposed Bylaws and Applicable Law

Section 203 of the DGCL affords us certain protections, such as prohibiting us from engaging in any business combination with any stockholder for a period of three years following the time that such stockholder (the "interested stockholder") came to own at least 15% of our outstanding voting stock (the "acquisition"), except if:

- our board of directors approved the acquisition prior to its consummation;
- the interested stockholder owned at least 85% of the outstanding voting stock upon consummation of the acquisition; or
- the business combination is approved by our board of directors, and by a two-thirds vote of the other stockholders in a meeting.

Generally, a "business combination" includes any merger, consolidation, asset or stock sale, or certain other transactions resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an "interested stockholder" is a person who, together with that person's affiliates and associates, owns, or within the previous three years owned, 15% or more of our voting stock.

Under certain circumstances, these anti-takeover provisions will make it more difficult for a person who would be an "interested stockholder" to effect various business combinations with us for a three-year period. This may encourage companies interested in acquiring us to negotiate in advance with our board of directors because the stockholder approval requirement would be avoided if our board of directors approves the acquisition that results in the stockholder becoming an interested stockholder.

This may also have the effect of preventing changes in our board of directors and may make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Authorized but Unissued Shares

The Charter provides that certain shares of authorized but unissued Common Stock and Preferred Stock will be available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future public offerings, to raise additional capital, or to facilitate acquisitions. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of the Company by means of a proxy contest, tender offer, merger, or otherwise.

Special Meetings of Stockholders

The Charter provides that special meetings of the stockholders of the Company may be called, for any purpose or purposes, at any time by the chairperson of the Board or a resolution adopted by the affirmative vote of the majority of the then-serving members of the Board, in accordance with the Bylaws, and shall not be called by stockholders or any other Person or Persons.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

The Bylaws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors, other than nominations made by or at the direction of the Board or a committee of the Board. In order to be "properly brought" before a meeting, a stockholder will have to comply with advance notice requirements and provide the Company with certain information. Generally, to be timely, a stockholder's notice must be received at the Company's principal executive offices not less than 90 days nor more than 120 days prior to the anniversary of the immediately preceding annual meeting of stockholders. The Bylaws also specify requirements as to the form and content of a stockholder's notice. The Bylaws allow the Board and/or the chairperson of the meeting at a meeting of the stockholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay, or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to influence or obtain control of the Company.

Limitation on Stockholder Action by Written Consent

The Charter provides that any action required or permitted to be taken by the stockholders of the Company must be effected at an annual or special meeting of the stockholders and may not be taken by written consent of the stockholders in lieu of a meeting.

Dissenter's Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, the Company's stockholders will have appraisal rights in connection with a merger or consolidation of the Company. Pursuant to the DGCL, stockholders who properly request and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Court.

Stockholders' Derivative Actions

Under the DGCL, any of the Company's stockholders may bring an action in the Company's name to procure a judgment in the Company's favor, also known as a derivative action; *provided* that the stockholder bringing the action is a holder of the Company's shares at the time of the transaction to which the action relates or such stockholder's shares thereafter devolved by operation of law.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors or officers of corporations and their stockholders for monetary damages for breaches of directors' or officers' fiduciary duties, subject to certain exceptions. The Charter includes a provision that eliminates the personal liability of directors or officers for monetary damages for any breach of fiduciary duty as a director or officer except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL as the same exists or may hereafter be amended.

The Bylaws provide that the Company must indemnify and hold harmless the directors and officers of the Company to the fullest extent authorized by the DGCL. The Company may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Company, or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust enterprise or non-profit entity against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Company would have the power to indemnify him or her against such liability under the provisions of the DGCL.

The limitation of liability, advancement and indemnification provisions in the Charter and Bylaws may discourage stockholders from bringing lawsuits against directors or officers for breach of their fiduciary duties. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit the Company and its stockholders. In addition, your investment may be adversely affected to the extent the Company pays the costs of settlement and damage awards against directors and officer pursuant to these indemnification provisions.

Transfer Agent, Warrant Agent and Registrar

The transfer agent for Common Stock is Continental Stock Transfer & Trust Company. The Company will agree to indemnify Continental Stock Transfer & Trust Company in its roles as transfer agent and warrant agent, its agents and each of its stockholders, directors, officers and employees against all claims and losses that may arise out of acts performed or omitted for its activities in that capacity, except for any liability due to any gross negligence or intentional misconduct of the indemnified person or entity.

Listing of Securities

Our Common Stock and Warrants are listed on Nasdaq under the symbols "MDAI" and "MDAIW," respectively.

RESTRICTIONS ON RESALE OF SECURITIES

Rule 144

Pursuant to Rule 144 under the Securities Act ("Rule 144"), a person who has beneficially owned restricted shares of our Common Stock or Warrants for at least six months would be entitled to sell their securities; *provided*, that (i) such person is not deemed to have been an affiliate of the Company at the time of, or at any time during the three months preceding, a sale and (ii) the Company is subject to the Exchange Act periodic reporting requirements for at least three months before the sale and has filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as it was required to file reports) preceding the sale.

Persons who have beneficially owned restricted shares of Common Stock or Warrants for at least six months but who are affiliates of the Company at the time of, or at any time during the three months preceding, a sale would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of shares of Common Stock then outstanding; or
- the average weekly reported trading volume our Common Stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by affiliates of the Company under Rule 144 are also limited by manner of sale provisions and notice requirements and by the availability of current public information about the Company.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business-combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials) other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10-type information with the SEC reflecting its status as an entity that is not a shell company.

As a result of the consummation of the Business Combination, we are no longer a shell company, and so, once the conditions listed above are satisfied, Rule 144 will become available for the resale of the above-noted restricted securities.

Lock-Up Provisions

On September 11, 2023, in connection with the consummation of the Business Combination and as contemplated by the Business Combination Agreement, the Company entered into the Original Registration Rights/Lock-Up Agreement with the Holders (as defined therein). The Original Registration Rights/Lock-Up Agreement contained lock-up provisions, pursuant to which the Holders agreed, among other things, that their shares received as merger consideration may not be transferred until the date on which the last reported sale price of the Common Stock equals or exceeds $12.50 per share for any ten (10) trading days within any thirty (30)-trading day period commencing after the Closing Date or, if earlier, the date that is 180 days after the Closing Date.

PLAN OF DISTRIBUTION

The shares of our Common Stock offered by this prospectus are being offered by the Selling Stockholder. The shares may be sold or distributed from time to time by Yorkville directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the shares of our Common Stock offered by this prospectus could be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for our Common Stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Yorkville is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Except as set forth above, we know of no existing arrangements between Yorkville and any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares of our Common Stock offered by this prospectus.

Brokers, dealers, underwriters or agents participating in the distribution of the shares of our Common Stock offered by this prospectus may receive compensation in the form of commissions, discounts, or concessions from the purchasers, for whom the broker-dealers may act as agent, of the shares sold by Yorkville through this prospectus. The compensation paid to any such particular broker-dealer by any such purchasers of shares of our Common Stock sold by Yorkville may be less than or in excess of customary commissions. Neither we nor Yorkville can presently estimate the amount of compensation that any agent will receive from any purchasers of shares of our Common Stock sold by Yorkville.

We may from time to time file with the SEC one or more supplements to this prospectus or amendments to the registration statement of which this prospectus forms a part to amend, supplement or update information contained in this prospectus, including, if and when required under the Securities Act, to disclose certain information relating to a particular sale of shares offered by this prospectus by Yorkville, including with respect to any compensation paid or payable by Yorkville to any brokers, dealers, underwriters or agents that participate in the distribution of such shares by Yorkville, and any other related information required to be disclosed under the Securities Act.

We will pay the expenses incident to the registration under the Securities Act of the offer and sale of the shares of our Common Stock covered by this prospectus by Yorkville.

As consideration for its irrevocable commitment to purchase our Common Stock at our direction under the SEPA, we have agreed to (i) issue to Yorkville 94,937 shares of our Common Stock as Commitment Shares, which Commitment Shares have a total aggregate value equal to 0.75% of Yorkville's $30.0 million total dollar amount purchase commitment under the SEPA (assuming a value of $2.37 per Commitment Share, representing the official closing price of the Common Stock on Nasdaq immediately preceding the execution of the SEPA), upon execution of the SEPA and the Registration Rights Agreement and (ii) pay Yorkville the Cash Commitment Fee in the amount of $75,000, which is equal to 0.25% of Yorkville's $30.0 million total dollar amount purchase commitment under the SEPA,

upon the six-month anniversary of the Effective Date. In accordance with FINRA Rule 5110, the 94,937 Commitment Shares and the $75,000 Cash Commitment Fee are deemed to be underwriting compensation in connection with sales of our shares of Common Stock by Yorkville to the public.

In addition, we reimbursed Yorkville for due diligence fees in an amount of $25,000.

We also have agreed to indemnify Yorkville and certain other persons against certain liabilities in connection with the offering of shares of our Common Stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Yorkville has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Yorkville specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

We estimate that the total expenses for the offering will be approximately $157,181.

Yorkville has represented to us that at no time prior to the date of the SEPA has Yorkville, its sole member, any of their respective officers, or any entity managed or controlled by Yorkville or its sole member, engaged in or effected, in any manner whatsoever, directly or indirectly, for its own account or for the account of any of its affiliates, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our Common Stock or any hedging transaction, which establishes a net short position with respect to our Common Stock. Yorkville has agreed that during the term of the SEPA, none of Yorkville, its sole member, any of their respective officers, or any entity managed or controlled by Yorkville or its sole member, will enter into or effect, directly or indirectly, any of the foregoing transactions for its own account or for the account of any other such person or entity.

We have advised Yorkville that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes Yorkville, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the date that all shares of our Common Stock offered by this prospectus have been sold by Yorkville.

Our Common Stock is currently listed on Nasdaq under the symbol “MDAI”.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a discussion of certain material U.S. federal income tax consequences to Non-U.S. holders (as defined below) of the ownership and disposition of shares of our Common Stock that are being offered pursuant to this prospectus. This discussion applies only to holders that hold shares of our Common Stock as capital assets within the meaning of Section 1221 of the Code (the "Code") (generally, property held for investment).

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to a particular holder in light of such holder's particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain net investment income and the different consequences that may apply if you are subject to special rules under U.S. federal income tax laws that apply to certain types of investors, including but not limited to:

- banks, financial institutions or financial services entities;
- broker, dealers or traders in securities;
- governments or agencies or instrumentalities thereof;
- regulated investment companies or mutual funds;
- real estate investment trusts;
- expatriates or former citizens or long-term residents of the United States;
- except as specifically provided below, persons that actually or constructively own five percent or more (by vote or value) of our Common Stock;
- persons that acquired shares of our Common Stock pursuant to an exercise of employee share options, in connection with employee share incentive plans or otherwise as compensation;
- insurance companies;
- persons subject to a mark-to-market method of accounting;
- persons holding shares of our Common Stock as part of a "straddle," constructive sale, hedge, wash sale, conversion or other integrated or similar transaction;
- partnerships or other pass-through entities or arrangements for U.S. federal income tax purposes and any holders of interests therein;
- tax-exempt entities;
- controlled foreign corporations;
- passive foreign investment companies; and
- U.S. holders.

If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds shares of our Common Stock, the tax treatment of a partner in such partnership will generally depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. If you are a partnership or a partner of a partnership holding shares of our Common Stock, you are urged to consult your tax advisor regarding the tax consequences of the ownership and disposition of shares of our Common Stock.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of U.S. state or local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and do not expect to seek, a ruling from the U.S. Internal Revenue Service (the "IRS") as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any U.S. state or local or non-U.S. jurisdiction.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN U.S. FEDERAL INCOME TAX CONSEQUENCES ASSOCIATED WITH THE OWNERSHIP AND DISPOSITION OF SHARES OF OUR COMMON STOCK THAT ARE BEING OFFERED PURSUANT TO THIS PROSPECTUS. EACH PROSPECTIVE INVESTOR IN SHARES OF OUR COMMON STOCK IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE OWNERSHIP AND DISPOSITION OF SHARES OF OUR COMMON STOCK, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL, STATE AND LOCAL, AND NON-U.S. TAX LAWS.

As used herein, the term "Non-U.S. holder" means a beneficial owner of shares of our Common Stock that is not a "U.S. person" for U.S. federal income tax purposes. A U.S. person is any person who or that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation) organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more United States persons (as defined in the Code) have authority to control all substantial decisions of the trust or (ii) it has a valid election in effect under Treasury Regulations to be treated as a United States person.

Taxation of Distributions.

In general, any distributions we make to a Non-U.S. holder of shares of our Common Stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base maintained by such Non-U.S. holder in the United States), us or the applicable withholding agent will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder's adjusted tax basis in its shares of our Common Stock and, to the extent such distribution exceeds the Non-U.S. holder's adjusted tax basis, as gain realized from the sale or other disposition of the Common Stock, which will be treated as described under "*Non-U.S. Holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Shares of Our Common Stock*" below.

The withholding tax generally does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States (and, if a tax treaty applies, are attributable to a permanent establishment or fixed base maintained by the Non-U.S. holder in the United States). Instead, the effectively connected dividends generally will be subject to regular U.S. federal income tax as if the Non-U.S. holder were a U.S. resident. A corporate Non-U.S. holder receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower applicable treaty rate).

Gain on Sale, Taxable Exchange or Other Taxable Disposition of Shares of Our Common Stock.

Subject to the discussion below regarding backup withholding and FATCA, a Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain realized on a sale, taxable exchange or other taxable disposition of shares of our Common Stock, unless:

- the gain is effectively connected with the conduct by the Non-U.S. holder of a trade or business within the United States (and, if an applicable income tax treaty so requires, is attributable to a permanent establishment or fixed base maintained by the Non-U.S. holder in the United States);
- the Non-U.S. holder is an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which such disposition occurs and certain other conditions are met; or
- we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the Non-U.S. holder's holding period for the Common Stock and, in the case where the shares of our Common Stock are "regularly traded on an established securities market" (within the meaning of applicable Treasury Regulations, referred to herein as "regularly traded"), the Non-U.S. holder has owned, whether actually or based on the application of constructive ownership rules, more than 5% of our Common Stock at any time within the shorter of the five-year period preceding such disposition of Common Stock or such Non-U.S. holder's holding period for such Common Stock. There can be no assurance that our Common Stock will be treated as regularly traded for this purpose.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also be subject to an additional "branch profits tax" imposed at a 30% rate (or lower applicable treaty rate). If the second bullet point applies to a Non-U.S. holder, such Non-U.S. holder will be subject to U.S. tax on such Non-U.S. holder's gain at a tax rate of 30%, which may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

If the third bullet point above applies to a Non-U.S. holder, gain recognized by such Non-U.S. holder will be subject to tax at generally applicable U.S. federal income tax rates. In addition, a buyer may be required to withhold U.S. federal income tax at a rate of 15% of the amount realized upon such disposition. We would be classified as a "United States real property holding corporation" if the fair market value of our "United States real property interests" (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes. We believe that we are not and do not anticipate becoming a "United States real property holding corporation;" however, such determination is factual in nature and subject to change and no assurance can be provided as to whether we will become a "United States real property holding corporation" in the future.

Information Reporting and Backup Withholding.

Information returns generally will be filed with the IRS in connection with payments of distributions and the proceeds from a sale or other disposition of shares of our Common Stock. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty generally will satisfy the certification requirements necessary to avoid the backup withholding as well. Backup withholding (currently at a 24% rate) is not an additional tax. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes.

Sections 1471 through 1474 of the Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred to as "FATCA") generally impose withholding of 30% on payments of dividends on shares of our Common Stock to "foreign financial institutions" (which is broadly defined for this purpose and in general includes investment vehicles) and certain other non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by United States persons of interests in or accounts with those entities) have been satisfied by, or an exemption applies to, the payee (typically certified as to by the delivery of a properly completed IRS Form W-8BEN-E). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such withholding taxes, and a non-U.S. holder might be required to file a U.S. federal income tax return to claim such refunds or credits. Withholding under FATCA was scheduled to apply to payments of gross proceeds from the sale or other disposition of property that produces U.S.-source interest or dividends beginning on January 1, 2019, but the IRS has released proposed regulations that, if finalized in their proposed form, generally would eliminate the obligation to withhold on gross proceeds. Such proposed regulations also delayed withholding on certain other payments received from other foreign financial institutions that are allocable, as provided for under final Treasury Regulations, to payments of U.S.-source dividends, and other fixed or determinable annual or periodic income. Although these proposed Treasury Regulations are not final, taxpayers generally may rely on them until final Treasury Regulations are issued. Non-U.S. holders should consult their tax advisors regarding the effects of FATCA on their ownership and disposition of shares of our Common Stock.

EXPERTS

The consolidated financial statements of Spectral AI, Inc. as of December 31, 2023 and 2022 included in this prospectus, have been audited by KPMG LLP, an independent registered public accounting firm, as set forth in their report thereon, appearing elsewhere in this prospectus. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

LEGAL MATTERS

The legality of the securities offered hereby will be passed upon for us by Reed Smith LLP.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. We have also filed a registration statement on Form S-1, including exhibits, under the Securities Act with respect to the shares of Common Stock offered by this prospectus. This prospectus is part of the registration statement, but does not contain all of the information included in the registration statement or the exhibits. Our SEC filings are available to the public on the internet at a website maintained by the SEC located at *http://www.sec.gov*. Those filings are also available to the public on, or accessible through, our website under the heading "SEC Filings" at *https://investors.spectral-ai.com/*. The information on our web site, however, is not, and should not be deemed to be, a part of this prospectus.

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	$ —

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF THE BUSINESS (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF THE BUSINESS (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)

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

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

3. RECAPITALIZATION (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

4. FAIR VALUE MEASUREMENTS (cont.)

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	
	Amount Financed	Interest Rate	Year Ended December 31, 2023	Year Ended December 31, 2022	December 31, 2023	December 31, 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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

7. NOTES PAYABLE (cont.)

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%

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. LEASES (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. STOCK-BASED COMPENSATION (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. STOCK-BASED COMPENSATION (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. STOCK-BASED COMPENSATION (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. INCOME TAXES (cont.)

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.

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. INCOME TAXES (cont.)

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

SPECTRAL AI, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 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.

Spectral AI, Inc.

6,369,937 Shares of Common Stock

PROSPECTUS

April 19, 2024