

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

FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**Spectral AI, Inc.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b>	<b>8731</b>	<b>85-3987148</b>
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

**2515 McKinney Avenue, Suite 1000  
Dallas, Texas 75201  
(972) 499-4934**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Wensheng Fan  
Chief Executive Officer  
2515 McKinney Avenue, Suite 1000  
Dallas, Texas 75201  
(972) 499-4934**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

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**Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer:	<input type="checkbox"/>	Accelerated filer:	<input type="checkbox"/>
Non-accelerated filer:	<input checked="" type="checkbox"/>	Smaller reporting company:	<input checked="" type="checkbox"/>
		Emerging growth company:	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion  
Preliminary Prospectus dated October 30, 2023.**



## **Spectral AI, Inc.**

### **PRIMARY OFFERING OF Up To 8,433,231 Shares of Common Stock Issuable Upon Exercise of Warrants**

### **SECONDARY OFFERING OF Up To 10,069,748 Shares of Common Stock**

This prospectus relates to the issuance by Spectral AI, Inc. (“we,” “us,” “our,” the “Company,” “Registrant,” and “Spectral”) of an aggregate of (a) up to 8,433,231 shares of our Class A common stock, par value \$0.0001 per share (the “Common Stock”) that are issuable upon the exercise of 8,433,231 warrants (the “Warrants”), which were originally issued in Rosecliff Acquisition Corp I’s (“RCLF”) initial public offering (the “RCLF IPO”) as part of RCLF’s units at a price of \$10.00 per unit (the “Units”), with each unit consisting of one share of Common Stock and one third of one Warrant, by the holders thereof. Each Warrant entitles the holder thereof to purchase one share of our Common Stock at a price of \$11.50 per share.

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

We will not receive any proceeds from the sale of shares of Common Stock by the selling stockholders pursuant to this prospectus. We will receive up to approximately \$96.9 million from the exercise of the Warrants for cash, but will not receive any proceeds from the sale of the shares of Common Stock issuable upon such exercise. Each Warrant entitles the holder thereof to purchase one share of Common Stock at a price of \$11.50 per share. On October 24, 2023, the closing price for our Common Stock was \$2.54.

We believe the likelihood that the holders will exercise their Warrants, as applicable, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock. If the trading price of our Common Stock is less than the exercise price thereof, we believe the holders are unlikely to exercise their Warrants. Conversely, the holders are more likely to exercise their Warrants the higher the price of our Common Stock is above the exercise price thereof. The Warrants are exercisable on a cashless basis under certain circumstances specified in the Warrant Agreement (as defined herein). To the extent that any Warrants are exercised on a cashless basis, the aggregate amount of cash we would receive from such exercises will decrease. We expect to use any such proceeds for general corporate and working capital purposes, which would increase our liquidity.

In connection with shareholder votes to approve Business Combination and related matters, shareholders of RCLF elected to redeem an aggregate of 178,231 shares of common stock, par value \$0.0001 per share, of RCLF initially sold in the RCLF IPO. As a result, an aggregate of approximately \$1.85 million was paid to such redeeming shareholders at or prior to the Closing out of the Trust Account. The selling stockholders can sell, under this prospectus, up to (a) 10,069,748 shares of Common Stock, constituting approximately 62.4% of our issued and outstanding shares of Common Stock as of October 24, 2023. Sales of a substantial number of our shares of Common Stock and/or Warrants in the public market by the selling stockholders and/or by our other existing securityholders, or the perception that those sales might occur, could increase the volatility of and cause a significant decline in the market price of our securities and could impair our ability to raise capital through the

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sale of additional equity securities. See “*Risk Factors — Sales of a substantial number of our securities in the public market by the selling stockholders and/or by our existing stockholders could cause the price of our shares of Common Stock and Warrants to fall.*”

The sale of all or a portion of the securities being offered in this prospectus could result in a significant decline in the public trading price of our securities. Despite such a decline in the public trading price, some of the selling stockholders may still experience a positive rate of return on the securities they purchased due to the price at which such selling stockholder initially purchased the securities. See “— *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.*”

We are registering the securities for resale pursuant to the selling stockholders’ registration rights under certain agreements between us, on the one hand, and the selling stockholders, on the other hand. Our registration of the securities covered by this prospectus does not mean that the selling stockholders will offer or sell any of the securities.

The selling stockholders may offer, sell or distribute all or a portion of their shares of Common Stock publicly or through private transactions at prevailing market prices or at negotiated prices. The selling stockholders will bear all commissions and discounts, if any, attributable to their sales of the shares of Common Stock.

We provide more information about how the selling stockholders may sell the shares of Common Stock or Warrants in the section titled “*Plan of Distribution.*”

We are an “emerging growth company” as defined in Section 2(a) of the Securities Act of 1933, as amended (the “Securities Act”), and are subject to reduced public company reporting requirements. This prospectus complies with the requirements that apply to an issuer that is an emerging growth company.

Our Common Stock and Warrants are listed on the Nasdaq Stock Market LLC (“Nasdaq”) under the symbols “MDAI” and “MDAIW,” respectively. On October 24, 2023, the closing price of our Common Stock was \$2.54 and the closing price for our Warrants was \$0.15.

**Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “*Risk Factors*” beginning on page 8 of this prospectus, and under similar headings in any amendment or supplements to this prospectus.**

**Neither the U.S. 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 October 30, 2023.**

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the SEC using a “shelf” registration process. By using a shelf registration statement, we may issue an aggregate of up to 8,433,231 shares of our Common Stock are issuable upon the exercise of 8,433,231 Warrants, which were originally issued in the RCLF IPO as part of RCLF’s Units, with each Unit consisting of one share of Common Stock and one third of one Warrant, by the holders thereof. Each Warrant entitles the holder thereof to purchase one share of our Common Stock at a price of \$11.50 per share.

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

We will not receive any proceeds from the sale of shares of Common Stock by the selling stockholders pursuant to this prospectus. We will receive up to approximately \$96.9 million from the exercise of the Warrants but will not receive any proceeds from the sale of the shares of Common Stock issuable upon such exercise. Each Warrant entitles the holder thereof to purchase one share of Common Stock at a price of \$11.50 per share. We believe the likelihood that the holders will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock. If the trading price of our Common Stock is less than the exercise price thereof, we believe the holders are unlikely to exercise their Warrants. Conversely, the holders are more likely to exercise their Warrants, the higher the price of our Common Stock is above the exercise price thereof. The Warrants are exercisable on a cashless basis under certain circumstances specified in the Warrant Agreement. To the extent that any Warrants are exercised on a cashless basis, the aggregate amount of cash we would receive from such exercises will decrease. We expect to use any such proceeds for general corporate and working capital purposes, which would increase our liquidity.

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 stockholders 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. Neither we nor the selling stockholders take responsibility for and can provide no assurance as to the reliability of any other information that others may give you. Neither we nor the selling stockholders will 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.

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 <sup>®</sup>, <sup>™</sup> and <sup>SM</sup> 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*” are to the closing of the Business Combination;

“*Closing Date*” are to September 11, 2023;

“*Code*” are to the U.S. Internal Revenue Code of 1986, as amended;

“*Common Stock*” are to shares of the Company’s Class A 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;

“*Equity Incentive Plan*” is to the Spectral AI, Inc. 2023 Equity Incentive Plan, which will be approved and adopted by the Company at its first annual meeting following the Business Combination;

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

“*First Effective Time*” is to the effective time of the First Merger;

“*Founder Shares*” are to the shares of RCLF Class B common stock initially purchased by the Initial Holders in a private placement prior to the RCLF IPO 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;

“*Initial Holders*” are to the Sponsor and each independent director of RCLF;

“*Investment Company Act*” is to the Investment Company Act of 1940, as amended;

“*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;

“*RCLF Class A common stock*” is to the RCLF Class A common stock, par value \$0.0001 per share, prior to the Business Combination;

“*RCLF Class B common stock*” is to the RCLF Class B common stock, par value \$0.0001 per share, prior to the Business Combination;

“*RCLF common stock*” are to the RCLF Class A common stock and RCLF Class B common stock prior to the Business Combination;

“*RCLF IPO*” are to the initial public offering by RCLF, which closed on February 17, 2021;

“*Registration Rights/Lock-Up Agreement*” is to the Amended and Restated Registration Rights Agreement to be 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;



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“SPACs” are to special purpose acquisition companies;

“Spectral Awards” are to the Spectral Options, Spectral Warrants and Spectral RSUs;

“Sponsor” is to Rosecliff Acquisition Sponsor I LLC, a Delaware limited liability company;

“Trust Account” are to the trust account established by RCLF for the benefit of its stockholders with Continental Stock Transfer & Trust Company.

Units” are to the Units sold in the RCLF IPO, with each unit consisting of one share of RCLF Class A common stock and one-third of one Warrant; and

Warrants” are to the warrants included as a component of the Units 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.

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:

- effectively develop and sell our product offerings and services;
- compete in the highly-competitive and evolving industry;
- manage risks associated with the healthcare industry;
- maintain key strategic relationships with partners and distributors;
- enhance future operating and financial results;
- adhere to the regulatory pathway for and timing of FDA, CE and UKCA regulatory submissions and proceeds;
- receive U.S. government contracts and future awards;
- achieve anticipated target markets for burn wound and diabetic foot ulcers;
- explore potential future indications and applications for DeepView and areas of interest supported by BARDA;
- secure future and pending U.S. patent applications and foreign and international patent applications;
- manage risks associated with the Company’s dependence on a small number of outside contract manufacturers;
- continue to develop new products and innovations to meet constantly evolving customer demands;
- comply with laws and regulations applicable to the business;
- stay abreast of modified or new laws and regulations applicable to the business;
- acquire or make investments in other businesses, patents, technologies, products or services to grow the business, and realize the anticipated benefits therefrom;
- attract, train, and retain effective officers, key employees or directors;
- respond to fluctuations in foreign currency exchange rates and political unrest and regulatory changes in international markets into which we expand or otherwise operate in;
- successfully defend litigation or administrative proceedings;
- upgrade and maintain information technology systems;
- acquire and protect intellectual property;

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- maintain the listing of its Common Stock and Warrants on Nasdaq;
- meet future liquidity requirements, which may require additional financing; and
- effectively respond to general economic and business conditions.

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 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 healing versus non-healing tissue invisible to the naked eye. DeepView 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. 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”).

### The Business Combination and Related Transactions

On April 11, 2023, RCLF, Merger Sub I, Merger Sub II, and Legacy Spectral entered into a Business Combination Agreement, (the “Business Combination Agreement”), pursuant to which, among other transactions, on the Closing Date, Merger Sub I merged with and into Legacy Spectral (the “First Merger”), with Legacy Spectral surviving the Merger as a wholly-owned subsidiary of RCLF, and, immediately following the First Merger, Legacy Spectral merged with and into Merger Sub II, with Merger Sub II surviving the Second Merger as a direct, wholly-owned subsidiary of RCLF (the “Second Merger” and, together with the First Merger and other transactions described in the Business Combination Agreement, the “Business Combination”). In connection with the Closing, RCLF changed its name to “Spectral AI, Inc.” and Merger Sub II changed its name to Spectral MD Holdings, LLC.

Under the terms of the Business Combination Agreement, at the effective time of the First Merger (the “First Effective Time”), each share of Legacy Spectral common stock issued and outstanding immediately prior to the First Effective Time (excluding shares issued and outstanding immediately prior to the First Effective Time held by a Legacy Spectral stockholder who has not voted in favor of adoption of the Business Combination Agreement or consented thereto in writing and who is entitled to demand and has properly exercised appraisal rights of such shares in accordance with Section 262 of the DGCL and otherwise complied with all of the provisions of the DGCL relevant to the exercise and perfection of dissenters’ rights (the “dissenting shares”) and each 10.31 shares of Legacy Spectral common stock subject to Legacy Spectral Awards (as defined below)) were cancelled and converted into the right to receive 1 share of Common Stock with any fractional shares rounded down to the nearest whole share.

At the Effective Time, each outstanding Legacy Spectral stock option (each, a “Legacy Spectral Option”), whether vested or unvested, was converted into an option to purchase that number of shares of the Common Stock equal to the quotient of (x) the number of shares of Legacy Spectral common stock underlying such Legacy Spectral Option immediately prior to the Closing divided by (y) 10.31, at an exercise price per share equal to (A) the exercise price per share of Legacy Spectral common stock underlying such Legacy Spectral Option immediately prior to the Closing multiplied by (B) 10.31 with any fractional Legacy Spectral Option rounded to the nearest whole Legacy Spectral Option.

At the Effective Time, after giving effect to the warrant exercise, each outstanding Legacy Spectral warrant to purchase Legacy Spectral common stock (each a “Legacy Spectral Warrant”), whether or not exercisable, was converted into a warrant to purchase that number of shares of Common Stock equal to the quotient of (x) the number of shares of Legacy Spectral common stock underlying such Legacy Spectral Warrant immediately prior to the Closing

divided by (y) 10.31, at an exercise price per share equal to (A) the exercise price per share of Legacy Spectral common stock underlying such Legacy Spectral Warrant immediately prior to the Closing multiplied by (B) 10.31 with any fractional share of Legacy Spectral common stock underlying such Warrant rounded down to the nearest whole share.

At the Effective Time, each Legacy Spectral restricted stock unit (whether to be settled in cash or shares) outstanding immediately prior to the First Effective Time (each, a “Legacy Spectral RSU” and, collectively, the “Legacy Spectral RSUs,” and, together with the Legacy Spectral options and Legacy Spectral warrants, the “Legacy Spectral Awards”) was converted into the right to receive a restricted stock unit based on shares of Common Stock (each, a “New RSU,” and, collectively, the “New RSUs”) with substantially the same terms and conditions as were applicable to such Legacy Spectral RSU immediately prior to the First Effective Time (including with respect to vesting and termination-related provisions), except that such New RSU relates to such number of shares of RCLF common stock equal to the quotient of (i) the number of shares of Legacy Spectral common stock subject to such Legacy Spectral RSU immediately prior to the First Effective Time, divided by (ii) 10.31, with any fractional shares rounded down to the nearest whole share.

Immediately after giving effect to the Business Combination, there were 15,688,268 issued and outstanding shares of Common Stock. RCLF’s public units separated into their component securities upon consummation of the Business Combination and, as a result, no longer trade as a separate security and were delisted from Nasdaq.

The Spectral’s Common Stock and Warrants commenced trading on Nasdaq under the symbols “MDAI” and “MDAIW”, respectively, on September 12, 2023.

The rights of holders of our Common Stock and Warrants are governed by our Charter, Bylaws, and the DGCL, and, in the case of the Warrants, the Warrant Agreement, dated as of February 11, 2021, by and between RCLF and Continental Stock Transfer & Trust Company, as warrant agent (the “Warrant Agreement”). For additional information, see the section entitled “*Description of 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 an amended and restated registration rights agreement (the “Registration Rights Agreement”) with the Sponsor, certain former stockholders of Legacy Spectral, set forth on Schedule 1 thereto (such stockholders, the “Target Holders”), and Frank S. Edmonds and Heather Bellini (together with Michael P. Murphy and Brian Radecki, collectively, the “Director Holders” and, collectively with the Sponsor, the Target Holders and any person or entity who thereafter becomes a party to the Registration Rights Agreement, the “Holders” and each, a “Holder”). Pursuant to the Registration Rights Agreement, among other things, the Company agreed to undertake certain shelf registration obligations in accordance with the Securities Act and certain subsequent related transactions and obligations, including, among other things, undertaking certain registration obligations, and the preparation and filing of required documents.

In addition, the Registration Rights 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.

#### **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 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 GEN 3 System may require new clearances, approvals, De Novo classifications, certifications, or new or amended certifications, and may require us to cease marketing or to recall the modified device until clearances, approvals, De Novo classifications, or the relevant certifications are obtained.*
- *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 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.*
- *Anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of us more difficult.*
- *The price of Common Stock and Warrants may be volatile.*
- *Sales of a substantial number of our securities in the public market by the selling stockholders and/or by our existing stockholders could cause the price of our shares of Common Stock and Warrants to fall.*
- *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 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.*
- *The Warrants may never be in the money, and they may expire worthless and the terms of the Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Warrants approve of such amendment.*
- *Your unexpired Warrants may be redeemed prior to their exercise at a time that is disadvantageous to you, thereby making your Warrants worthless.*

#### **Emerging Growth 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 our 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.

#### **Exercise of Warrants**

The exercise price of our Warrants is \$11.50 per share of Common Stock. We believe the likelihood that Warrant holders will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock. If the trading price of our Common Stock is less than \$11.50 per share, we believe holders of our Warrants are unlikely to exercise their Warrants. Conversely, the Warrant holders are more likely to exercise their Warrants the higher the price of our Common Stock is above \$11.50 per share. The closing price of our Common Stock on the Nasdaq on October 24, 2023 was \$2.54, which is below the \$11.50 exercise price of the Warrants. The Warrants are exercisable on a cashless basis under certain circumstances specified in the Warrant Agreement. To the extent that any Warrants are exercised on a cashless basis, the aggregate amount of cash we would receive from the exercise of the Warrants will decrease.

#### **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 us	8,433,231 shares of Common Stock issuable upon exercise of Warrants.
Shares of Common Stock offered by the selling stockholders	10,069,748 shares of Common Stock.
Shares of Common Stock outstanding prior to this offering	15,688,268 shares of Common Stock (as of October 24, 2023).
Warrants outstanding prior to this offering	8,433,231 Warrants (as of October 24, 2023).
Exercise price per Warrant	\$11.50.
Use of proceeds	We will not receive any proceeds from the sale of shares of Common Stock by the selling stockholders pursuant to this prospectus. We will receive any proceeds from the exercise of the Warrants for cash, but not from the sale of the shares of Common Stock issuable upon such exercise.
Risk factors	You should carefully read the “ <i>Risk Factors</i> ” beginning on page 8 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 or Warrants.
Nasdaq symbol for our Common Stock	“MDAI”
Nasdaq symbol for our Warrants	“MDAIW”
Lock-Up Restrictions	Substantially all of our stockholders, including the selling stockholders, are subject to certain restrictions on transfer until the termination of applicable lock-up periods. See “ <i>Restrictions on Resale of Securities.</i> ”

**INFORMATION RELATED TO THE OFFERED SECURITIES**

This prospectus relates to the issuance by us of an aggregate of an aggregate of up to 8,433,231 shares of our Common Stock are issuable upon the exercise of 8,433,231 Warrants, which were originally issued in the RCLF IPO as part of RCLF's Units, with each unit consisting of one share of Common Stock and one third of one Warrant, by the holders thereof. Each Warrant entitles the holder thereof to purchase one share of our Common Stock at a price of \$11.50 per share.

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

The following table includes information relating to the securities held by the selling stockholders, including the price each selling stockholder paid for the securities, the potential profit relating to such securities and any applicable lock-up restrictions. The following table is derived in part from our internal records and is for illustrative purposes only. The table should not be relied upon for any purpose outside of its illustrative nature. The public offering price in the RCLF IPO was \$10.00 per share. Consequently, as set forth in the table below, some of the selling stockholders may realize a positive rate of return on the sale of their Common Stock covered by this prospectus even if the market price per share of our Common Stock is below \$10.00 per share, in which case the public shareholders may experience a negative rate of return on their investment.

<b>Selling Stockholder</b>	<b>Number of Offered Securities</b>	<b>Effective Purchase Price per Offered Security</b>	<b>Potential Profit per Offered Security<sup>(1)</sup></b>	<b>Potential Aggregate Gross Profit<sup>(1)</sup></b>	<b>Lock-Up Restrictions</b>
Certain Legacy Spectral stockholders	8,623,081	\$ 10.00	\$ (7.46)	\$ (64,328,184)	<sup>(2)</sup>
Founder Shares	880,000	\$ 0.004	\$ 2.536	\$ 2,231,680	<sup>(2)</sup>
BTIG, LLC	166,667	\$ 7.50	\$ (4.96)	\$ (826,668)	<sup>(3)</sup>
Cantor Fitzgerald, L.P.	400,000	\$ 7.50	\$ (4.96)	\$ (1,984,000)	<sup>(3)</sup>

- (1) Notwithstanding any restrictions on the transferability of the shares of our Common Stock, the potential profit per security offered and potential aggregate gross profit are calculated assuming that all such shares of Common Stock were sold at a price of \$2.54 per share, which was the closing price of our Common Stock on October 24, 2023. The trading price of our Common Stock may be different at the time a selling stockholder decides to sell its securities.
- (2) The Sponsor, certain former stockholders of Legacy Spectral, and the Director Holders (as defined in the Registration Rights Agreement) are subject to certain lock-up restrictions contained in the Registration Rights Agreement. For more information on the lock-up restrictions, see “*Restrictions on Resale of Securities — Lock-up Provisions.*”
- (3) Certain investment banks provided services to the Company in connection with the Business Combination and their fees were satisfied through the issuance of shares of Common Stock and/or a combination of Common Stock and a cash payment, as applicable. The investment banks are not subject to any lock-up or other restrictions on transfer.

## 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 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 six months ended June 30, 2023 and the year ended December 31 2022, on a pro-forma and consolidated basis, we incurred net losses of \$8,893 million and \$8.130 million, respectively, and on a pro forma basis our consolidated cash balance at September 30, 2023 was expected to be \$7,855 million. We had an accumulated deficit of \$28.3 million as of June 30, 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.

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, as a U.S. public company, we will 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 fixed fees and costs payable by the Biomedical Advanced Research and Development Authority (“BARDA”), which is part of the U.S. Health and Human Services (“HHS”) Office of the Assistant Secretary for Preparedness and Response in the United States, 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 \$149.9 million, including an initial award of approximately \$55.0 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. The Company is also completing work on the Option 1B of its prior contract award relating to our Burn Training study, which was extended through December 31, 2023 upon which the Company will receive approximately \$2.0 million of additional funding. 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.

The DHA Department of Defense Small Business Technology Transfer (“STTR”) Phase II contract expires on October 31, 2023. We intend to seek to enter into an extension of the Phase II contract or a new Phase III contract to pursue commercial applications of the research or development completed in the current Phase II contract. Though

the Company has no reason to believe that it will not be offered a Phase III contract, and while DHA contracts have been renewed or extended historically, there is no guarantee that the contract will be extended after the base period 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, would 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.***

As of June 30, 2023, on a pro-forma consolidated basis, we had \$7.855 million in cash and cash equivalents, and an accumulated deficit of \$28.3 million. Based on our current operating plan, we believe that our cash and cash equivalents, together with the remaining funding available to us under the BARDA contract, will be sufficient to meet our capital requirements and fund our operations through at least the next 12 months from the release date of the consolidated financial statements included in this prospectus. 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. Moreover, we expect to incur additional expenses associated with operating as a U.S. public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. 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.

We have historically received 510(k) clearance from the FDA for previous generations of our DeepView technology and we believe that our BDD status, and clinical partners with regulatory experience who have been identified in Europe, will assist us in securing the required regulatory clearances, approvals, or De Novo classifications for our third generation DeepView System (“DeepView GEN 3 System”). However, there is no guarantee that our DeepView GEN 3 System or any future products will receive the requisite regulatory clearance, 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 technology, 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 regulatory clearances, approvals, or De Novo classifications for our DeepView GEN 3 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. 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 European Conformity (“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.”

Furthermore, regulatory clearance, 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, 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 substantially equivalent, in the case of a 510(k) clearance, safe or effective for their intended uses, in the case of a PMA, or 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 clearance, approval, 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 regulatory clearance, approval, 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 regulatory clearance, approval, 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 regulatory approval, clearance, 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 regulatory clearance or approval, 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 clears, approves, 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 GEN 3 System may require new clearances, approvals, De Novo classifications, certifications, or new or amended certifications, and may require us to cease marketing or to recall the modified device until clearances, approvals, De Novo classifications, or the relevant certifications are obtained.***

We have obtained 510(k) clearances for the previous versions of our DeepView System (DeepView GEN1 and GEN2), although we have not commercially marketed the devices. 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 clearance, approval, 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 clear, approve, grant 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 clearance, approval, 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.**

We have obtained 510(k) clearances for the previous versions of our DeepView System (DeepView Gen1 and GEN2), although we have not commercially marketed the devices. 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 clearance, approval, 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 regulatory clearance, approval, 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 of capital.

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

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

We currently outsource all of our manufacturing through an original equipment 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 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 regulatory approvals, 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 200 subjects (both adult and pediatric) 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 prediction. 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 June 30, 2023, we had 77 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.

The COVID-19 pandemic increased the risk of cybersecurity intrusions. Our reliance on internet technology and the number of our employees who worked remotely during the pandemic created additional opportunities for cybercriminals to exploit vulnerabilities. For example, there was an increase in phishing and spam emails as well as social engineering attempts from "hackers" hoping to use the COVID-19 pandemic to their advantage. Furthermore, 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 data 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 data 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.

We also expect that operating as a U.S. public company will 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, 2022, approximately 263 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 our 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 10 issued and allowed U.S. patents with five U.S. patent applications pending. We have 10 issued and allowed international patents with 29 foreign and international patent applications pending. We protect our DeepView System trademarks primarily in four classes: pre-recorded/downloadable software, surgical, medical apparatus, computer and scientific services and medical and healthcare services. As of March 31, 2023, we maintain a portfolio of 57 trademarks and seven 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 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 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.***

As a public company, the Company has and will continue to incur significant legal, accounting and other expenses that Legacy Spectral did not incur as a private company. 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 that Legacy Spectral did not previously incur. The Company's entire management team and many of its other employees will need to devote substantial time to compliance, and may not effectively or efficiently manage its transition into a public company.

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.

The Company expects the rules and regulations applicable to public companies to lead to significant legal and financial compliance costs and to make some activities more time-consuming and costly. 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.

***Anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of us more difficult.***

The Charter, the Bylaws and Delaware law contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by the Company’s board of directors. Among other things, the Charter and/or the Bylaws include the following provisions:

- limitations on convening special stockholder meetings, which could make it difficult for our stockholders to adopt desired governance changes;
- a prohibition on stockholder action by written consent, which means that our stockholders will only be able to take action at a meeting of stockholders and will not be able to take action by written consent for any matter;
- a forum selection clause, which means certain litigation against us can only be brought in the State of Delaware;
- the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without further action by our stockholders; and
- advance notice procedures, which apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents interested stockholders, such as certain stockholders holding more than 15% of our outstanding common stock, from engaging in certain business combinations unless (i) prior to the time such stockholder became an interested stockholder, the board of directors approved the transaction that resulted in such stockholder becoming an interested stockholder, or (ii) upon consummation of the transaction that resulted in such stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the common stock.

Any provision of the Charter, the Bylaws or Delaware law that has the effect of delaying, preventing or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

***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. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver, and for a period of time, customers of the bank did not have access to their funds and there was uncertainty as to when, if at all, customers would have access to funds in excess of the FDIC insured amounts. Although we did not maintain any funds at SVB, 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.

***Sales of a substantial number of our securities in the public market by the selling stockholders and/or by our existing stockholders could cause the price of our shares of Common Stock and Warrants to fall.***

Approximately 64.2% of our issued and outstanding Common Stock as of October 24, 2023 is being registered for resale pursuant to the registration statement of which this prospectus forms a part. The selling stockholders can sell, under this prospectus, (i) up to 10,069,748 shares of Common Stock, which consists of (a) up to 8,623,081 shares of Common Stock issued in connection with the Closing at an equity consideration value of \$10.00 per share, (b) up to 880,000 shares of Common Stock that were originally issued to the Initial Holders in the form of founder shares prior to the RCLF IPO at a price of approximately \$0.004 per share, and (c) up to 566,667 shares of Common Stock that were issued to certain service providers of the Company in connection with the Closing.

The sale of all or a portion of the securities being offered in this prospectus could result in a significant decline in the public trading price of our securities. Despite such a decline in the public trading price, some of the selling stockholders may still experience a positive rate of return on the securities they purchased due to the price at which such selling stockholder initially purchased the securities. See "*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.*" below.

Sales of a substantial number of our shares of Common Stock and/or Warrants in the public market by the selling stockholders 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 Warrants and could impair our ability to raise capital through the sale of additional equity securities.

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

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

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

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

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

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

***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.



***The Company is a holding company and our only significant asset is our ownership interest in our subsidiaries and such ownership may not be sufficient to pay dividends or make distributions or loans to enable us to pay any dividends on the Common Stock or satisfy our other financial obligations, including taxes.***

The Company is a holding company with no material assets other than its ownership of our subsidiaries. As a result, the Company has no independent means of generating revenue or cash flow. The Company's ability to pay taxes and pay dividends will depend on the financial results and cash flows of our subsidiaries and the distributions we receive from our subsidiaries. Deterioration in the financial condition, earnings or cash flow of our subsidiaries for any reason could limit or impair our subsidiaries' ability to pay such distributions. Additionally, to the extent that the Company needs funds and our subsidiaries are restricted from making such distributions under applicable law or regulation or under the terms of any financing arrangements, or our subsidiaries are otherwise unable to provide such funds, it could materially adversely affect the Company's liquidity and financial condition.

Dividends on the Common Stock, if any, will be paid at the discretion of the Board, which will consider, among other things, the Company's business, operating results, financial condition, current and expected cash needs, plans for expansion and any legal or contractual limitations on its ability to pay such dividends. Financing arrangements may include restrictive covenants that restrict the Company's ability to pay dividends or make other distributions to its stockholders. In addition, the Company is generally prohibited under Delaware law from making a distribution to stockholders to the extent that, at the time of the distribution, after giving effect to the distribution, liabilities of the Company (with certain exceptions) exceed the fair value of its assets. If our subsidiaries do not have sufficient funds to make distributions, the Company's ability to declare and pay cash dividends may also be restricted or impaired.

***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 to be reserved for future issuance under the Equity Incentive Plan is expected to equal approximately 3,000,000 shares.

We expect to file one or more registration statements 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. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market. The initial registration statement on Form S-8 is expected to cover approximately 3,000,000 shares of our common stock.

***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.***

Certain stockholders in the Company, including certain of the selling stockholders, acquired, or may acquire, shares of our Common Stock or Warrants at prices below the current trading price of our Common Stock, and may experience a positive rate of return based on the current trading price.

This prospectus relates to the offer and resale from time to time by the selling stockholders of (i) up to 10,069,748 shares of Common Stock, constituting approximately 64.2% of our issued and outstanding Common Stock as of October 24, 2023, which consists of (a) up to 8,623,081 shares of Common Stock issued in connection with the Closing at an equity consideration value of \$10.00 per share, (b) up to 880,000 shares of Common Stock that were originally issued to the Initial Holders in the form of founder shares prior to the RCLF IPO at a price of approximately \$0.004 per share, and (c) up to 566,667 shares of Common Stock that were issued to certain service providers of the Company in connection with the Closing.

For example, based on the closing price of our Common Stock of \$2.54 on October 24, 2023, the Initial Holders may experience potential profit of up to \$2.536 per share of Common Stock, or \$2,231,680 in the aggregate, based on the Initial Holders' initial purchase price of shares of Common Stock in the form of founder shares prior to the RCLF IPO at a price of approximately \$0.004 per share. See the section entitled "*Information Related to the Offered Securities*" for additional information on the potential profits the other selling stockholders may experience.

Public stockholders may not be able to experience the same positive rates of return on securities they purchase due to the low price at which the Sponsor purchased shares of our Common Stock and Warrants.

***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 8,433,231 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, subject to adjustment as discussed below. Common Stock issued upon exercise of the Warrants are subject to the lock-up agreements described in the section title "*Other Agreements — Lockup Agreement.*" 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 Warrants may never be in the money, and they may expire worthless and the terms of the Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Warrants approve of such amendment.***

The warrants were issued in registered form under the Warrant Agreement. 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 the holders of at least a majority of the then outstanding Warrants to make any change that adversely affects the interests of the registered holders of Warrants. Accordingly, the Company may amend the terms of the warrants in a manner adverse to a holder if holders of at least a majority of the then outstanding warrants approve of such amendment. Although the Company's ability to amend the terms of the Warrants with the consent of at least a majority of the then outstanding Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Warrants, shorten the exercise period or decrease the number of shares of the Common Stock, as applicable, purchasable upon exercise of a Warrant.

***The Warrant Agreement contains an exclusive forum clause, which could limit a Warrant holder's ability to obtain a favorable judicial forum for disputes arising under the Warrant Agreement.***

The Warrant Agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us or the warrant agent arising out of or relating in any way to the Warrant Agreement, including under the Securities Act, 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 (ii) that we irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We will waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

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. Any person or entity purchasing or otherwise acquiring any interest in any of the Warrants shall be deemed to have notice of and to have consented to the forum provisions in the Warrant Agreement. If any action, the subject matter of which is within the scope of the forum provisions of the Warrant Agreement, is filed in a court other than a court of the State of New York or the United States District Court for the Southern District of New York (a “foreign action”) in the name of any holder of the Warrants, such holder shall be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (an “enforcement action”), and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder’s counsel in the foreign action as agent for such warrant holder.

This choice of forum provision may limit a Warrant holder’s ability to bring, and increase the cost of, a claim in a judicial forum that it finds favorable for disputes the Company, which may discourage such lawsuits. Alternatively, if a court were to find this provision of the Warrant Agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

***Your unexpired Warrants may be redeemed prior to their exercise at a time that is disadvantageous to you, thereby making your Warrants worthless.***

We have the ability to redeem the outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant if, among other things, the last reported sale price of shares of Common Stock for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which we send the notice of redemption to the Warrant holders (the “Reference Value”) equals or exceeds \$18.00 per share (as adjusted). If and when the Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. As a result, we may redeem the Warrants as set forth above even if the holders are otherwise unable to exercise the Warrants. Redemption of the outstanding Warrants as described above could force you to: (1) exercise your Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so; (2) sell your Warrants at the then-current market price when you might otherwise wish to hold your Warrants; or (3) accept the nominal redemption price which, at the time the outstanding Warrants are called for redemption, we expect would be substantially less than the market value of your Warrants.

In addition, we have the ability to redeem the outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.10 per Warrant if, among other things, the Reference Value equals or exceeds \$10.00 per share (as adjusted). In such a case, the holders will be able to exercise their Warrants prior to redemption for a number of shares of Common Stock determined based on the redemption date and the fair market value of our Common Stock. Any such redemption may have similar consequences to a cash redemption described above. In addition, such redemption may occur at a time when the Warrants are “out-of-the-money,” in which case you would lose any potential embedded value from a subsequent increase in the value of the Common Stock had your Warrants remained outstanding. The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the warrants, including because the number of shares of Common Stock received is capped at 0.361 shares of Common Stock per Warrant (subject to adjustment) irrespective of the remaining life of the Warrants.

## **USE OF PROCEEDS**

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

The Company will receive up to an aggregate of approximately \$96.9 million from the exercise of the Warrants, assuming the exercise in full of all of the Warrants for cash. The Company expects to use any such net proceeds from the exercise of the Warrants for general corporate and working capital purposes. The Company will have broad discretion over the use of proceeds from the exercise of the Warrants. There is no assurance that the holders of the Warrants will elect to exercise any or all of such warrants or options, as applicable, for cash.

The exercise price of our Warrants is \$11.50 per share of Common Stock. We believe the likelihood that the holders will exercise their Warrants, as applicable, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock. If the trading price of our Common Stock is less than the exercise price thereof, we believe the holders are unlikely to exercise their Warrants. Conversely, the holders are more likely to exercise their Warrants, as applicable, the higher the price of our Common Stock is above the exercise price thereof. The closing price of our Common Stock on Nasdaq on October 24, 2023 was below the applicable exercise price of our Warrants. The Warrants are exercisable on a cashless basis under certain circumstances specified in the Warrant Agreement, respectively. To the extent that any Warrants are exercised on a cashless basis, the aggregate amount of cash we would receive from such exercises will decrease.

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 the selling stockholders under this prospectus.

## 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 October 24, 2023, there were 72 holders of record of our Common Stock and one holder 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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the sections titled "Unaudited pro forma condensed combined financial information" and our audited annual consolidated financial statements as of and for the years ended December 31, 2022 and 2021, and unaudited interim consolidated financial statements as of June 30, 2023, and for the three months ended June 30, 2023 and 2022, together with the respective related notes, in each case, included elsewhere in this prospectus. 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" included elsewhere in this prospectus. Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future. Unless otherwise indicated or the context otherwise requires, references in this section to "we," "our," "us," "the Company" or other similar terms refer to the business and operations of Spectral MD Holdings, Ltd. and its subsidiaries prior to the Business Combination ("Legacy Spectral") and Spectral AI, Inc. following the consummation of the Business Combination ("Spectral"). References to "RCLF" refer to Rosecliff Acquisition Corp I prior to the consummation of the Business Combination.*

### Overview

We are an AI company focused on predictive medical diagnostics. We operate in one segment. We are devoting substantially all of our efforts towards research and development of our DeepView System, an internally developed MSI device which has designated FDA BDD status. 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. In 2022 and 2023, we expanded our focus to include the diabetic foot ulcer ("DFU") indication.

In the case of DFUs, a non-healing assessment would provide the physician with the appropriate justifications to use an advanced wound care therapy on "Day One", in seconds, 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 of 50% to 75%, respectively, at best, according to industry literature.<sup>1</sup> 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, reporting at 70-80% accuracy, and non-burn specialist physicians, reporting at 50-60% accuracy.<sup>2</sup> 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 identify the burn assessment accuracy in both surgery and non-surgical treatment.

- 1 Henk Hoeksema, Karlien Van de Sijpe, Thiery Tondou, 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>.

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, including from agencies such as 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 NSF, NIH and the DHA. Since 2013, we have received approximately \$280.0 million in funding from government contracts, primarily from BARDA, which accounts for \$172.9 million. This has allowed us to develop our technology and further our clinical trials. We are currently in our third contract with BARDA, referred to as BARDA Burn III, which was signed in September, 2023 and is due to be completed in July 2030. Under this contract, we expect to further the DeepView System design, develop the AI algorithm, and take the necessary steps to obtain FDA approval for our DeepView GEN 3 System. However, approval from the FDA or other regulatory agencies, foreign or domestic, cannot be guaranteed and may take longer than planned. On September 27, 2023, the Company executed a new contract with BARDA, providing the Company with additional funding of up to \$149.9 million, including an initial award of approximately \$55.0 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. The Company is also completing work on the Option 1B of its prior contract award relating to our Burn Training study, which was extended through December 31, 2023 upon which the Company will receive approximately \$2.0 million of additional funding. This grant funding is non-dilutive to our shareholders, and we believe it validates the important nature of its mission and technology.

In April 2023, we received a \$4.0 million grant award from the Medical Technology Enterprise Consortium (“MTEC”), which, building on prior awards from DHA, is to be used to support military battlefield burn evaluation via a handheld DeepView. The MTEC Agreement extends the DHA Phase II 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 is scheduled to extend through at least July 2023 and is focused on the planning, design and testing of the handheld device for its intended applications. Phase 1 has a funding budget of \$1,170,000. Once Phase 1 is completed, Phase 2 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.

Our DeepView System recently 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).

We anticipate that the DeepView System will have two revenue streams, a SaMD (software as a medical device), and an imaging device component. The SaMD model applies a SaaS 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 April 11, 2023, we entered into the Business Combination Agreement with Rosecliff Acquisition Corp I (“RCLF”), Ghost Merger Sub I Inc. (“Merger Sub I”) and Ghost Merger Sub II LLC (“Merger Sub II”), which was consummated on September 11, 2023 (the “Closing”). Pursuant to the Business Combination Agreement, on the Closing, in sequential order: (a) Ghost Merger Sub I merged with and into Spectral, with Spectral continuing as the surviving company and a wholly owned subsidiary of Spectral (the “Spectral Merger”) and then, (b) Spectral merged with and into Ghost Merger Sub II (the “SPAC Merger”, together with the Spectral Merger (the “Mergers”)), with Ghost Merger Sub II surviving the SPAC Merger as a direct wholly-owned subsidiary of Rosecliff. Rosecliff was renamed

Spectral AI, Inc. (“Spectral AI” or the “Combined Company”), (the “Business Combination”). On September 12, 2023, Spectral AI began trading its shares on the NASDAQ stock exchange under the ticker symbol “MDAI” after delisting its shares from the AIM market of the London Stock Exchange on September 7, 2023.

In September 2023, prior to the closing of the Business Combination, the Company issued 7,679,198 shares of common stock for \$3.4 million (the “Equity Issuance”).

The Business Combination is expected to be accounted for as a reverse recapitalization in accordance with GAAP. Under the guidance in Accounting Standards Codification (“ASC”) 805, Business Combinations, RCLF, which is the legal acquirer, will be treated as the “acquired” company for financial reporting purposes and Spectral will be treated as the accounting acquirer. This determination was primarily based on the following:

- (i) Spectral expecting to have a majority of the voting power of the Combined Company;
- (ii) Spectral’s senior management comprising all of the senior management of the Combined Company;
- (iii) Spectral is expected to select six of the seven of the directors for the Board of Directors of the Combined Company;
- (iv) Spectral’s relative size of assets and operations compared to RCLF; and
- (v) Spectral’s operations comprising the ongoing operations of the post-combination company.

Accordingly, for accounting purposes, the Business Combination will be treated as the equivalent of a capital transaction in which we are issuing stock for the net assets of RCLF. The net assets of RCLF will be stated at historical cost, with no goodwill or other intangible assets recorded. Historical operations presented in future financial statements, prior to the Business Combination will be ours.

The most significant changes in our future reported financial position and results are expected to be a net decrease in cash (as compared to our consolidated balance sheet as of June 30, 2023) of approximately \$0.3 million.

#### **Public Company Costs**

Upon consummation of the Business Combination, the Combined Company has continued as an SEC-registered and Nasdaq-listed company. We expect to hire additional staff and implement new processes and procedures to address public company requirements in anticipation of and following the completion of the Business Combination. We also expect to incur substantial additional expenses for, among other things, directors’ and officers’ liability insurance, director fees, internal control compliance, and additional costs for investor relations, accounting, audit, legal and other functions.

#### **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.



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The following table sets forth these metrics for the three and six months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(In thousands)			
Research and development revenue	\$ 4,251	\$ 6,390	\$ 9,329	\$ 12,234
Gross Profit	1,791	2,712	3,972	5,102
Gross margin	42.1%	42.4%	42.6%	41.7%
Operating loss	(2,990)	(6)	(5,889)	(627)
Net loss	(3,070)	(265)	(6,679)	(793)
Adjusted EBITDA	(2,591)	290	(5,188)	6

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 the 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 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 margin can be used to understand our financial performance and efficiency and allows 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, plant and equipment (including any related impairment charges), amortization of intangible assets (including any related impairment charges), interest expense, stock compensation, any non-operating financial income and expense. 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. In addition, it is possible that, depending on the outcome of our SSN application to BARDA, we may receive additional and potentially significant U.S. government awards. Our revenues may continue to be almost exclusively dependent upon the terms of those awards.

*Gross Margin.* As we begin commercial sales of the DeepView System, we may need to adjust our 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 production, there remain global supply chain challenges and logistics constraints, including 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.

## **Components of Consolidated Statements of Operations**

### ***Research and Development Revenue***

Our primary source of revenue is research and development revenue. Currently, we are highly dependent upon the reimbursement from BARDA for the burn diagnostic testing of our DeepView System. 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. Our revenue growth is dependent on a number of factors including expanding the research and development expense 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.

### ***Cost of Revenue***

Our cost of revenues consists primarily of direct and indirect costs associated with the research and development expenses relating to the BARDA contract. Our revenue costs are affected by the extent of research and development expenses 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 each contract award. Our gross profit represents this reimbursement rate plus a variable component relating to non-reimbursed expenses incurred in connection with the work completed on these contracts.

### ***Operating Costs and Expenses***

Operating costs and expenses consist of general and administrative expenses. These expenses relate to our operating expenses that are not reimbursed as part of the research and development revenue and reflect our organization's support and operations staff. General and administrative expense consist primarily of salaries and benefits for this group of our employees and has increased from prior three months based on the increase in our personnel in these functions.

### ***Other income (expense)***

Other income (expense) primarily consists of interest expense, change in fair value of warrant liabilities and foreign exchange transaction gains/losses. Historic foreign exchange transaction loss primarily relates to the reduced exchange rate between the U.S. dollar 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.

## Results of Operations

The following table sets forth a summary of our consolidated statements of operations for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(In thousands)			
<b>Research and development revenue</b>	4,251	6,390	9,329	12,234
<b>Cost of revenue</b>	(2,460)	(3,678)	(5,357)	(7,132)
<b>Gross profit</b>	1,791	2,712	3,972	5,102
<b>Operating costs and expenses:</b>				
General and administrative	4,781	2,718	9,861	5,729
<b>Total operating costs and expenses</b>	4,781	2,718	9,861	5,729
<b>Operating loss</b>	(2,990)	(6)	(5,889)	(627)
<b>Other income (expense):</b>				
Net interest income (expenses)	41	3	86	(1)
Change in fair value of warrant liability	(81)	(38)	(65)	28
Foreign exchange transaction gain (loss)	—	(232)	13	(204)
Transaction costs	—	—	(738)	—
Other income	—	19	—	17
<b>Total other expense</b>	(40)	(248)	(704)	(160)
<b>Loss before income taxes</b>	(3,030)	(254)	(6,593)	(787)
Provision for income taxes	(40)	(11)	(86)	(6)
<b>Net loss</b>	(3,070)	(265)	(6,679)	(793)

### Research and development revenue

	Three Months Ended June 30,		Change in		Six Months Ended June 30,		Change in	
	2023	2022	\$	%	2023	2022	\$	%
	(In thousands, except percentages)							
Research and development revenue	\$ 4,251	\$ 6,390	\$ (2,139)	(33.5)%	\$ 9,329	\$ 12,234	\$ (2,905)	(23.7)%

Research and development revenue decreased by 33.5% and 23.7%, respectively, or approximately \$2.1 million and \$2.9 million, respectively, for the three and six months ended June 30, 2023, as compared to the comparable periods in 2022, primarily due to decreased research and development work performed pursuant to the BARDA Burn II contract. New patient enrollments in our BARDA clinical study decreased in the three months ended June 30, 2023 compared to the three months ended June 30, 2022 as the Company is completing enrollment and transitioning to the closeout phase of the study.

For the three and six months ended June 30, 2023 and 2022, the Company's revenues disaggregated by the major sources was as follows:

	Three Months Ended June 30,		Change in		Six Months Ended June 30,		Change in	
	2023	2022	\$	%	2023	2022	\$	%
	(In thousands, except percentages)							
BARDA	\$ 4,020	\$ 6,255	\$ (2,235)	(35.7)%	\$ 8,963	\$ 11,963	\$ (3,000)	(25.1)%
Other U.S. governmental authorities	231	135	96	71.1%	366	271	95	35.1%
<b>Total research and development revenue</b>	<b>\$ 4,251</b>	<b>\$ 6,390</b>	<b>\$ (2,139)</b>	<b>(33.5)%</b>	<b>\$ 9,329</b>	<b>\$ 12,234</b>	<b>\$ (2,905)</b>	<b>(23.7)%</b>

**Cost of Revenues and Gross Profit**

	Three Months Ended June 30,		Change in		Six Months Ended June 30,		Change in	
	2023	2022	\$	%	2023	2022	\$	%
	(In thousands, except percentages)							
Cost of revenue	\$ 2,460	\$ 3,678	\$ (1,218)	(33.1)%	\$ 5,357	\$ 7,132	\$ (1,775)	(24.9)%
Gross profit	1,791	2,712	(921)	(34.0)%	3,972	5,102	(1,130)	(22.1)%
Gross margin	42.1%	42.4%			42.6%	41.7%		

Cost of revenue for the three and six months ended June 30, 2023 compared to the comparable periods in 2022 decreased by 33.1% and 24.9% respectively, or approximately \$1.2 million and \$1.8 million, respectively, primarily due to decreased activity to fulfill our U.S. governmental contracts, which is consistent with decreased research and development revenue.

Gross margin was relatively consistent for the three and six months ended June 30, 2023, as compared to the comparable periods in 2022.

**General and Administrative**

	Three Months Ended June 30,		Change in		Six Months Ended June 30,		Change in	
	2023	2022	\$	%	2023	2022	\$	%
	(In thousands, except percentages)							
General and administrative	\$ 4,781	\$ 2,718	\$ 2,063	75.9%	\$ 9,861	\$ 5,729	\$ 4,132	72.1%
Percentage of revenue, net	112.5%	42.5%			105.7%	46.8%		

General and administrative expense increased by 75.9% and 72.1%, respectively, or approximately \$2.1 million and \$4.1 million, respectively, for the three and six months ended June 30, 2023, as compared to the comparable periods in 2022. The increase was primarily due to an increase in our administrative staffing since 2022. Our headcount grew from 63 employees as of June 30, 2022 to 80 full-time employees as of June 30, 2023 resulting in an increase in general and administrative expense of approximately \$0.7 million and \$1.4 million, respectively, for the three and six months ended June 30, 2023. Additionally, R&D activities outside of BARDA have increased by approximately \$0.9 million and \$1.6 million, respectively, in the three and six months ended June 30, 2023 compared to the comparable periods in 2022.

**Other income (expense)**

	Three Months Ended June 30,		Change in		Six Months Ended June 30,		Change in	
	2023	2022	\$		2023	2022	\$	
	(In thousands, except percentages)							
Net interest income (expense)	\$ 41	\$ 3	\$ 38		\$ 86	\$ (1)	\$ 87	
Change in fair value of warrant liability	(81)	(38)	(43)		(65)	28	(93)	
Foreign exchange transaction (loss) gain	—	(232)	232		13	(204)	217	
Transaction costs	—	—	—		(738)	—	(738)	
Other income	—	19	(19)		—	17	(17)	
Total other expense	\$ (40)	\$ (248)	\$ 208		\$ (704)	\$ (160)	\$ (544)	

Net interest income for the three and six months ended June 30, 2023 primarily relates to cash interest received by us from our deposit accounts.

Change in the fair value of warrant liability decreased by approximately \$43,000 and \$93,000, respectively, for the three and six months ended June 30, 2023, as compared to the comparable period in 2022. The loss during the three and six months ended June 30, 2023, was primarily due to the increased present value calculation of the warrants issued to SP Angel Corporate Finance LLP (“SP Angel”) as part of the Offering (defined below) in 2021. In conjunction with the closing of the Offering, we issued 762,712 warrants, with a strike price of \$0.89 per share and a five-year life, to SP Angel, who acts as our nominated advisor (“NOMAD”) and joint broker. As of June 30, 2023, the strike price of the warrants was \$0.75 per share as compared to \$0.72 as of June 30, 2022. The change in the strike price is due to the change in exchange rates, as the warrants will settle in shares denominated in British pound sterling. As our stock price had a greater increase for the three months ended June 30, 2023 as compared to the three months ended June 30, 2022, the fair value of the warrants correspondingly had a greater increase in the three months ended June 30, 2023. As our stock price had an increase for the six months ended June 30, 2023 as compared to a decrease for the six months ended June 30, 2022, the fair value of the warrants correspondingly had an increase for the six months ended June 30, 2023 as compared to a decrease for the six months ended June 30, 2022.

Foreign exchange transaction loss for the three and six months ended June 30, 2022 relates to the decreased exchange rate between the U.S. dollar and the British pound sterling during the second quarter of 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. Foreign exchange transaction loss for the three and six months ended June 30, 2023 is immaterial due to much 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.

Transaction costs for the six months ended June 30, 2023 relate to non-recurring legal, accounting and consulting costs expended for potential business combinations that did not occur.

### **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 management assesses underlying performance.

### ***Adjusted EBITDA***

We define Adjusted EBITDA as net income/(loss) excluding income taxes, depreciation of property, plant and equipment (including any related impairment charges), amortization of intangible assets (including any related impairment charges), interest expense, stock compensation, any non-operating financial income and expense.

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The following table presents our Adjusted EBITDA for the three and six months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(In thousands)			
Net loss	\$ (3,070)	\$ (265)	\$ (6,679)	\$ (793)
Adjust:				
Depreciation expense	3	2	5	6
Provision for income taxes	40	11	86	6
Net interest (income) expense	(41)	(3)	(86)	1
<b>EBITDA</b>	<b>(3,068)</b>	<b>(255)</b>	<b>(6,674)</b>	<b>(780)</b>
Additional adjustments:				
Stock-based compensation	396	294	696	627
Change in fair value of warrant liability	81	38	65	(28)
Foreign exchange transaction loss (gain)	—	232	(13)	204
Transaction costs	—	—	738	—
Other income	—	(19)	—	(17)
<b>Adjusted EBITDA</b>	<b>(2,591)</b>	<b>290</b>	<b>(5,188)</b>	<b>6</b>

### Liquidity and Capital Resources

#### Sources of Liquidity

As of June 30, 2023 we had approximately \$8.2 million in cash, and an accumulated deficit of approximately \$18.6 million.

Prior to our initial public offering (the “Offering”) on the AIM Market of the London Stock Exchange in June, 2021, we historically funded our operations through the issuance of notes and the sale of preferred stock and common stock. We raised approximately \$17.0 million from the oversubscribed Offering on the AIM market to fund the development of the DFU indication for our Deepview System. In September 2023, we were awarded additional funding of \$149.9 million associated with a new contract award with BARDA. The purpose of the BARDA contract funding is to execute the clinical training study of our DeepView System for burn wound healing assessment. See “*Research and Development Revenue*” above. With the proceeds from closing of our Offering during 2021 and the remaining funding under the BARDA contract, we believe that with the remaining proceeds from the Offering and the remaining funding under the BARDA contract we have sufficient working capital to fund operations for at least 12 months beyond the release date of the consolidated financial statements. Additionally, our contract with BARDA has a potential funding of up to \$149.9 million, in the aggregate, if all future options are executed.

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 six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,	
	2023	2022
	(In thousands)	
Net cash (used in) provided by operating activities	\$ (5,527)	\$ 38
Net cash used in financing activities	(481)	(583)

*Cash Flows (Used in) Provided by Operating Activities*

Net cash used in operating activities increased by approximately \$5.6 million for the six months ended June 30, 2023, as compared to the six months ended June 30, 2022 resulting primarily from a decrease in net income, adjusted for non-cash items, of approximately \$5.6 million. This decrease is primarily driven by decreased research and development activity for the BARDA contract. The decrease is partially offset by a net increase of \$0.1 million cash flows from changes in operating assets and liabilities primarily driven by accounts receivable collections in excess of payments of accounts payable.

*Cash Flows Used in Financing Activities*

Net cash used in financing activities decreased approximately \$0.1 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. This was primarily attributable to repayment of \$0.4 million for the Company's Paycheck Protection Program Loan during the six months ended June 30, 2022, partially offset by payments of \$0.3 million of offering costs related to the Business Combination that have been deferred until the closing of the Business Combination.

**Current Indebtedness**

As of June 30, 2023, we do not have any debt. In June 2022, we entered into a financing arrangement for a portion of our insurance premium for approximately \$0.4 million (the "Note"). The Note bears interest at 6.7% per annum and is payable in equal monthly payments of principal and interest, maturing in May 2023. By June 30, 2023 the balance of this note has been fully paid.

**Related Party Transactions**

For the six months ended June 30, 2023 and 2022 and the years ended December 31, 2022 and 2021, 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 our Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies for the years ended December 31, 2022 and 2021 included in the Prospectus.

**Recent Accounting Pronouncements**

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

**Emerging Growth Company**

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 with new or revised accounting pronouncements as of public company effective dates.

## **Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate, foreign exchange, credit and inflation risks.

### ***Interest Rate Sensitivity***

We maintain a large amount of our assets in cash and cash equivalents. Our cash and cash equivalents are held primarily in cash deposits. The fair value of our cash and cash equivalents would not be significantly affected by either an increase or decrease in interest rates due mainly to the short-term nature of these instruments. Additionally, changes to interest rates will impact on the cost of our future borrowings. With respect to our current “borrowings”, the interest rate on the Note for insurance premiums is fixed. Changes in prevailing interest rates could have a material impact on our results of operations.

### ***Foreign Currency Risk***

Our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States and UK, with an insignificant portion of expenses incurred in our wholly owned subsidiaries in the UK and denominated in British pound sterling.

### ***Credit Risk***

Financial instruments that subject us to concentrations of credit risk consist primarily of cash, cash equivalents and accounts receivable. The vast majority of our cash and cash equivalents are held in U.S. financial institutions which, at times, exceed federally insured limits. We have not recognized any losses from credit risks on such accounts. We believe we are not exposed to significant credit risk on cash and cash equivalents.

Additional credit risk is related to our concentration of receivables and revenues. One customer (which is a U.S. government agency) represents the majority of our research and development revenue and accounts receivable.

### ***Inflation Risk***

The recent increase in inflation partially contributed to the increase in the cost of our research and development as well as operating costs. If the cost of our products, employee costs, or other costs continue to be subject to significant inflationary pressures, such inflationary pressure may have an adverse effect on our ability to maintain current levels of gross margin and selling, general and administrative expenses. Further, we may not be able to offset these increased costs through price increases. As a result, our inability to quickly respond to inflation could harm its cash flows and results of operations in the future.



## BUSINESS

### Company Overview

We are an AI company focused on predictive medical diagnostics. We are devoting substantially all of our efforts towards research and development of our DeepView System, an internally developed AI driven MSI device which has FDA BDD status since 2018. Our DeepView System uses proprietary AI algorithms to distinguish between fully damaged, partially damaged and healthy human tissue characters invisible to the naked eye, providing a “Day One” healing potential assessments in seconds. 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 wounds. Our focus from 2013 through 2021 was on the burn indication. In 2022, we expanded our focus to include the DFU indication.

In the case of DFUs, a non-healing assessment would provide the physician with the appropriate justifications to use an advanced wound care therapy on “Day One” in seconds, 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 of 50% to 75%, respectively, at best, according to industry literature. 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, reporting at 70-80% accuracy, and non-burn specialist physicians, reporting at 50-60% accuracy.<sup>2</sup> 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 identify the burn assessment accuracy in both surgery and non-surgical treatment.

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). Subject to our receipt of additional necessary regulatory clearances, approvals, De Novo classifications or certifications, our business will 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 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 DeepView System technology 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. DeepView’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 263 billion pixels of DFU and burn data as of December 31, 2022.

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- 1 Henk Hoeksema, Karlien Van de Sijpe, Thiery Tondou, 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>.

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

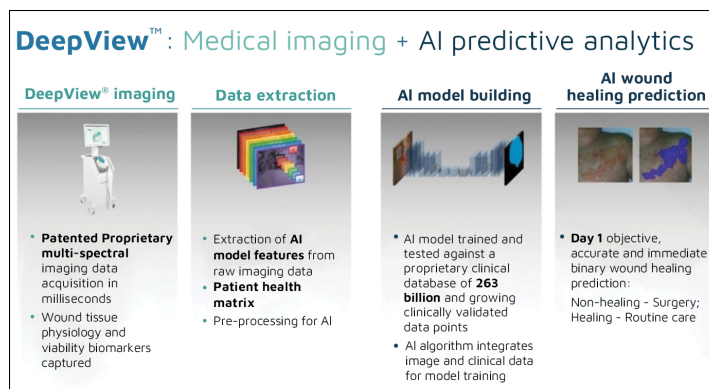


Figure 1 — DeepView Imaging technology

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 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 or are in need of advanced wound care products and procedures including surgical interventions.

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 received approximately \$280.0 million in funding 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. On September 27, 2023, the Company executed a new contract with BARDA, providing the Company with additional funding of up to \$149.9 million, including an initial award of approximately \$55.0 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. The Company is also completing work on the Option 1B of its prior contract award relating to our Burn Training study, which was extended through December 31, 2023 upon which the Company will receive approximately \$2.0 million of additional funding. This grant funding is non-dilutive to our stockholders, and we believe it validates the important nature of its mission and technology.

Subject to our receipt of the necessary regulatory clearances, approvals, De Novo classifications, or certifications, we intend to initially sell the DeepView technology throughout the United States for its burn indication and in the UK for its DFU indication. 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 triage 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 cares, for quick and accurate surgical planning. Therefore, we plan to target our sales efforts to these facilities through our highly-trained technical sales support staff given the nature of DeepView as a truly disruptive AI driven diagnostic 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 States' 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 regulatory clearances, approvals, De Novo classifications, or certifications, 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 France, Germany, Italy and Spain ("EU4"). Preliminary discussions with distributors are expected to occur 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 early 2024, with the EU4 to follow in 2024, 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 a market access consulting firm 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 clearances, approvals, De Novo classifications, or certifications, we anticipate including the DFU diagnosis indication in the DeepView Systems that are distributed through the burn indication sales efforts in hospitals' emergency rooms and trauma centers, given that we can run multiple indications on the same imaging devices. In addition, podiatry practices are typically the first line of specialty care for DFUs in the United States. Vascular and cardiology companies and outpatient wound centers 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 clearances, approvals, De Novo classifications, or certifications, 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.

We have obtained 510(k) clearance for the first two generations of our DeepView System. DeepView GEN 1, which employed photoplethysmography ("PPG"), an optical technique used to detect volumetric changes in blood in peripheral circulation, and received 510(k) FDA clearance in 2013, and DeepView GEN 2, which employed PPG and MSI, a technique which captures image data within specific wavelength ranges across the electromagnetic spectrum, and received 510(k) FDA clearance in 2017.

The DeepView GEN 1 device used PPG for analysis of blood flow in the microcirculation of a patient's skin. The output from this device to the clinician was an image representing the strength of pulsatile blood flow within the skin computed using the PPG waveform by measuring the interaction of near-IR light with dynamic changes in vascularized tissues. These outputs were then used to evaluate tissue perfusion in wounds and their surrounding skin.

The DeepView GEN2 device, which received FDA clearance in 2017, was also indicated for analysis of blood flow in the microcirculation using PPG waveforms and incorporated a MSI sensor for later deployment of software to expand indications into AI assessments.

Despite receiving the necessary clearances, we decided not to fully commercialize these two previous iterations. Instead, we have been focusing on utilizing the BARDA contracts and DHA contracts to further integrate MSI light spectral analysis with our AI algorithms and improved optics throughout 2022 in order to further enhance the utility of our DeepView GEN 3 System.

Our DeepView GEN 3 System is being studied for its ability to accurately and rapidly assess, by quantitative prediction, the potential for burn injuries and DFU wounds to heal by delineating the viable to non-viable tissue. It has generated a 92% and 86% accuracy rating, respectively, in our clinical studies. The DeepView GEN 3 System collects the

tissue reflectance spectrum of wavelengths of near UV to visible to near infrared (400 nm–1100 nm) wavelengths. We combine this injured tissue spectral signature with in-house developed AI upon a proprietary clinical database, to create optical imaging technology is aimed at improving wound assessment as an aid to therapeutic management of wound cares.

In 2018, the FDA designated our DeepView System with BDD status for its burn indication. The FDA's designation as a Breakthrough Device 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 the EU. In 2022, we completed our first validation 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% (from the previous 81% and 83% respectively). In April 2023, we commenced our validation study with an additional 100 adult subjects at 10 well-known medical facilities. This study is expected to be completed in the third quarter of 2023. We have also signed with international partners such as the Royal College of Surgeons in Ireland, a well-respected institution 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 application in the United States in 2023, while targeting for the FDA's grant of our de novo request in 2024.

As discussed above, a fundamental difference between the 510(k) clearance and de novo classification pathways is that the 510(k) clearance pathway is available to devices that are substantially equivalent to predicate devices, 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. On the other hand, the de novo classification pathway 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.

Generally speaking, the types of support that are required for both pathways are similar in that the pathways are both intended for devices of low to moderate risks. For example, both require a description of the device that is the subject of the application, and a statement of the proposed intended use, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, and a description, where appropriate, of the patient population for which the device is intended. Depending on the exact device, the pathways may require submission of conclusions that are drawn from non-clinical and clinical tests to demonstrate that the device is safe and effective although generally speaking, it is more likely that a de novo classification request will need to be supported by data from a clinical trial than a 510(k) clearance application. At other times, references to certain industry or technological standards or testing, or voluntary consensus standards may be included within the applications. With regard to the timing of the review, the FDCA provides 90 days for FDA to review a 510(k) clearance application substantively, although as a practical matter, the agency's review may take significantly longer if FDA needs additional information or has questions about the submitted information. Similarly, the law provides 120 days for FDA's review of a de novo classification request but the review may take significantly longer if the agency has questions or needs additional information.

There are also certain differences between the information that needs to be submitted for each regulatory pathway. For example, the application for the 510(k) clearance must include identification of the predicate device and a comparison of the subject device to the predicate device. If the subject device has different technological characteristics from the predicate device, an explanation should be included regarding their impact on safety and effectiveness. These discussions are not included in a de novo classification request, considering that a device that is subject to the de novo classification pathway does not have a predicate to which the applicant compares it. On the other hand, a de novo classification request must include information such as (a) discussion of practices and procedures that may be an alternative to the subject device, where a description of existing alternative practices or procedures is provided, (b) if not subject to a previous 510(k) submission, information showing the searches used to establish that no

predicate exists; and a list of classification regulations, 510(k) clearances, premarket approvals, and other information regarding devices that are potentially similar to the subject device, and (c) a summary of risks and mitigations for the subject device, among others.

Subject to our receipt of the necessary regulatory clearance or approval, 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”). Subject to our receipt of regulatory authorization to affix the CE Mark, we would expect to commence post-market studies in the UK and Germany. Subject to our receipt of the necessary regulatory clearance, approval or De Novo classification, we would expect to initiate commercialization in the United States during 2024. We are targeting initial sales in Europe in early 2024, subject to our receipt of the necessary regulatory approvals or authorizations. We intend to submit for FDA review of the burn application in 2025 in accordance with the projected timeline for our BARDA contract.

### **Burn Indication**

Following the successful completion of our expanded proof of concept (“ePOC”) multi-center clinical study in the first quarter of 2021, we received two additional grants from BARDA, \$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 our 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 the BARDA contract was granted six months ahead of schedule, which enables us to accelerate the initiation of the second stage of our clinical training study with confidence. In August 2022, we received additional contract option funding of \$8.2 million under a modification of Option 1B of the BARDA contract to set a qualified production line and enable the IT integration of DeepView into hospital infrastructure. In 2023, provided we reach certain milestones and decision gates as noted above, we expect to receive an additional \$21.9 million pursuant to BARDA’s execution of Option 2 of the existing contract to further our clinical studies for validation and FDA submission needs. These awards expand the current clinical training study for burn wounds by adding clinical sites, further increase DeepView’s interoperability with health systems’ electronic health records (“EHRs”) and boosts the Company’s manufacturing capacity readiness. See “Information about Spectral — The BARDA Contract” for further details.

The Option 1B funding has expanded our clinical trial studies through 12 sites and up to 250 clinical subjects, including 190 adult and 60 pediatric burn subjects, resulting in one of the largest prospective multi-center burn studies ever conducted. The upcoming Option 2 funding is earmarked for our validation study prior to submission to the FDA for clearance of our DeepView GEN 3 System. We are focused on advancing our validation study in the third quarter of 2023 with 150 adult and pediatric subjects at up to 15 clinical sites.

The unpredictability of severe burn injuries is a complex critical care problem. As training in burn injuries is no longer required during medical training residency, the correct determination of burn depths is extremely low. In published literature, non-burn care providers are accurate 50% of the time, as compared to burn care physicians’ diagnostic accuracy of between 50%-75% of the time, in predicting early healing potential in burn injuries using visual clinical judgment. Due to the lack of lab tests and diagnostic tools, some Emergency Department (“ED”) physicians often adopt the “wait and see” approach for wound progression for 3-7 days, thereby occupying valuable bed space, additional costs, longer hospital stays and over-excision of viable skin. Some physicians prefer to directly transfer the patient to a specialty burn center. This practice is confirmed by the published Journal of Burn Care Research, which found that 41% of patients with Total Body Surface Area less than 10% were unnecessarily transferred to burn centers for specialized treatment and discharged within 24 hours.

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 to “ground truth” 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 surgery and non-surgical treatment.

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, 2022, our proprietary and clinically validated database for burns is comprised of approximately 263 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.

In alignment with BARDA's emergency preparedness mission, the \$8.2 million contract expansion awarded in August 2022 provides funding to expand the current Burn AI dataset to include ED patient enrollment. The addition of EDs will facilitate our establishing a clinical benchmark for DeepView's ED burn healing assessment, which we anticipate will have a major impact in the delivery of care for burns in that setting. In February 2022, the Company and the FDA conducted a pre-submission meeting for alignment on our ED strategy. The FDA's feedback confirmed our ED approach and stated that they see utility of DeepView in Emergency Rooms across the United States.

On February 2, 2023, BARDA also announced its Sources Sought Notice ("SSN") for Burn Wound Imaging Technologies. This SSN is the first step in BARDA's procurement process. The SSN stated parameters for the program "seeking burn wound imaging technologies that could enable physicians to efficiently triage burn patients and make more informed treatment decisions. The technologies sought are expected to function in routine healthcare settings such as emergency departments as well as in specialized burn centers and trauma units. Imaging technologies that are well-integrated in routine healthcare settings inherently build national preparedness and the capability to apply these tools during mass casualties involving burn injuries." We meet all of the requirements set forth in the SSN notification and filed our application by the deadline of February 28, 2023.

### **DFU Indication**

In November 2021, we completed enrollment for our Institutional Review Board ("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.

The DFU images and clinical data collected are currently being incorporated into the database for the development of DeepView's DFU algorithm. The data will also inform on key datapoints that will be captured in a planned validation study, and the incorporation of additional newly developed features. Data collected throughout the study will support our applications for FDA clearance and CE mark approval for DeepView's DFU indication — one of the necessary milestones required to commercialize DeepView's DFU application. While we believe the Company is well positioned to obtain both FDA clearance and CE mark approval, based on prior FDA BDD clearances for our DeepView GEN 1 and 2 Systems, there can be no assurance that the Company will be able to obtain FDA clearance or CE mark approval of our DeepView System.

We made substantial progress in our U.S. DFU Clinical Validation Study (the "US DFU Clinical Study") in 2022. The endpoint of the clinical study is to predict on "Day One" whether the DFU wound will reduce in size by 50% by week four. In 2022, with additional analyses our DeepView System showed improvement of the AI diagnostic accuracy by five percentage points 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 have continued to enroll subjects in the US DFU Clinical Study to finalize our admission goal. Following effective cost management mainly related to the US DFU Clinical Study, we expect to increase investment in the DFU indication in 2023 to drive our commercialization strategy. In preparation of submitting for regulatory clearance, we will hold a pre-submission meeting with the FDA to ensure alignment for our future final regulatory submission. We intend to submit for U.K. Conformity Assessment ("UKCA") regulatory evaluations early in 2024. We are currently targeting to receive the required UKCA certificates early in 2024, and to receive FDA clearance in 2024, although these approvals and clearances 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 clearance, and EU CE Mark. Our DeepView System recently 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).

#### **Other DeepView Programs in Development**

Funding from the U.S. government funding 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 wound care facilities should be expanded to provide greater utility of the DeepView System in such settings.

#### ***DeepView SnapShot M***

Our primarily additional indication 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 new indication 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. We were awarded a \$4.0 million grant from the Medical Technology Enterprise Consortium (“MTEC”), a 501(c)(3) biomedical technology consortium working in partnership with the Department of Defense, in April 2023, to develop our DeepView SnapShot M device in a Phase III feasibility and commercialization study. This grant, along with prior awards from DHA, based on our development of this device. 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 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 wound 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 new technology 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.

#### ***Other Horizon Indication Opportunities***

We envision additional “Horizon” indication opportunities for our DeepView System across the spectrum of the wound care market, including venous leg ulcer, critical limb ischemia, amputation, cosmetics, and other digitally guided diagnostic opportunities, which are sometimes referred to as “Horizon indications.” We envision these or other indications being utilized on our current cart-based DeepView System in emergency rooms and other wound/trauma centers as software to be utilized with the existing machines.

From a regulatory perspective, we believe that these follow-on applications would all follow a similar 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 device is classified as a Class III 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 may be categorized in two parts: (1) we will continue to fulfill our contractual obligations and meet milestones under our BARDA Burn II 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 Burn II contract are to deliver on the current phase of the contract (Phase 1a), and to complete the remaining phases of the BARDA Burn II contract. Completion of these contractual phases support our long-term goal of entering into a federal procurement contract with BARDA.

We intend to submit for FDA clearance of the burn application in 2025 in accordance with the projected timeline for the BARDA contract. We have scheduled a Quality Management System (“QMS”) certification audit in compliance with ISO 13485:2016 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. On July 14, 2023, Spectral completed its UKCA Mark registration for the DeepView Imaging System. Figure 2 below provides a summary of our key anticipated regulatory submissions. There can be no assurance that we will be able to obtain FDA clearance, UKCA or CE mark approval of our DeepView GEN 3 System on our projected timeline, or at all.

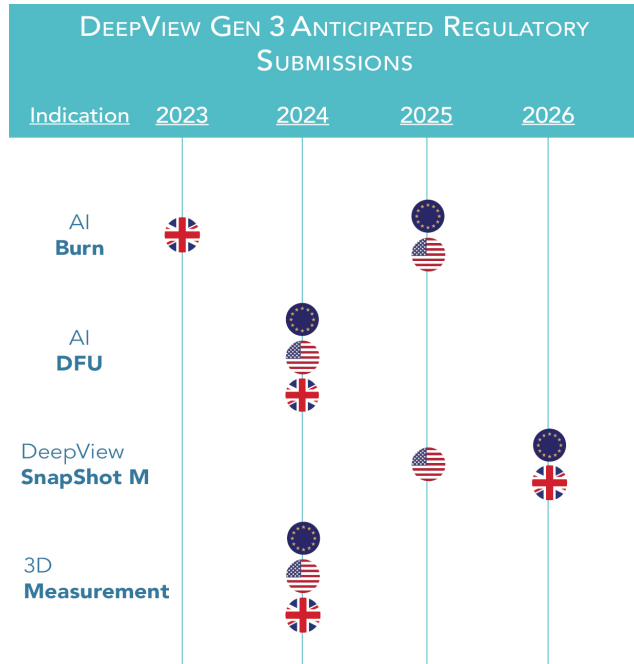


Figure 2 — Summary of key regulatory submissions

**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” healing assessment 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 for wound prediction. It is non-invasive, non-radiation, non-laser and does not require the use of injectable dye. This integration can be characterized into four distinct components: DeepView imaging, data extraction, AI model building and AI wound healing prediction.

- 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 263 billion pixels of DFU and burn data as of December 31, 2022.
- The AI algorithm then seeks to produce an objective, accurate, and immediate binary wound healing prediction. This prediction would be graphically represented to the clinician through a colored overlay of the original image that annotates the non-healing portion of the wound (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 allow clinicians to make accurate, timely, and informed decisions regarding the treatment of the patient’s wound. In the case of DFUs, a non-healing assessment would provide the physician with the appropriate justification to use an advanced wound care therapy on “Day One” as opposed to waiting 30 days 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 of 50%. Subject to FDA clearance 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 is 92%, compared with current physician accuracy of 50 to 75%, according to industry literature. 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, 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 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 diagnostic 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.

### DeepView Development Program

The multi-generational development of our DeepView System is summarized below.

<b>Generational Advancements</b>	<b>Technology</b>	<b>FDA Clearance Date</b>
DeepView Gen 1	Photoplethysmography (PPG)	2013
DeepView Gen 2	PPG and Multi-Spectral Imaging (MSI)	2017
DeepView Gen 3	MSI and AI Algorithms	Targeting 2025 (subject to FDA clearance)

The first generation of our DeepView System, DeepView GEN 1, which gained FDA clearance in 2013 (510(k) pre-market notification, K124049), was based on generating reflectance PPG signals by measuring light interaction with dynamic changes in the vascularized tissues. This technique produced a map of blood flow in the microcirculation of tissue to detect relative difference in blood flow in tissues. Spectral’s PPG imaging was used in clinical studies to investigate blood-flow changes in chronic wounds (e.g., pressure ulcers), surgical wounds (e.g., incision sites), and burns. This device was also used in animal studies to investigate its ability to differentiate viable tissue from burn tissue in an animal model of burn excision surgery. However, the data acquisition process for PPG signal collection involved video recording of 30 seconds which introduces artifacts in the signal when the patient cannot be still.

The second generation, DeepView GEN 2, which gained FDA clearance in 2017 (510(k), K163339), utilized, in addition to PPG, wide field MSI system to rapidly capture multiple reflectance measurements of pre-selected wavelengths of light characteristic of the target tissue damage. Unlike its predecessor, this device captured PPG signals in a seven second video and thus reduced motion related noise signal.

Following BARDA funding in 2014, we began focusing our technology on the integration of MSI and AI algorithms for tissue classification. Pre-clinical animal testing resulted in initial machine learning algorithms for the classification of seven tissue types found in burn excision surgery including blood, viable skin, viable wound dermis, non-viable skin (burned skin), and burned dermis to name a few. Following pre-clinical testing, we completed feasibility testing of burn assessment with this technique in 38 human subjects at a single burn center in 2018. In addition, we began exploring other clinical applications, such as determining the healing potential of DFUs and predicting the appropriate amputation site on the lower extremity for patients with critical limb ischemia.

The DeepView GEN 3 System differs from its predecessors in that it:

- (i) utilizes a proprietary multispectral imaging sensor called the SnapShot imaging sensor (US Patent No. 11,631,164, 2020);
- (ii) is re-designed to be a much more portable version with a smaller footprint; and
- (iii) stores the AI algorithms for burn and DFU assessment within the onboard software.

DeepView GEN 3 utilizes a proprietary illumination system for tissue imaging with a patented high-resolution multi-aperture SnapShot multispectral sensor. This sensor captures all required MSI data for processing in one 0.2 second image capture data. This sensor is rapid enough to essentially eliminate the noise from patient motion during image acquisition. The eight reflectance measurements captured at the experimentally pre-determined visible and near-infrared wavelengths are processed to yield the reflectance profile of the tissue at each image pixel location, or multispectral signature, characteristic of the tissue composition. Different wavelengths have different tissue penetration depths for tissue characterization. Differences in the spectral signatures between healing and non-healing tissue are utilized to make predictions of wound healing. We have not yet applied for or received the FDA's review for the DeepView GEN 3 device.

AI is in development for the GEN3 clinical indications, including classification of burn and DFU healing potential. The AI methods have been established for prediction of healing/non-healing tissue via Deep Learning ("DL") developed using proprietary MSI data collected in from patients in clinical studies sponsored by Spectral. There are nine patent prosecution families that protect the intellectual property behind the imaging modality and clinical applications of DeepView GEN 3. Clinical data collection with the DeepView GEN 3 System device started in April 2020.

### **Technical Characterization**

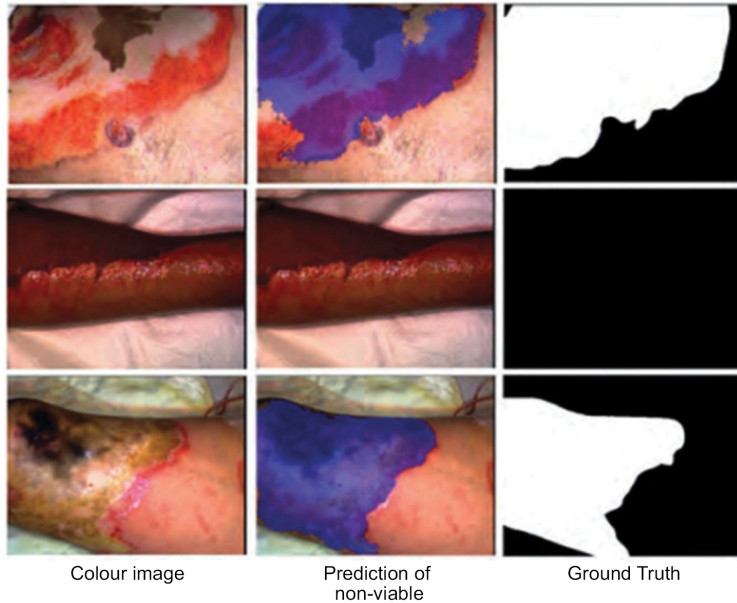
There are a number of non-contact, non-invasive, non-radiation optical modalities available for the assessment of burn wound severity such as near infrared spectroscopy, terahertz spectroscopy, laser Doppler imaging, optical coherence tomography, laser speckle imaging, special frequency domain imaging. 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 GEN3 device. 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 a dermatopathologists are involved in the 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 true 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 GEN 3 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.

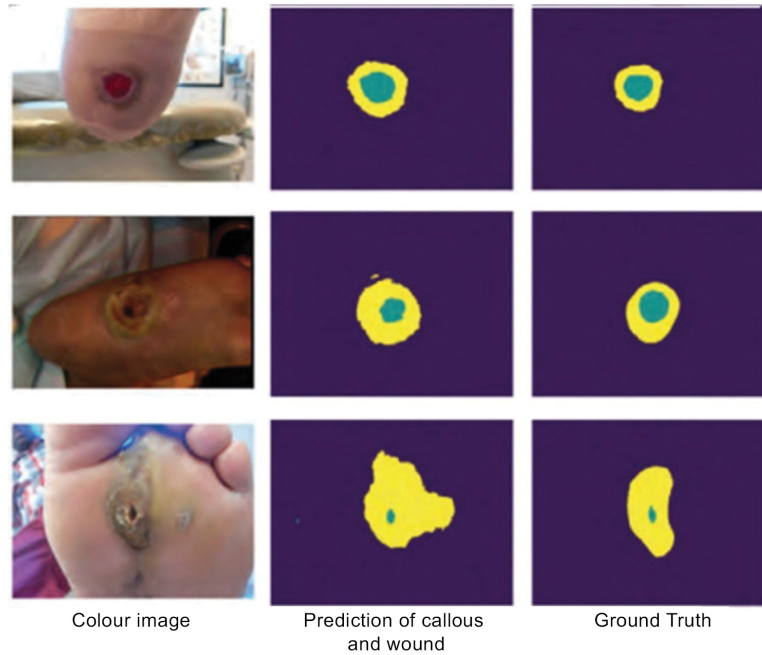


*Figure 5 — Illustration of DeepView’s highlighted region that marks the predicted non-healing portion of the wound*

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. Below is a schematic representation of one way this prediction can be obtained using a DL approach (Figure 7). 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.

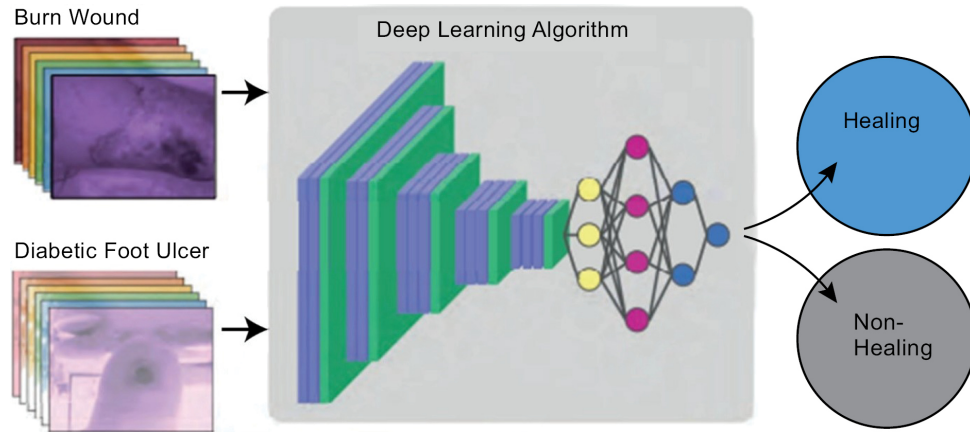


Figure 7 — Schematic representation of the steps involved in generating DeepView GEN 3 System output

### Medical Imaging Solutions

Central to the DeepView GEN 3 System is the proprietary AI analytics for the assessment, diagnosis, and quantitative prediction 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 interrogate 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, 2022, approximately 263 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 optical technology to assist clinicians to make more accurate and faster 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 meaningful physicians. We own and control the entirety of our data pipeline. We do not rely on stock images or databases for our algorithms, only images and data



that the solution collects in a controlled clinical environment. All optical technology has been developed in-house and is specifically engineered to collect this imaging data. A current image of our cart-based DeepView System appears below in Figure 8.



Figure 8 — DeepView Generation 3 System

### **Unmet Clinical Need**

The biggest unmet need for clinicians treating DFU and burn wounds is the lack of a diagnostic tool that provides an objective wound healing determination on “Day One.” While burns and DFUs appear to be very different types of wounds, they are in fact similar from the perspective of assessment and diagnosis. The treatment pathways for each of these wounds can be generally characterized by a subjective initial assessment from the physician followed by multiple days 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. We believe that this unmet need for effectiveness and efficient assessment and treatment of burn wounds is recognized by BARDA, as demonstrated by their significant and continuing investment in us to date.

### **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 China, South Korea, Japan, the Middle East, and South America.

**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. We are expanding the indication usage of the DeepView System to incorporate a wound and burn measurement diagnostic tool for clinicians in concert with BARDA. We have also explored the technology’s potential in diagnosis for venous leg ulcers, 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 diagnostic analyses. However, we would need to conduct a clinical study 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 similar 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 the device is classified as a Class III device.

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

Since 2013, we have received approximately \$280.0 million in funding 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. On September 27, 2023, the Company executed a new contract with BARDA, providing the Company with additional funding of up to \$149.9 million, including an initial award of approximately \$55.0 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. The Company is also completing work on the Option 1B of its prior contract award relating to our Burn Training study, which was extended through December 31, 2023 upon which the Company will receive approximately \$2.0 million of additional funding. This grant funding is non-dilutive to our stockholders, and we believe it validates the important nature of its mission and technology. See “Information about Spectral — The BARDA Contract” for further details.

***Significant Wound Data Repository from Artificial Neural Network***

As of December 31, 2022, approximately 263 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 Glyndeboume 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 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 only provides 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 clearance. As noted above, although we have received FDA BDD clearance for our DeepView GEN 1 and DeepView GEN 2 Systems received FDA BDD clearance, there can be no assurance that we will be able to obtain FDA clearance, UKCA or CE mark approval of our DeepView System.

**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.

The purpose of the validation study will be to test the algorithm's wound healing prediction capability on a new set of patients. 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. We expect that a few of the enrolling sites from the training study will be used in the validation study. The output from the validation study will be used to support the FDA and CE Mark regulatory applications, which are expected to be submitted in 2024. Our goal is for the Burn application to follow a similar clinical and regulatory framework with a forecasted 510(k) submission to the FDA in 2025.

### ***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 will be conducting a clinical validation study 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 150 subjects (both adult and pediatric) across at least 15 clinical sites in the United States and the EU, beginning in the third quarter of 2023.

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.

### **Clinical Validation and Regulatory Pathway**

Based on the evaluated risk of the technology, we believe that DeepView may be subject to the Class II de novo classification pathway. We have received a recommendation from HPRA for a Class IIa designation for CE Mark certification in the EU.

We intend to present the DFU application as the first indication for regulatory approval in the United States, UK and EU4. The burn indication for use may follow as a 510(k), subject to review and agreement by the FDA, supported by clinical data that is evaluated by a methodology similar to 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 \$280.0 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 \$149.9 million, including an initial award of approximately \$55.0 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. The Company is also completing work on the Option 1B of its prior contract award relating to our Burn Training study, which was extended through December 31, 2023 upon which the Company will receive approximately \$2.0 million of additional funding. Under this contract, we expect to further the DeepView System design, develop the AI algorithm, and take the necessary steps to obtain FDA approval for our DeepView GEN 3 System. However, approval 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 wound healing potential in mass casualty an 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 expires on October 31, 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.

The DHA Department of Defense STTR Phase I and initial Phase II contract expired on January 26, 2021. On July 1, 2021, we entered into a supplemental Phase II contract that extends the length of the award until October 2023 to pursue research and development of commercial applications. Under the terms of our current contract with DHA, the Company is required to provide 26 monthly reports and one final technical report at the end of the contract. 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 Phase II 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 is scheduled to extend through at least July 2023 and is focused on the planning, design and testing of the handheld device for its intended applications. Phase 1 has a funding budget of \$1,170,000. Once Phase 1 is completed, Phase 2 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 approval 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 clearances or approvals, we intend to market our DeepView System using a sales force to inpatient and outpatient sites of care throughout the United States. Podiatry practices are typically the first line of specialty care for DFUs in the United States, but vascular and cardiology groups and outpatient wound centers also treat wounds. Sales will initially target podiatry practices presiding in areas with high prevalence of diabetes such as the south and southeastern areas of the United States. We will also target large hospital systems with outpatient wound care centers as they serve a large volume of DFU patients. As noted above, subject to our receipt of the necessary regulatory clearances, approvals, De Novo classifications and clearances, 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.

We expect to internally market the DeepView System to U.S. customers. The sales team will consist of sales executives, clinical education and technical field engineer to service the account and technology as well as having sales and relationship responsibility for their respective geographies. For the burn indication, the primary customer base will be emergency departments located in approximately 5,400 federal and community hospitals throughout the United States. Subject to our receipt of the necessary clearances and approvals, commercial sales are expected to commence in 2024 for the DFU indication in the UK and in 2025 for burns indication, although the burn indication is expected to continue to attract considerable government funding through BARDA, having recently elected to enter Option 1B and Option 2 of our existing contract, which extends the term through July 2024, if not supplemented or revised beforehand.

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

### *Regulatory*

Due to the regulatory changes implemented post Brexit, we were able to receive a UKCA mark in September 2023 for both the DeepView Imaging System, and plan to submit to receive a UKCA mark for its Burn AI software application since both are classified as a Class 1 device in the United Kingdom. For the majority of developed countries, the AI is a medical device classified as Class 2 and comes with a deeper evaluation and timeline of a minimum of six months for regulatory review. On July 14, 2023, Spectral completed its UKCA Mark registration for the imaging components of the DeepView System. In the United States, we expect that the DeepView System will be under a DeNovo application due to previously awarded BDD status. We expect to submit the DFU application to the FDA in early 2024. The new MDR requirements to obtain a CE mark are extensive. As such, we expect to submit our application for a CE mark in the first half of 2024.

### *Clinical Evidence*

Even if the DeepView System receives the necessary regulatory clearances and approval, each country with a national reimbursement payer system will require additional post-approval clinical evidence with their population and processes to show the patient outcomes utilizing this new technology and the health economic impact. This clinical evidence is an important step towards developing key opinion leaders and establishing reimbursement.

### *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 site of service. The process of reimbursement varies greatly between the two. The DeepView burn indication will be used inpatient both in EDs and Burn Centers and we expect that it will be reimbursed as an expense under the existing nationwide Diagnosis Related Group (“DRG”) codes for burns. We plan to apply for Centers for Medicare & Medicaid

Services (“CMS”) New Technology Add-On Payment (“NTAP”) as our BDD status already fulfills CMS’ requirement for demonstrating substantial clinical improvement. NTAP is a payment mechanism that is tied to burn diagnosis codes and allows additional payment to the site of service that diagnoses the patient. This will be a positive impact for our burn application in the ED setting. The DeepView DFU indication will utilize existing CPT codes while gaining the clinical evidence to apply for a unique CPT. The reimbursement for the DFU indication could vary regionally and from CMS to private payers.

#### *Adoption*

We view our DeepView technology as disruptive by nature and there will be those who will want to “wait and see.” This emphasizes the importance of having the right strategic partnerships, institutions, and physician key opinion leaders as early adopters. 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 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. We employ experienced regulatory and quality control personnel to ensure that our manufacturing processes and quality management systems are in compliance with FDA and CE Mark 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 success will depend significantly on our ability to obtain and maintain patent and trade secret protection for our technology, our ability to defend and enforce our intellectual property rights and our ability to operate without infringing any valid and enforceable intellectual property rights of third parties.

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



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As of the date of this prospectus, we have 10 issued and allowed U.S. patents with 5 U.S. patent applications pending. We have 10 issued and allowed international patents with 29 foreign and international patent applications pending.

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**

<b>Patent No.</b>	<b>Description</b>	<b>Type of Patent Protection</b>	<b>Jurisdiction</b>	<b>Expiration</b>
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
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

**Pending U.S. Patent Applications**

<b>Application No.</b>	<b>Description</b>	<b>Type of Patent Protection</b>	<b>Jurisdiction</b>
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
18/177,493	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

**Issued Foreign Patents**

<b>Patent No.</b>	<b>Description</b>	<b>Type of Patent Protection</b>	<b>Jurisdiction</b>	<b>Expiration</b>
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
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
7186298	High-precision, multi-aperture, MSI snapshot imaging	Utility	Japan	December 11, 2039

**Pending Foreign Patent Applications**

<b>Application No.</b>	<b>Description</b>	<b>Type of Patent Protection</b>	<b>Jurisdiction</b>
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
10-2018-7014959	Tissue classification based on combined MSI and PPG	Utility	South Korea
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



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<b>Application No.</b>	<b>Description</b>	<b>Type of Patent Protection</b>	<b>Jurisdiction</b>
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
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
2021-533805	DFU healing potential prediction and wound assessment based on MSI, machine learning, healthcare metrics	Utility	Japan
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/US2022/022398	High-precision, single-aperture, MSI snapshot imaging with multiplexed illumination	Utility	International PCT Application
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 March 31, 2023, we maintain a portfolio of 57 trademarks and seven trademark applications pending relating to our DeepView 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 look to protect our intellectual property in the United States, UK and the EU as those are the first commercial markets for our products.

The duration of trademark registrations varies from country to country; however, trademarks 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 either FDA clearance of a premarket notification submitted under Section 510(k) of the FDCA, 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. 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, although we have received FDA BDD clearance for our DeepView GEN 1 and DeepView GEN 2 Systems, there can be no assurance that we will be able to obtain FDA clearance, UKCA or CE mark approval for our DeepView GEN 3 System.

*510(k) Clearance Marketing Pathway*

Our current products are subject to requirements for pre-market notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit 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. 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. We plan to pursue FDA clearance (de novo) for the DFU application in 2024.

We plan to submit for FDA clearance 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, Spectral completed its UKCA Mark registration for the imaging components of the DeepView System. There can be no assurance, however, that we will be able to obtain FDA clearance, UKCA or CE mark approval of our DeepView GEN 3 System, despite having received FDA BDD clearance for our DeepView GEN 1 and 2 Systems.

#### *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 expires in March 2024. While we believe our current facilities are sufficient to meet our current and anticipated future needs, we are actively seeking new leased space that will support the anticipated expansion of our operations. We anticipate leasing a new facility in 2024 which will be significantly larger than the current leased space to accommodate the planned expansion of our operations.

## **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 2023 as we continue to build a focused and highly skilled team. We added 16 employees during the fiscal year 2022 and, at December 31, 2022 had 71 full-time employees in the United States and UK and have and will continue to make additional hires over the course of 2023 and beyond. The 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 2023 and 2024.

With the Company accelerating towards commercialization, much focus has been given to the development, hiring, and retention of highly skilled individuals with proven commercial track records. In 2022, we saw a headcount growth of +29% with the addition of 16 full-time employees. We continue to prioritize recruitment in the areas of operations, production, regulatory, marketing, government contracts, and product development, which we believe will enable it to meet technology, IP, clinical, regulatory and commercialization readiness goals in 2023 and 2024. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our team is comprised of a diverse group of different backgrounds, orientations, beliefs, perspectives and capabilities. We are committed to a culture where diversity, respect, belonging and authenticity are valued. We are committed to hiring the best talent. Our recruiting strategy involves utilization of social media, employee referral programs, as well as internal and external recruiters.

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**

We are not subject to any material legal proceedings.

**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.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive Officers</b>		
Wensheng Fan	54	Chief Executive Officer and Director
Niko Pagoulatos, Ph.D.	50	Chief Operating Officer
Nils Windler	49	Chief Financial Officer
Jeffrey Thatcher, Ph.D.	40	Chief Scientist
<b>Non-Employee Directors</b>		
Cynthia Cai	59	Director
Richard Cotton	62	Director
Martin Mellish	65	Director
Michael Murphy	51	Director
Deepak Sadagopan	49	Director

**Executive Officers****Wensheng Fan**

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

**Niko Pagoulatos, Ph.D.**

Niko Pagoulatos, Ph.D. is a technology executive and innovator with 25+ years of experience in engineering, clinical and business aspects of specialized medical ultrasound imaging. Dr. Pagoulatos is a team-oriented and results-driven leader with extensive experience and a strong track record in building and leading cross-functional teams to successfully commercialize innovative medical technologies with global clinical impact. Prior to joining Spectral, Dr. Pagoulatos held multiple executive roles at EchoNous, a global healthcare AI-focused medical ultrasound innovation company. Prior to EchoNous, Dr. Pagoulatos held director and advanced research and development engineering roles at FUJIFILM SonoSite, the world leader in point-of-care ultrasound, DYSIS Medical, a company focused on early detection and diagnosis of cervical disease using biophotonics, and Siemens Healthcare. Dr. Pagoulatos earned his B.S. in Physics from the University of Athens in Greece and completed his graduate studies at the University of Washington in Seattle, where he earned a M.S. in Bioengineering in addition to a M.S. and Ph.D. in Electrical Engineering.

**Nils Windler**

Mr. Windler brings more than 20 years of Finance and Operations experience and is recognized as a hands-on, forward-thinking executive and business strategist who leverages extensive financial, operations and sales experience to fuel revenue growth, enhance profitability and seamlessly execute organizational turnarounds and transformations. Prior to joining Spectral, Mr. Windler served as Senior Finance Leader and Business Finance Transformation Leader at 3M. Prior to its acquisition, Mr. Windler also served as Vice President of Finance for Americas at KCI, an Acclivity company. Mr. Windler holds an MBA, General Management from The Berlin School of Economics & Law & Anglia Ruskin University in Cambridge, U.K. and a BA, Business Administration, Banking Management, Finance & Investments from The Berlin School of Economics and Law.

***Jeffrey Thatcher, Ph.D.***

Jeffrey Thatcher, Ph.D. serves as the Chief Scientist at Spectral. He currently oversees technology and applications research for medical imaging systems. He is a former Howard Hughes Medical Institute (HHMI) undergraduate research fellow, has served as PI on three National Science Foundation (NSF) grants, and is currently the PI of a Health and Human Services Biomedical Advanced Research and Development Authority (HHS/BARDA) government contract to develop an imaging device to assist with burn care. Dr. Thatcher received a B.S. in molecular biology from Texas Tech University and Ph.D. in biomedical engineering from University of Texas Southwestern Medical Center.

**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 has a wealth of experience in senior financial roles in life sciences and other sectors, including broadcast and photographic, automotive, filtration and metals. His experience covers all financial management and value creation activities from R&D, to manufacturing and commercial in international organizations. He has significant experience in the development and successful execution of strategy, corporate finance and M&A, capital markets and governance. Mr. Cotton was Chief Financial Officer of FTSE250 animal health company Dechra Pharmaceuticals plc, and prior to that Chief Financial Officer of medical device and drug formulation business Consort Medical plc. He was also Finance Director of Vitec Group plc, Group Finance Director at Wagon plc and Group Finance Director of McLeod Russel plc. Prior to this he held senior finance roles in Alcoa Inc. Fellow of the Chartered Institute of Management Accountants, Mr. Cotton holds a BA (Hons) in Business Studies from Kingston University.

***Martin Mellish***

Martin Mellish has served as founding director of Aspen Advisory Services Ltd., since 1994. Aspen is a London-based private office overseeing investments in North America, Europe, and Asia. Mr. Mellish serves as non-executive director of Nucana Ltd (NASDAQ: 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.

***Michael P. Murphy***

Michael P. Murphy served as Chief Executive Officer of RCLF and a member of its Board of Directors since the company's inception. Mr. Murphy began his investing career over 25 years ago. His career has been focused on being an entrepreneur in the investing and financial service industry. In the past, he was the Founder of a wealth management

firm, hedge fund and multiple commercial real estate portfolios. In 2016, Mr. Murphy founded Rosecliff Ventures and has served as its Managing Partner since its inception. Over the past four years, Rosecliff Ventures has made over 80 investments, raised over \$1 billion in assets under management, launched seven investment funds and experienced multiple portfolio company exits. A few select transactions from the Rosecliff Ventures portfolio include; Allbirds, Casper, Postmates, Ro, Thirty Madison, Petal and Wheels Up. Mr. Murphy is currently a board member of multiple private, venture capital backed companies. Mr. Murphy previously was a contributor on CNBC and regularly appeared on the network's FASTMONEY segment. Currently, Mr. Murphy is a regular weekly contributor on Fox Network. Mr. Murphy earned a Bachelor of Arts in Business Administration from Hofstra University.

### **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.

### **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 six directors, with an additional director to be nominated by the Board. 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) Wensheng Fan, (ii) Cynthia Cai, (iii) Richard Cotton, (iv) Martin Mellish, (v) Michael P. Murphy, (vi) Deepak Sadagopan and (vii) one individual who shall be nominated by the Board.

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. Fan. Our Board believes that combining the positions of Chief Executive Officer and Chairman helps to ensure that our Board and management act with a common purpose. In addition, our Board believes that a combined Chief Executive Officer and Chairman is better positioned to act as a bridge between management and our Board, facilitating the regular flow of information. Our Board also believes that it is advantageous to have a chairperson with significant history with and extensive knowledge of the Company, as is the case with Mr. Fan.

## **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 three standing committees: 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.

### ***Audit Committee***

The audit committee provides assistance to our Board 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 rules of Nasdaq and Rule 10A-3 of the Exchange Act require that the audit committee of a listed company be comprised solely of independent directors. Our audit committee meets the requirements for independence of audit committee members under applicable SEC and Nasdaq rules. All of the members of our audit committee (Martin Mellish (Chairperson), Richard Cotton and Deepak Sadagopan) meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. In addition, Mr. Mellish qualifies as our “audit committee financial expert,” as such term is defined in Item 407 of Regulation S-K.

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 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. Our compensation committee consists of Cynthia Cai (Chairperson) and Martin Mellish. The composition of our compensation committee satisfies Nasdaq's additional independence standards for compensation committee members.

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 is responsible for making recommendations to our Board regarding candidates for directorships and the size and composition of the Board, and consists of Richard Cotton (Chairperson) and Cynthia Cai. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance and reporting and making recommendations to the Board concerning corporate governance matters. The following member(s) of our nominating and corporate governance committee are independent, as defined under the Nasdaq listing rules: Richard Cotton and Cynthia Cai.

Our Board has adopted a new written charter for the nominating and corporate governance committee, which will be available on our website after adoption.

#### ***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 have entered into employment agreements with certain of our executive officers that govern certain terms and conditions of such executive officers' employment as executive officers of the Company. The employment agreements with each of Wensheng Fan, Nils Windler and Dr. Niko Pagoloutus are described under "*Executive Officer and Director Compensation — Employment Agreements.*"

### ***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***

Our Board has approved a non-employee director compensation program. 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 2022 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, 2022, which consist of our principal executive officer and the next two most highly compensated executive officers who were serving as executive officers as of December 31, 2022, are:

- Wensheng Fan, Chief Executive Officer;
- Nils Windler; and
- Jeffrey Thatcher.

### Summary Compensation Table

The following table summarizes the compensation earned by each of our named executive officers for the fiscal year ended December 31, 2022.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards <sup>(1)</sup> (\$)	All Other Compensation <sup>(2)</sup> (\$)	Total (\$)
Wensheng Fan <i>Chief Executive Officer</i>	2022	500,000	425,000		232,000	44,412	1,201,412
Nils Windler <i>Chief Financial Officer</i>	2022	350,000	110,000		—	19,814	479,814
Dr. Jeffrey Thatcher <i>Chief Scientist</i>	2022	225,000	—		72,500	34,717	332,217

(1) The amounts shown in this column represent the grant date fair values of option awards granted in 2022 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.

(2) For Mr. Fan, 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, the amount included in this column consists of \$19,814 for health benefits provided to him.  
For Dr. Thatcher, the amount in this column consists of \$13,552 in matching contributions to Dr. Thatcher’s 401(K) plan and \$21,165 for health benefits provided to him.

**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 2022, 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 2022 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 2022 Fiscal Year-End**

The following table provides information regarding outstanding equity awards held by each of our named executive officers as of December 31, 2022

Name	Grant Date	Option Awards <sup>(1)</sup>			
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Wensheng Fan <sup>(2)</sup>	5/1/2019	9,000,000	—	0.10	5/1/2029
	6/25/2020	2,700,000	900,000	0.21	6/25/2030
	6/25/2020	900,000	—	0.21	6/25/2030
	11/20/2020	358,572	—	0.20	11/20/2023
	1/15/2021	3,528,000	1,176,000	0.21	1/15/2031
	10/8/2021	100,000	66,667	0.53	10/8/2031
	2/3/2022	800,000	533,334	0.48	2/3/2032

Name	Grant Date	Option Awards <sup>(1)</sup>			
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Nils Windler <sup>(2)</sup>	12/17/2021	1,000,000	555,556	0.51	12/17/2031
Dr. Jeffrey Thatcher <sup>(4)</sup>	5/1/2019	6,000,000	—	0.10	5/1/2029
	6/25/2020	2,400,000	800,000	0.21	6/25/2030
	2/3/2022	250,000	166,667	0.48	2/3/2032

- (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) The option awarded to Mr. Windler vests over approximately 36-months, with 6/36<sup>th</sup> vesting occurring on the last day of the month following the 180-day anniversary of the commencement of his provision of service to us and thereafter, the remaining unvested options vest in 30 equal tranches on the last day of each calendar month during the continued period of service such that the entire option will be fully vested as of the 36 month anniversary of the date of grant.
- (4) The options awarded to Dr. Thatcher vest in three equal annual installments beginning on the grant date, subject to his continued provision of service to us on each vesting date.

#### Retirement Benefits, Termination and Change in Control Provisions at December 31, 2022

During fiscal 2022, 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.

The 2018 Plan provides that upon a “Change in Control” (as defined therein), our remuneration committee may accelerate the vesting of options granted pursuant to the 2018 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 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.

#### Non-Employee Director Compensation

In 2022, Spectral paid its 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 executive and non-executive member of the Board of Directors for 2022:

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Martin Mellish	92,098			92,098
Gerry Beaney	79,816			79,816
Richard Cotton	79,816			79,816
Cynthia Cai	79,816			79,816
Erich Spangenberg	37,021			37,021

- (1) Mr. Spangenberg resigned from the Board of Directors effective as of October 31, 2022.

**Executive Officer and Director Compensation Arrangements to be Adopted in Connection with the Business Combination**

*Equity*

In connection with the Business Combination, the equity-based awards for Spectral's named executive officers will be 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, Nils Windler and Dr. Niko Pagoloutus, 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

### **Certain Relationships and Related Person Transactions — Company**

#### ***Registration Rights Agreement***

Pursuant to the Business Combination Agreement, at the Closing, the Company, Sponsor and certain stockholders of Spectral entered into the Registration Rights 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.

### **Certain Relationships and Related Person Transactions — RCLF**

#### ***Founder Shares***

During the period ended December 31, 2020, the Sponsor paid \$25,000 to cover certain of RCLF's offering costs in exchange for 5,750,000 Founder Shares. On February 11, 2021, RCLF effected a 1:1.1 stock split of its Class B common stock, resulting in an aggregate of 6,325,000 shares outstanding. All share and per-share amounts have been retroactively restated to reflect the stock split. The Founder Shares included an aggregate of up to 825,000 shares subject to forfeiture to the extent that the underwriters' over-allotment was not exercised in full or in part, so that the number of Founder Shares would equal, on an as-converted basis, approximately 20% of RCLF's issued and outstanding common stock upon the consummation of the Initial Public Offering. As a result of the underwriter's election to fully exercise its over-allotment option, no Founder Shares were subject to forfeiture. In connection with the Business Combination and pursuant to the Sponsor Letter Agreement, the Sponsor agreed to forfeit a certain number of Founder Shares.

#### ***Amount Due to Sponsor***

At December 31, 2022 and 2021, RCLF had advances owed to the Sponsor in the amount of \$16,152 and \$0, respectively.

#### ***Private Placement Warrants***

Simultaneously with the closing of the Initial Public Offering, the Sponsor purchased an aggregate of 4,706,667 warrants in a private placement (the "Private Placement Warrants") at a price of \$1.50 per Private Placement Warrant (\$7,060,000 in the aggregate) from RCLF in a private placement. Each whole Private Placement Warrant was exercisable to purchase one share of Class A common stock at a price of \$11.50 per share, subject to adjustment. A portion of the proceeds from the sale of the Private Placement Warrants were added to the net proceeds from the Initial Public Offering held in the Trust Account. In connection with the Business Combination and pursuant to the Sponsor Letter Agreement, the Sponsor agreed to forfeit all of the Private Placement Warrants.

#### ***Registration Rights***

Pursuant to a registration rights agreement entered into on February 11, 2021, the holders of the Founder Shares, Private Placement Warrants and warrants that may be issued upon conversion of Working Capital Loans (and any shares of Class A common stock issuable upon the exercise of the Private Placement Warrants or warrants that may be issued upon conversion of Working Capital Loans and upon conversion of the Founder Shares) will be entitled to registration rights requiring us to register such securities for resale (in the case of the Founder Shares, only after conversion to shares of Class A common stock). The holders of these securities will be entitled to make up to three demands, excluding short form registration demands, that we register such securities. In addition, the holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to the completion of a Business Combination and rights to require us to register for resale such securities pursuant to Rule 415 under the Securities Act. However, the registration rights agreement provides that we will not be required to effect or permit any registration or cause any registration statement to become effective until termination of the applicable lock-up period. The registration rights agreement does not contain liquidated damages or other cash settlement provisions resulting



from delays in registering our securities. We will bear the expenses incurred in connection with the filing of any such registration statements. In connection with the Business Combination, the registration rights agreement was amended and restated.

### **Sponsor Letter Agreement**

Concurrently with the execution of the Business Combination Agreement, the Sponsor, RCLF and Legacy Spectral entered into the Sponsor Letter Agreement, pursuant to which, among other things, the Sponsor agreed to: (i) vote in favor of the Business Combination Agreement and the transactions contemplated thereby; (ii) vote against an arrangement, merger, amalgamation, consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution or winding up of RCLF; (iii) vote against any changes in the business, management or RCLF's board other than as required to effect the Business Combination; and (iv) vote against any action, agreement or transaction or proposal that would reasonably be expected to result in a breach of any covenant, representation or warranty or any other obligation or agreement of RCLF, Merger Sub I or Merger Sub II under the Business Combination Agreement or that would reasonably be expected to result in the failure of the Business Combination from being consummated in each case, on the terms and subject to the conditions set forth of the Sponsor Letter Agreement. In addition, the Sponsor agreed to (i) not redeem or elect to redeem or tender or submit any of its Subject Parent Equity Securities (as defined in the Sponsor Letter Agreement) and (ii) not, directly or indirectly, (a) sell, assign, transfer, pledge, dispose of or otherwise encumber any of the Subject Parent Equity Securities held by the Sponsor, (b) deposit any Subject Parent Equity Securities held by the Sponsor into a voting trust or enter into a voting agreement or arrangement or grant any proxy or power of attorney with respect to any Subject Parent Equity Securities held by the Sponsor that is inconsistent with the Sponsor Letter Agreement, or (c) enter into any contract, option or other arrangement or undertaking with respect to the direct or indirect acquisition or sale, assignment, transfer or other disposition of any Subject Parent Equity Securities held by the Sponsor.

The Sponsor agreed to surrender and forfeit to RCLF the Private Placement Warrants. In addition, the Sponsor and RCLF, was required to notify Legacy Spectral if the accrued and unpaid Parent Expenses (as defined in the Sponsor Letter Agreement) then outstanding were expected to exceed \$3,250,000 (the "Excess Expense Amount"). At Closing, the Sponsor took necessary actions such that the Sponsor Credit (as defined in the Sponsor Letter Agreement) equaled or exceeded the Excess Expense Amount; *provided* that Sponsor was not required to invest in the Sponsor PIPE (as defined below) if Sponsor elected to forfeit 750,000 Sponsor Shares (as defined below). The Sponsor was entitled to a \$5.00 credit against the Excess Expense Amount for each Sponsor Share that the Sponsor forfeited and surrendered prior to the Closing. The Sponsor did not need to forfeit any Sponsor Shares.

### **Administrative Services Agreement**

Commencing on February 11, 2021 through the earlier of the consummation of an initial Business Combination and the liquidation of RCLF, RCLF agreed to pay the Sponsor a total of \$10,000 per month for office space, support and administrative services. For the three months ended March 31, 2023 and 2022, we accrued \$30,000 and \$30,000 in fees for these services, of which such amount is included in accrued expenses in the accompanying balance sheet.

### **Certain Relationships and Related Person Transactions — Legacy Spectral**

#### **Legacy Spectral Related Party Transactions**

Since January 1, 2020, Legacy Spectral did not have any transactions with related parties.

#### **Policies and Procedures for Related Party Transactions**

Upon consummation of the Business Combination, it is anticipated 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 at any time during the applicable period was, one of the Company’s executive officers or a member of the Board of the Company;
- any person who is known by the Company to be the beneficial owner of more than 5% of its voting stock;
- 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, daughter-in-law, brother-in-law or sister-in-law of a director, officer or a beneficial owner of more than 5% of the Company’s voting stock, and any person (other than a tenant or employee) sharing the household of such director, executive officer or beneficial owner of more than 5% of the Company’s voting stock; and
- any firm, corporation or other entity in which any of the foregoing persons is a partner or principal or in a similar position or in which such person has a 10% or greater beneficial ownership interest.

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**

The following table sets forth information regarding the beneficial ownership of shares of our Common Stock as of October 24, 2023 by:

- each person known by us to be the beneficial owner of more than 5% of our Common Stock;
- each person who is a named executive officer or director of the Company; and
- all executive officers and directors of the Company, as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. A person is a “beneficial owner” of a security if that person has or shares “voting power,” which includes the power to vote or to direct the voting of the security, or “investment power,” which includes the power to dispose of or to direct the disposition of the security, or has the right to acquire such powers within 60 days.

The beneficial ownership of shares of common stock is calculated based on 15,688,268 shares of Common Stock outstanding as of October 24, 2023.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, the persons and entities named in the table have sole voting and investment power with respect to their beneficially owned common stock.

Name and Address of Beneficial Owner <sup>(1)(2)</sup>	Number of Shares Beneficially Owned	%
<b><i>Directors and Named Executive Officers of the Company</i></b>		
Wensheng Fan <sup>(5)</sup>	519,733	3.31%
Cynthia Cai	—	
Richard Cotton	32,879	*
Martin Mellish	—	
Michael P. Murphy <sup>(3)(4)</sup>	848,333	5.41%
Deepak Sadagopan	—	*
Niko Pagoulatos, Ph.D. <sup>(6)</sup>	32,007	*
Nils Windler <sup>(7)</sup>	32,007	*
Jeffrey Thatcher, Ph.D. <sup>(8)</sup>	833,413	5.31%
Vincent Capone <sup>(9)</sup>	32,104	*
<b>All Directors and Executive Officers of the Company as a Group (10 Individuals)<sup>(10)</sup></b>	1,810,743	11.54%
<b><i>Five Percent Holders</i></b>		
Erich Spangenberg <sup>(11)</sup>	5,313,705	33.87%
John Michael DiMaio <sup>(12)</sup>	2,479,053	15.79%
Board of Regents of the University of Texas System for the Benefit of the University of Texas Southwestern Medical Center <sup>(13)</sup>	862,269	5.50%
Octopus Investments plc <sup>(14)</sup>	960,211	6.12%

\* 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 IPO, as such warrants are not exercisable until 30 days after the Closing.

(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).

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- (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 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 our 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 519,733 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (6) Consists of 32,007 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (7) Consists of 32,007 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (8) Includes 810,135 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (9) Includes 22,405 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (10) Includes 1,416,287 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (11) 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.
- (12) The business address for Mr. Dimaio is 4708 Alliance Blvd., Pavilion I, Suite 540, Plano, Texas 75093.
- (13) 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
- (14) 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.

**SELLING STOCKHOLDERS**

This prospectus relates to the possible resale from time to time by the selling stockholders listed in the table below of any or all of the shares of Common Stock or Warrants set forth below pursuant to this prospectus. We are registering such shares of Common Stock and Warrants pursuant to the provisions of the Registration Rights Agreement in order to permit such selling stockholders to offer the Common Stock or Warrants for resale from time to time. When we refer to the “selling stockholders” in this prospectus, we refer to the persons listed in the table below, and the pledgees, donees, transferees, assignees, successors and other permitted transferees that hold any of the selling stockholders’ interest in the shares of Common Stock and Warrants after the date of this prospectus.

The table below presents information relating to the selling stockholders concerning the Common Stock and Warrants that may be offered from time to time by each selling stockholder pursuant to this prospectus. This table is prepared based on information supplied to us by or on behalf of the selling stockholders, and reflects holdings as of October 24, 2023. The number of shares of Common Stock and Warrants in the column titled “Securities to be Offered Pursuant to this Prospectus” represents all of the shares of Common Stock and Warrants that the selling stockholders may offer and sell under this prospectus. The selling stockholders may sell some, all or none of their respective shares of Common Stock and Warrants, as applicable, in this offering. We do not know how long the selling stockholders will hold their shares of Common Stock and Warrants before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares of Common Stock or Warrants.

The selling stockholders identified below may have sold, transferred or otherwise disposed of all or a portion of their securities after the date on which they provided us with information regarding their securities. Any changed or new information given to us by the selling stockholders, including regarding the identity of, and the securities held by, each selling stockholder, will be set forth in a prospectus supplement or amendments to the registration statement of which this prospectus is a part, if and when necessary. See “Plan of Distribution.”

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. A person is a “beneficial owner” of a security if that person has or shares “voting power,” which includes the power to vote or to direct the voting of the security, or “investment power,” which includes the power to dispose of or to direct the disposition of the security, or has the right to acquire such powers within 60 days. The applicable percentage of shares of Common Stock beneficially owned by the selling stockholders shown in the table below is based on an aggregate of 15,688,268 shares of our Common Stock.

Unless otherwise noted, the address of each selling stockholder c/o Spectral AI, Inc., 2515 McKinney Avenue, Suite 1000, Dallas, Texas 75201.

Names and Addresses	Securities Beneficially Owned prior to this Offering	Securities to be Offered in this Offering	Securities Beneficially Owned after this Offering <sup>(1)</sup>	
	Shares of Common Stock	Shares of Common Stock <sup>(2)</sup>	Shares of Common Stock	Percentage
Board of Regents of the University of Texas System for the Benefit of the University of Texas Southwestern Medical Center <sup>(3)</sup>	862,269	862,269	—	—
Brian Radecki <sup>(4)</sup>	50,000	50,000	—	—
ELS 1960 Family, L.P. <sup>(5)</sup>	4,158,557	4,158,557	—	—
Frank S. Edmunds <sup>(6)</sup>	40,000	40,000	—	—
Heather Bellini <sup>(7)</sup>	40,000	40,000	—	—
Jeffrey Thatcher, Ph.D. <sup>(8)</sup>	833,413	23,278	810,135	5.16%
John Michael DiMaio <sup>(9)</sup>	2,477,855	2,477,855	—	—
Michael P. Murphy <sup>(10)</sup>	848,333	848,333	—	—
Octopus Investments plc <sup>(11)</sup>	960,211	960,211	—	—
Richard Cotton <sup>(12)</sup>	52,277	32,879	19,398	—
Vincent Capone <sup>(13)</sup>	32,104	9,699	22,405	*
BTIG, LLC <sup>(14)</sup>	—	166,667	—	—
Cantor Fitzgerald & Co. <sup>(15)</sup>	—	400,000	—	—

\* Represents beneficial ownership of less than 1% of the outstanding shares of our Common Stock.

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- (1) Assumes the sale of all shares being offered pursuant to this prospectus.
- (2) The amounts set forth in this column are the number of shares of Common Stock that may be offered by such selling stockholder using this prospectus. These amounts do not represent any other shares of our Common Stock that the selling stockholder may own beneficially or otherwise.
- (3) 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.
- (4) Consists of 50,000 shares of Common Stock following the conversion of Class B common stock upon the Closing. The business address for Brian Radecki is 767 5<sup>th</sup> Avenue, 34<sup>th</sup> Floor, New York, New York 10153.
- (5) 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.
- (6) Consists of 40,000 shares of Common Stock following the conversion of Class B common stock upon the Closing. The business address for Frank S. Edmunds is 767 5<sup>th</sup> Avenue, 34<sup>th</sup> Floor, New York, New York 10153.
- (7) Consists of 40,000 shares of Common Stock following the conversion of Class B common stock upon the Closing. The business address for Heather Bellini is 767 5<sup>th</sup> Avenue, 34<sup>th</sup> Floor, New York, New York 10153.
- (8) Consists of (i) 23,278 shares of Common Stock and (ii) 810,135 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (9) The business address for Mr. Dimaio is 4708 Alliance Blvd., Pavilion I, Suite 540, Plano, Texas 75093.
- (10) 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 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 our 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.
- (11) 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.
- (12) Consists of (i) 32,879 shares of Common Stock and (ii) 19,398 shares issuable upon exercise of restricted stock units of the Company, which are exercisable within 60 days of the Closing Date.
- (13) Consists of (i) 9,699 shares of Common Stock and (ii) 22,405 shares issuable upon exercise of stock options of the Company which are exercisable within 60 days of the Closing Date.
- (14) The business address for BTIG, LLC is 600 Montgomery Street, 5<sup>th</sup> Floor, San Francisco, CA 94111. BTIG, LLC provided services to the Company in connection with the Business Combination and their fees were satisfied through the issuance of shares of Common Stock. BTIG, LLC is not subject to any lock-up or other restrictions on transfer.
- (15) Cantor Fitzgerald & Co. is the record owner of the securities. CF Group Management, Inc. ("CFGM") is the managing general partner of Cantor Fitzgerald, L.P. ("CFLP") and directly or indirectly controls the managing general partner of CF&CO. Howard Lutnick is Chairman and Chief Executive of CFGM and trustee of CFGM's sole stockholder. CFLP, indirectly, holds a majority of the ownership interests in CF&CO. As such, each of CFLP, CFGM, and Mr. Lutnick may be deemed to have beneficial ownership of the securities directly held by CF&CO. Each such entity or person disclaims any beneficial ownership of the reported shares other than to the extent of any pecuniary interest they may have therein, directly or indirectly. The foregoing should not be construed in and of itself as an admission by any of CFLP, CFGM, or Mr. Lutnick as to beneficial ownership of the securities beneficially owned, directly, by CF&CO. The business address of CF&CO is 110 East 59<sup>th</sup> Street, New York, NY 10022.

## 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.

### **Registration Rights and Lock-up Agreement**

At the Closing, the Company, the Sponsor and certain stockholders of Legacy Spectral and RCLF entered into 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, shares of Common Stock that are held by the parties thereto from time to time. Pursuant to the 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 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 Registration Rights/Lock-Up Agreement will provides that the Company will pay certain expenses relating to such registrations and indemnify the stockholders against certain liabilities.

In addition, pursuant to the 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.

### **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 Registration Rights Agreement with the Holders. The Registration Rights 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

We are registering the issuance by us of up to 8,433,231 shares Common Stock that may be issued upon exercise of Warrants to purchase Common Stock. We are also registering the resale by the selling stockholders or their permitted transferees of up to 10,069,748 shares of Common Stock. We will not receive any of the proceeds from the sale of the Common Stock by the selling stockholders. We will receive proceeds from Warrants exercised in the event that such Warrants are exercised for cash. The aggregate proceeds to the selling stockholders will be the purchase price of the securities less any discounts and commissions borne by the selling stockholders.

The Common Stock beneficially owned by the selling stockholders covered by this prospectus may be offered and sold from time to time by the selling stockholders. The term “selling stockholders” includes donees, pledgees, transferees or other successors in interest selling securities received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer so long as we are required to provide such transferees with registration rights under the Registration Rights Agreement. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling stockholders may sell their Common Stock by one or more of, or a combination of, the following methods:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an over-the-counter distribution in accordance with the rules of Nasdaq;
- through trading plans entered into by a selling stockholder pursuant to Rule 10b5-1 under the Exchange Act, that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
- to or through underwriters or broker-dealers;
- in “at the market” offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
- in privately negotiated transactions;
- in options transactions;
- through a combination of any of the above methods of sale; or
- any other method permitted pursuant to applicable law.

In addition, any shares that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with distributions of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of Common Stock in the course of hedging transactions, and broker-dealers or other financial institutions may engage in short sales of Common Stock in the course of hedging the positions they assume with selling stockholders. The selling stockholders may also sell Common Stock short and redeliver the shares to close out such short positions. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer

or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders may also pledge shares to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

A selling stockholder may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by any selling stockholder or borrowed from any selling stockholder or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from any selling stockholder in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment). In addition, any selling stockholder may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

In effecting sales, broker-dealers or agents engaged by the selling stockholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling stockholders in amounts to be negotiated immediately prior to the sale.

In offering the shares covered by this prospectus, the selling stockholders and any broker-dealers who execute sales for the selling stockholders may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. Any profits realized by the selling stockholders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions 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 applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of shares is made, if required, a prospectus supplement will be distributed that will set forth the number of shares being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallocated or paid to any dealer, and the proposed selling price to the public.

A holder of Warrants may exercise its Warrants in accordance with the Warrant Agreement on or before the expiration date set forth therein by surrendering, at the office of the warrant agent, Continental Stock Transfer & Trust Company, the certificate evidencing such Warrant, if any, with the form of election to purchase set forth thereon, properly completed and duly executed, accompanied by full payment of the exercise price and any and all applicable taxes due in connection with the exercise of the Warrant, subject to any applicable provisions relating to cashless exercises in accordance with the Warrant Agreement.

The selling stockholders may agree, to indemnify the underwriters, their officers, directors and each person who controls such underwriters (within the meaning of the Securities Act), against certain liabilities related to the sale of the securities, including liabilities under the Securities Act.

#### **Restrictions to Sell**

Refer to the section titled “*Restrictions on Resale of Securities — Lock-up Provisions.*”

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

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

This discussion does not address the U.S. federal income tax consequences of the exercise of Warrants by existing holders of such Warrants or the ownership or disposition of shares of our Common Stock received in connection with any such exercise, and such holders should consult their own tax advisors regarding the U.S. federal income tax consequences to them of their receipt of Common Stock in connection with an exercise of such Warrants and the ownership or disposition of any such Common Stock. 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 our Offered Securities 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 with respect to our Offered Securities;
- persons holding our Offered Securities as part of a “straddle,” constructive sale, hedge, wash sale, conversion or other integrated or similar transaction;
- U.S. holders whose functional currency is not the U.S. dollar;
- 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; and
- passive foreign investment companies.

If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our Offered Securities, 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 our Offered Securities, you are urged to consult your tax advisor regarding the tax consequences of the ownership and disposition of our Offered Securities.



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 OUR OFFERED SECURITIES. EACH PROSPECTIVE INVESTOR IN OUR OFFERED SECURITIES IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE OWNERSHIP AND DISPOSITION OF OUR OFFERED SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL, STATE AND LOCAL, AND NON-U.S. TAX LAWS.**

#### **U.S. Holders**

This section applies to you if you are a “U.S. holder.” A U.S. holder is a beneficial owner of our Offered Securities 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 taxable 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.*

If we pay distributions in cash or other property to U.S. holders of shares of our Common Stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder’s adjusted tax basis in our Common Stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the Common Stock and will be treated as described under “U.S. Holders — Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Offered Securities” below.

Dividends we pay to a U.S. holder that is treated as a corporation for U.S. federal income tax purposes generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute “qualified dividend income” that would be subject to tax at the preferential tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a U.S. holder that is treated as a corporation for U.S. federal income tax purposes may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and a non-corporate U.S. holder may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

*Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Offered Securities.*

Upon a sale or other taxable disposition of our Offered Securities, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the Offered Securities. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for the Offered Securities so disposed of exceeds one year. Long-term capital gains recognized by non-corporate U.S. holders may be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its Offered Securities so disposed of. A U.S. holder's adjusted tax basis in its Common Stock generally will equal the U.S. holder's acquisition cost (or, in the case of Common Stock received upon exercise of an Offered Warrant, the U.S. holder's initial basis for such Common Stock, as discussed below under "U.S. Holders — Exercise, Lapse or Redemption of an Offered Warrant"), less any prior distributions treated as a return of capital. A U.S. holder's adjusted tax basis in its Offered Warrants generally will equal the U.S. holder's acquisition cost, increased by the amount of any constructive distributions included in income by such U.S. holder, as described below under "U.S. Holders — Possible Constructive Distributions." The amount and character of gain or loss generally will be computed separately for each block of Common Stock or Offered Warrant so disposed by the U.S. holder on the same day at the same price.

*Exercise, Lapse or Redemption of an Offered Warrant.*

A U.S. holder generally will not recognize taxable gain or loss on the acquisition of our Common Stock upon exercise of an Offered Warrant for cash. The U.S. holder's tax basis in the share of our Common Stock received upon exercise of the Offered Warrant generally will be an amount equal to the sum of the U.S. holder's initial investment in the Offered Warrant and the exercise price. It is unclear whether the U.S. holder's holding period for the Common Stock received upon exercise of the Offered Warrants will begin on the date following the date of exercise or on the date of exercise of the Offered Warrants; however, in either case, the holding period will not include the period during which the U.S. holder held the Offered Warrants. If an Offered Warrant is allowed to lapse unexercised, a U.S. holder generally will recognize a capital loss equal to such holder's tax basis in the Offered Warrant. The deductibility of capital losses is subject to certain limitations.

The tax consequences of a cashless exercise of an Offered Warrant are not clear under current tax law. A cashless exercise may not be taxable, either because the exercise is not a realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either situation, a U.S. holder's basis in the Common Stock received would equal the holder's basis in the Offered Warrants exercised therefor. If the cashless exercise were treated as not being a realization event, it is unclear whether a U.S. holder's holding period in the Common Stock would be treated as commencing on the date following the date of exercise or on the date of exercise of the Offered Warrants; however, in either case, the holding period would not include the period during which the U.S. holder held the Offered Warrants. If the cashless exercise were treated as a recapitalization, the holding period of the Common Stock would include the holding period of the Offered Warrants exercised therefor.

It is also possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. holder could be deemed to have surrendered a number of Offered Warrants equal to the number of shares of Common Stock having a value equal to the exercise price for the total number of Offered Warrants to be exercised. In such case, the U.S. holder would recognize capital gain or loss with respect to the Offered Warrants deemed surrendered in an amount equal to the difference between the fair market value of the Common Stock that would have been received in a regular exercise of the Offered Warrants deemed surrendered and the U.S. holder's tax basis in the Offered Warrants deemed surrendered. In this case, a U.S. holder's aggregate tax basis in the Common Stock received would equal the sum of the U.S. holder's initial investment in the Offered Warrants deemed exercised and the aggregate exercise price of such Offered Warrants. It is unclear whether a U.S. holder's holding period for the Common Stock would commence on the date following the date of exercise or on the date of exercise of the Offered Warrants; however, in either case, the holding period would not include the period during which the U.S. holder held the Offered Warrants.

Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, including when a U.S. holder's holding period would commence with respect to the Common Stock received, there can be no assurance regarding which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their tax advisors regarding the tax consequences of a cashless exercise.

If we redeem Offered Warrants for cash pursuant to the redemption provisions described in the section of this prospectus entitled "*Description of Securities — Warrants*" or if we purchase Offered Warrants in an open market transaction, such redemption or purchase generally will be treated as a taxable disposition to the U.S. holder, taxed as described above under "*U.S. Holders — Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Offered Securities.*"

*Possible Constructive Distributions.*

The terms of each Offered Warrant provide for an adjustment to the number of shares of Common Stock for which the Offered Warrant may be exercised or to the exercise price of the Offered Warrant in certain events, as discussed in the section of this prospectus entitled "*Description of Securities — Warrants.*" An adjustment which has the effect of preventing dilution generally is not taxable. A U.S. holder of the Offered Warrants would, however, be treated as receiving a constructive distribution from us if, for example, the adjustment increases the Offered Warrant holder's proportionate interest in our assets or earnings and profits (for example, through an increase in the number of shares of Common Stock that would be obtained upon exercise or through a decrease in the exercise price of the Offered Warrant as a result of a distribution of cash or other property to holders of shares of Common Stock which is taxable to the holders of such shares as a distribution as described under "*U.S. Holders — Taxation of Distributions*" above). Such constructive distribution would be subject to tax as described under that section in the same manner as if such U.S. holder of the Offered Warrants received a cash distribution from us equal to the fair market value of such increased interest. The rules governing constructive distributions as a result of certain adjustments with respect to an Offered Warrant are complex, and U.S. holders are urged to consult their tax advisors on the tax consequences any such constructive distribution with respect to an Offered Warrant.

*Information Reporting and Backup Withholding.*

In general, information reporting requirements may apply to distributions paid to a U.S. holder and to the proceeds of the sale or other disposition of our Offered Securities, unless the U.S. holder is an exempt recipient. Backup withholding (currently at a 24% rate) may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required information is timely furnished to the IRS. U.S. holders should consult their tax advisors regarding the application of information reporting and backup withholding to them.

**Non-U.S. Holders**

This section applies to you if you are a "Non-U.S. holder." As used herein, the term "Non-U.S. holder" means a beneficial owner of our Offered Securities who or that (i) is for U.S. federal income tax purposes, an individual, a corporation (or other entity taxable as a corporation), an estate or a trust, and (ii) is not a U.S. holder.

*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 Offered Securities*" 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 Offered Securities.*

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 Offered Securities, 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 applicable security and, in the case where 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"), (i) the Non-U.S. holder is disposing of Common Stock and has owned, whether actually or based on the application of constructive ownership rules, more than 5% our Common Stock at all times 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 or (ii) the Non-U.S. holder is disposing of Offered Warrants and has owned, whether actually or based on the application of constructive ownership rules, more than 5% of the total fair market value of our Warrants (provided our Warrants are considered to be regularly traded) at all times within the shorter of the five-year period preceding such disposition of Offered Warrants or such Non-U.S. holder's holding period for such Offered Warrants. There can be no assurance that our Common Stock will be treated as regularly traded for this purpose. It is unclear how the rules for determining the 5% threshold for this purpose would be applied with respect to our Common Stock and Offered Warrants, including how a Non-U.S. holder's ownership of Offered Warrants impacts the 5% threshold determination with respect to its Common Stock. In addition, special rules may apply in the case of a disposition of Offered Warrants if our Common Stock is considered to be regularly traded, but the Offered Warrants are not considered to be regularly traded. Non-U.S. holders should consult their own tax advisors regarding the application of the foregoing rules in light of their particular facts and circumstances.

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 net capital gain for such year (including any gain realized in connection with the redemption) at a tax rate of 30%.

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.

*Exercise, Lapse or Redemption of an Offered Warrant.*

The U.S. federal income tax treatment of a Non-U.S. holder’s exercise of an Offered Warrant, or the lapse of an Offered Warrant held by a Non-U.S. holder, generally will correspond to the U.S. federal income tax treatment of the exercise or lapse of an Offered Warrant by a U.S. holder, as described under “U.S. Holders — Exercise, Lapse or Redemption of an Offered Warrant” above, although to the extent a cashless exercise results in a taxable exchange, the consequences would be similar to those described below in “Non-U.S. Holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Offered Securities”.

The characterization for U.S. federal income tax purposes of the redemption of the Non-U.S. holder’s Offered Warrants generally will correspond to the U.S. federal income tax treatment of such a redemption of a U.S. holder’s Offered Warrants, as described under “U.S. Holders — Exercise, Lapse or Redemption of an Offered Warrant” above, and the consequences of the redemption to the Non-U.S. holder will be as described below under the heading “Non-U.S. Holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Offered Securities” depending on such characterization.

*Possible Constructive Distributions.*

The terms of each Offered Warrant provide for an adjustment to the number of shares of Common Stock for which the Offered Warrant may be exercised or to the exercise price of the Offered Warrant in certain events, as discussed in the section of this prospectus entitled “Description of Securities — Warrants.” An adjustment which has the effect of preventing dilution generally is not a taxable event. Nevertheless, a Non-U.S. holder of Offered Warrants would be treated as receiving a constructive distribution from us if, for example, the adjustment increases the holder’s proportionate interest in our assets or earnings and profits (for example, through an increase in the number of shares of Common Stock that would be obtained upon exercise or through a decrease in the exercise price of the Offered Warrants as a result of a distribution of cash or other property to holders of shares of our Common Stock which is taxable to such holders as a distribution as described under “Non-U.S. Holders — Taxation of Distributions” above). Any constructive distribution received by a Non-U.S. holder would be subject to U.S. federal income tax (including any applicable withholding) in the same manner as if such Non-U.S. holder received a cash distribution from us equal to the fair market value of such increased interest without any corresponding receipt of cash. This withholding tax will be imposed even though there is no corresponding cash distribution, and it is possible that any such withholding tax might be satisfied by us or the applicable withholding agent through a sale of a portion of the Non-U.S. holder’s shares of Common Stock, Warrants or other property held or controlled by us or the applicable withholding agent on behalf of the Non-U.S. holder or might be withheld from distributions or proceeds subsequently paid or credited to the Non-U.S. holder. The rules governing constructive distributions as a result of certain adjustments with respect to an Offered Warrant are complex, and non-U.S. holders are urged to consult their tax advisors on the tax consequences any such constructive distribution with respect to an Offered Warrant.

*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 our Offered Securities. 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 (including constructive dividends) on our Offered Securities 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 our Offered Securities.

#### **EXPERTS**

The consolidated financial statements of Spectral MD Holdings, Ltd. as of December 31, 2022 and 2021, and for each of the years in the two-year period ended December 31, 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 and Warrants 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 “Investors Relations” at <https://www.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 MD Holdings, Ltd.**  
**Unaudited Condensed Consolidated Financial Statements**  
**As of and for the Six Months Ended June 30, 2023 and 2022**

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**UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION**

*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 Legacy Spectral MD Holdings, Ltd., and its subsidiaries prior to the business combination with Rosecliff Acquisition Corp I (“Rosecliff”). The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited quarterly condensed financial statements and related notes included elsewhere in this prospectus, as well as our audited annual consolidated financial statements and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as of and for the years ended December 31, 2022 and 2021 included in Rosecliff’s final prospectus, as amended, on form S-4/A filed with the Securities and Exchange Commission (“SEC”) on August 10, 2023 (the “Prospectus”). 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” included in the Prospectus. Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future.*

**Spectral MD Holdings, Ltd.**  
**Unaudited Condensed Consolidated Balance Sheets**  
**(in thousands, except share and per share data)**

	June 30, 2023	December 31, 2022
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 8,166	\$ 14,174
Accounts receivable, net	1,520	2,294
Unbilled revenue	91	618
Prepaid expenses	342	331
Deferred offering costs	1,124	—
Other current assets	598	270
<b>Total current assets</b>	<u>11,841</u>	<u>17,687</u>
<b>Non-current assets:</b>		
Property and equipment, net	16	21
Right-of-use assets	1,141	1,008
<b>Total Assets</b>	<u>\$ 12,998</u>	<u>\$ 18,716</u>
<b>Commitments and contingencies (Note 7)</b>		
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,657	\$ 2,759
Accrued expenses	2,394	2,631
Deferred revenue	509	—
Lease liabilities, short-term	773	680
Notes payable	—	175
Warrant liability	194	129
<b>Total current liabilities</b>	<u>6,527</u>	<u>6,374</u>
Lease liabilities, long-term	452	346
<b>Total Liabilities</b>	<u>6,979</u>	<u>6,720</u>
<b>Stockholders' Equity</b>		
Common stock (\$0.001 par value); 400,000,000 shares authorized; 136,261,515 and 135,409,564 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	136	135
Additional paid-in capital	24,496	23,795
Accumulated deficit	(18,613)	(11,934)
<b>Total stockholders' equity</b>	<u>6,019</u>	<u>11,996</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 12,998</u>	<u>\$ 18,716</u>

*See accompanying notes to the condensed consolidated financial statements*

**Spectral MD Holdings, Ltd.**  
**Unaudited Condensed Consolidated Statements of Operations**  
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>Research and development revenue</b>	\$ 4,251	\$ 6,390	\$ 9,329	\$ 12,234
<b>Cost of revenue</b>	(2,460)	(3,678)	(5,357)	(7,132)
<b>Gross profit</b>	1,791	2,712	3,972	5,102
<b>Operating costs and expenses:</b>				
General and administrative	4,781	2,718	9,861	5,729
<b>Total operating costs and expenses</b>	4,781	2,718	9,861	5,729
<b>Operating loss</b>	(2,990)	(6)	(5,889)	(627)
<b>Other income (expense):</b>				
Net interest income (expense)	41	3	86	(1)
Change in fair value of warrant liability	(81)	(38)	(65)	28
Foreign exchange transaction gain (loss)	—	(232)	13	(204)
Transaction costs	—	—	(738)	—
Other income	—	19	—	17
<b>Total other income (expense)</b>	(40)	(248)	(704)	(160)
<b>Loss before income taxes</b>	(3,030)	(254)	(6,593)	(787)
Provision for income taxes	(40)	(11)	(86)	(6)
<b>Net loss</b>	\$ (3,070)	\$ (265)	\$ (6,679)	\$ (793)
<b>Net loss per share of common stock</b>				
Basic and Diluted	\$ (0.02)	\$ (0.00)	\$ (0.05)	\$ (0.01)
<b>Weighted average common shares outstanding</b>				
Basic and Diluted	136,198,713	135,347,064	136,097,641	135,323,279

*See accompanying notes to the condensed consolidated financial statements*

**Spectral MD Holdings, Ltd.**  
**Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity**  
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance at December 31, 2022</b>	135,409,564	\$ 135	\$ 23,795	\$ (11,934)	\$ 11,996
Stock-based compensation	562,500	1	299	—	300
Stock option exercises	104,451	—	—	—	—
Net loss	—	—	—	(3,609)	(3,609)
<b>Balance at March 31, 2023</b>	136,076,515	\$ 136	\$ 24,094	\$ (15,543)	\$ 8,687
Stock-based compensation	125,000	—	396	—	396
Stock options exercise	60,000	—	6	—	6
Net loss	—	—	—	(3,070)	(3,070)
<b>Balance at June 30, 2023</b>	136,261,515	\$ 136	\$ 24,496	\$ (18,613)	\$ 6,019

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance at December 31, 2021</b>	135,034,564	\$ 135	\$ 22,640	\$ (9,022)	\$ 13,753
Stock-based compensation	187,500	—	333	—	333
Net loss	—	—	—	(528)	(528)
<b>Balance at March 31, 2022</b>	135,222,064	\$ 135	\$ 22,973	\$ (9,550)	\$ 13,558
Stock option exercises	150,000	—	—	—	—
Stock-based compensation	187,500	1	293	—	294
Net loss	—	—	—	(265)	(265)
<b>Balance at June 30, 2022</b>	135,559,564	\$ 136	\$ 23,266	\$ (9,815)	\$ 13,587

*See accompanying notes to the condensed consolidated financial statements*

**Spectral MD Holdings, Ltd.**  
**Unaudited Condensed Consolidated Statements of Cash Flows**  
(in thousands)

	Six Months Ended June 30,	
	2023	2022
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6,679)	\$ (793)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation expense	5	6
Stock-based compensation	696	627
Amortization of right-of-use assets	350	251
Change in fair value of warrant liability	65	(28)
Changes in operating assets and liabilities:		
Accounts receivable	774	(431)
Unbilled revenue	527	(681)
Prepaid expenses	(11)	415
Other current assets	(322)	(107)
Other assets	—	40
Accounts payable	(752)	1,587
Accrued expenses	(405)	(548)
Deferred revenue	509	—
Lease liabilities	(284)	(300)
Net cash (used in) provided by operating activities	<u>(5,527)</u>	<u>38</u>
<b>Cash flows from financing activities:</b>		
Payments of deferred offering costs	(306)	—
Payments for notes payable	(175)	(583)
Net cash used in financing activities	<u>(481)</u>	<u>(583)</u>
Net decrease in cash and cash equivalents	<u>(6,008)</u>	<u>(545)</u>
Cash and cash equivalents, beginning of period	14,174	16,121
Cash and cash equivalents, end of period	<u>\$ 8,166</u>	<u>\$ 15,576</u>
<b>Supplemental cash flow information:</b>		
Cash paid for interest	\$ 3	\$ 11
<b>Noncash operating and financing activities disclosure:</b>		
Recognition of Right-of-use assets and related lease liabilities upon adoption of ASC 842	\$ —	\$ 624
Recognition of Right-of-use assets and related lease liabilities upon lease amendment	\$ 483	\$ —
Unpaid deferred offering costs	\$ 818	\$ —
Broker receivable for stock option exercises	\$ 6	\$ —

*See accompanying notes to the condensed consolidated financial statements*

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

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

Spectral MD Holdings, Ltd, (the “Company”), headquartered in Dallas, Texas, was incorporated in Delaware on March 9, 2009. The Company currently trades on the AIM market of the London Stock Exchange (the “AIM”).

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

On April 11, 2023, the Company entered into a Business Combination Agreement (as it may be amended, supplemented or otherwise modified from time to time), by and among Rosecliff Acquisition Corp I (“Rosecliff”), Rosecliff Ghost Merger Sub I Inc. and Ghost Merger Sub II LLC, whereby all of the Company’s shares were exchanged with Rosecliff for 17,000,000 ordinary shares of Rosecliff with an aggregate equity value of \$170.0 million (the “Business Combination”).

Pursuant to the Business Combination Agreement, on the Closing, in sequential order: (a) Ghost Merger Sub I will merge with and into the Company, with the Company continuing as the surviving company as a wholly owned subsidiary of Rosecliff (the “Spectral Merger”) and then, (b) the Company will merge with and into Ghost Merger Sub II (the “SPAC Merger”, together with the Spectral Merger (the “Merger”)), with Ghost Merger Sub II surviving the SPAC Merger as a direct wholly-owned subsidiary of Rosecliff. Ghost Merger Sub II will be renamed Spectral AI, Inc. (the “Combined Company”).

**Liquidity**

As of June 30, 2023 and December 31, 2022, the Company had approximately \$8.2 million and \$14.2 million, respectively, in cash, and an accumulated deficit of \$18.6 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. During 2022, the Company was awarded additional funding of \$8.2 million associated with option 1B of the contract with BARDA. During 2021, the Company executed Options 1A and 1B of the contract with BARDA for funding of \$39.4 million and during 2022 was awarded additional funding of \$8.2 million associated with option 1B, resulting in aggregated funding for Options 1A and 1B of \$47.6 million, of which \$4.1 million is remaining as of June 30, 2023. The BARDA contract funding is to execute the clinical training study of DeepView® Wound Imaging System (“DeepView System”) for burn wound healing assessment. In April, 2023, the Company received a \$4.0 million grant from Medical Technology Enterprise Consortium (“MTEC”) for a project that is expected to be completed by April 2024. The MTEC project is for the development of a handheld device for the DeepView System. See Research and Development Revenue below. In September 2023, the Company issued 7,679,198 shares of common stock for \$3.4 million (the “Equity Raise”). With the remaining funding under the BARDA contract, the MTEC funding and the Equity Raise, the Company believes it will have sufficient working capital to fund operations for at least one year beyond the release date of the condensed consolidated financial statements. Additionally, the contract with BARDA has a potential funding of up to \$96.9 million, in aggregate for Option 1A, 1B and 2, if all future options are executed.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The Company’s condensed 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”).

The accompanying condensed consolidated balance sheet as of June 30, 2023, the condensed consolidated statements of operations and stockholders’ equity for the three and six months ended June 30, 2023 and 2022, and statements of cash flows for the six months ended June 30, 2023 and 2022 are unaudited. The interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

statements and, in management's opinion, include all adjustments consisting of only normal recurring adjustments necessary for the fair statement of the Company's financial position as of June 30, 2023 and its results of operations and cash flows for the three and six months ended June 30, 2023 and 2022. The results of operations for the three and six months ended June 30, 2023 and 2022 are not necessarily indicative of the results to be expected for the full fiscal year or any other period.

These interim condensed consolidated financial statements should be read in conjunction with the Company's annual consolidated financial statements for the year ended December 31, 2022.

Certain reclassifications have been made to prior year financial statements to conform with current year presentation.

**Principles of Consolidation**

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

**Use of Estimates**

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

**Cash and Cash Equivalents**

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

**Accounts Receivable, Net and Unbilled Revenue**

Accounts receivable represent amounts due from US government agencies pursuant to research and development contracts associated with the Company's DeepView<sup>®</sup> Wound Imaging System. Accounts receivable amounted to approximately \$1.5 million and \$2.3 million as of June 30, 2023 and December 31, 2022, respectively.

The Company evaluates the collectability of its receivables based on a variety of factors, including the length of time the receivables are past due, the financial health of its customers and historical experience. Based upon the review of these factors, the Company recorded no allowance for doubtful accounts as of June 30, 2023 and December 31, 2022.

The Company records unbilled revenue when revenue is recognized prior to billing customers. Unbilled revenue amounted to approximately \$0.1 million and \$0.6 million as of June 30, 2023 and December 31, 2022, respectively.

**Concentrations of Credit Risk**

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

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

Additional credit risk is related to the Company's concentration of receivables. As of June 30, 2023 and December 31, 2022, receivables were concentrated from one customer (which is a US. government agency) representing 71% and 96% of total net receivables, respectively. No allowance for doubtful accounts were recorded as of June 30, 2023 and December 31, 2022.

One customer (which is a U.S. government agency) accounted for 95% and 96% for the three and six months ended June 30, 2023, respectively, and 87% and 92%, for the three and six months ended June 30, 2022, respectively, of the recognized research and development revenue.

**Deferred offering costs**

Deferred offering costs consist of legal, accounting and other direct expenses incurred through the balance sheet date that are directly related to the Business Combination and that will be charged to stockholders' equity upon the completion of the Business Combination. Should the Business Combination prove to be unsuccessful these deferred costs, as well as additional expenses to be incurred, will be charged to other expense. Offering costs in excess of proceeds from the Business Combination, if any, will be charged to other expense. As of June 30, 2023, the Company recorded \$1.1 million of deferred offering costs, of which \$0.8 million are unpaid.

**Fair Value**

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

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

**Fair Value of Financial Instruments**

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

**Foreign Currency**

The reporting currency for the condensed consolidated financial statements of the Company is the US dollar. The functional currency of the Company and its wholly owned subsidiary Spectral MD, Inc. is the US dollar. The functional currency of Spectral MD UK is its local currency, the British pound. The assets and liabilities of Spectral MD UK is 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 June 30, 2023 and December 31, 2022, the Company's translation adjustments are not material.



**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

Monetary assets and liabilities denominated in currencies other than the functional currency are translated at exchange rates in effect at the balance sheet date. Resulting unrealized gains and losses are included in other income, net in the condensed consolidated statements of operations. For the three and six months ended June 30, 2023 the Company recorded approximately \$0 and \$13,000, respectively, of foreign exchange transaction gain. For the three and six months ended June 30, 2022, the Company recorded approximately \$0.2 million foreign exchange transaction loss for both periods, primarily related to the Company's bank account denominated in British Pounds and accounts payable denominated in British Pounds, included in foreign exchange transaction loss in the condensed consolidated statements of operations.

**Leases**

The Company accounts for its leases under ASC 842, Leases. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded in the condensed consolidated balance sheets as both a right of use asset and a lease liability, calculated by discounting fixed lease payments 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 elects 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.

For the three and six months ended June 30, 2023 and 2022, the Company did not have any finance leases.

**Warrant Liability**

On June 22, 2021, in conjunction with the closing of the Company's IPO, the Company issued 762,712 warrants, with strike price of \$0.89 and a five-year life, to SP Angel Corporate Finance LLP ("SP Angel"), who acts as nominated adviser and broker to the Company for the purposes of the AIM Rules. As of June 30, 2023, there are 762,712 warrants outstanding with an exchange rate adjusted exercise price of \$0.75.

The Company accounts for its warrants issued to SP Angel as derivative liabilities in accordance with ASC 815, Derivatives and Hedging ("ASC 815"). Accordingly, the Company recognizes the instruments as liabilities at fair value, determined using the Black-Scholes option-pricing model, and adjusts the instruments to fair value at the end of each reporting period. The liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's condensed consolidated statements of operations.

**Research and Development Revenue**

The Company recognizes revenue when the Company's customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services by analyzing the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation. In order to transfer control to the customer for contract development and manufacturing services, the Company must have a present right to payment, legal title must have passed to the customer, and the customer must have the significant

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

risks and rewards of ownership. Research and development revenue contracts are generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with transferring control of the good or service over time.

The Company generates research and development revenue primarily from cost-plus-fee contracts associated with development of certain product candidates. Revenues from reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. The Company uses this input method to measure progress as the customer has the benefit of access to the development research under these projects and therefore benefits from the Company's performance incrementally as research and development activities occur under each project. We consider fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. Revenue for long-term development contracts is considered variable consideration because the deliverable is dependent on the successful completion of development and is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with satisfying the performance obligation over time. The Company was awarded multiyear contracts in 2019 and 2021 (modified for additional funding in 2022) by BARDA for the development of the Company's DeepView<sup>®</sup> Wound Imaging Solution. BARDA may award contracts that are less than 12 months depending on the scope of work and deliverables.

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

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

**Research and Development Expense**

The Company expenses research and development costs as operating expenses as incurred. These expenses include salaries for research and development personnel, consulting fees, product development, pre-clinical studies, clinical trial costs, and other fees and costs related to the development of the technology. For the three months ended June 30, 2023 and 2022, research and development expense was \$3.7 million and \$4.0 million, respectively, of which \$2.5 million and \$3.7 million, respectively, is related to the BARDA contract and included in cost of revenue and \$1.2 million and \$0.3 million, respectively, is included in general and administrative expenses. For the six months ended June 30, 2023 and 2022, research and development expense was \$7.7 million and \$7.9 million, respectively, of which \$5.4 million and \$7.1 million, respectively, is related to the BARDA contract and included in cost of revenue and \$2.3 million and \$0.8 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, restricted stock units ("RSUs"), restricted stock awards ("RSAs") and stock options with non-market performance conditions ("PSOs") to be recognized in the condensed consolidated financial statements, based on their respective grant date fair values. The Company estimates the fair value of stock option grants and PSOs using the Black-Scholes option pricing model. The 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 and stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company expenses stock-based compensation related to stock options, 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.

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

**Income Taxes**

Income taxes are recorded in accordance with ASC 740, Income Taxes (“ASC 740”), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the condensed 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.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company has no uncertain tax positions as of June 30, 2023 and December 31, 2022 that qualify for either recognition or disclosure in the condensed 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 condensed consolidated statements of operations. There were no amounts accrued for interest or penalties for the three and six months ended June 30, 2023 and 2022.

**Comprehensive Loss**

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

**Net Loss per Share of Common Stock**

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

**Recently Adopted Accounting Standards**

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments — Credit Losses, which was subsequently amended by ASU 2018-19 and ASU 2019-10. This standard requires the measurement of expected credit losses for financial instruments carried at amortized cost held at the reporting date based on historical experience, current conditions and reasonable forecasts. The updated guidance also amends the current other-than-temporary impairment model for available-for-sale debt securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security’s amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The Company adopted this standard on January 1, 2023, with no impact on its condensed consolidated financial statements and related disclosures.

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont.)**

**Recently Issued Accounting Standards**

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic 820 “Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions”. The FASB is issuing this update (1) to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. The amendments in this update are effective for the Company on January 1, 2025. 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 condensed consolidated financial statements.

**3. 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 June 30, 2023 and December 31, 2022, by level within the fair value hierarchy (in thousands):

	Fair value measured as of June 30, 2023			
	Fair value at June 30, 2023	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 194	\$ —	\$ —	\$ 194
	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 liability	\$ 129	\$ —	\$ —	\$ 129

There were no transfers between Level 1, 2 or 3 during the three and six months ended June 30, 2023 and 2022.

The following table presents changes in Level 3 liabilities measured at fair value for the three and six months ended June 30, 2023 and 2022 (in thousands).

Balance – January 1, 2023	\$ 129
Change in fair value	(16)
<b>Balance – March 31, 2023</b>	<b>\$ 113</b>
Change in fair value	81
<b>Balance – June 30, 2023</b>	<b>\$ 194</b>
Balance – January 1, 2022	\$ 186
Change in fair value	(66)
<b>Balance – March 31, 2022</b>	<b>\$ 120</b>
Change in fair value	38
<b>Balance – June 30, 2022</b>	<b>\$ 158</b>

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

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**3. FAIR VALUE MEASUREMENTS (cont.)**

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

	<b>June 30, 2023</b>	<b>December 31, 2022</b>
Strike price (per share)	\$ 0.75	\$ 0.71
Contractual term (years)	4.0	4.5
Volatility (annual)	71.2%	72.6%
Risk-free rate	4.1%	4.0%
Dividend yield (per share)	0.0%	0.0%

**4. RESEARCH AND DEVELOPMENT REVENUE**

For the three and six months ended June 30, 2023 and 2022, the Company's revenues disaggregated by the major sources was as follows (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
BARDA	\$ 4,020	\$ 6,255	\$ 8,963	\$ 11,963
Other U.S governmental authorities	231	135	366	271
<b>Total revenue</b>	<b>\$ 4,251</b>	<b>\$ 6,390</b>	<b>\$ 9,329</b>	<b>\$ 12,234</b>

**5. ACCRUED EXPENSES**

Accrued expenses consist of the following as of June 30, 2023 and December 31, 2022 (in thousands):

	<b>June 30, 2023</b>	<b>December 31, 2022</b>
Salary and wages	\$ 1,106	\$ 1,135
Provision operating expenses	414	736
Benefits	790	650
Franchise tax	84	110
<b>Total accrued expenses</b>	<b>\$ 2,394</b>	<b>\$ 2,631</b>

**6. NOTES PAYABLE**

**Insurance Note**

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

During the six months ended June 30, 2023, the Company repaid the remaining balance of approximately \$0.2 million of principal and interest for the 2022 Insurance Note. As of December 31, 2022, the Company had an outstanding balance of \$0.2 million, respectively, for the 2022 Insurance Note.

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**6. NOTES PAYABLE (cont.)**

During the six months ended June 30, 2022, the Company repaid the remaining balance of approximately \$0.2 million, respectively, for the 2021 Insurance Note. There was no outstanding balance for the 2021 Insurance Note as of December 31, 2022.

**PPP Loan**

On April 13, 2020, the Company entered into a promissory note with JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program (“PPP”) of the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) for \$768,575 (the “PPP Loan”). The PPP Loan, which matured on April 13, 2022 and bears interest at 1% per annum, can be prepaid at any time prior to maturity with no prepayment penalties. The Company could defer interest and principal payments until September 13, 2021. Beginning on September 13, 2021, the Company was required to make equal monthly payments of principal and interest until the loan maturity on April 13, 2022. The PPP Loan is subject to customary terms for payment defaults and breaches of representations and warranties. The Company did not request the PPP Loan to be forgiven. During the six months ended June 30, 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.

**7. COMMITMENTS AND CONTINGENCIES**

**Legal Matters**

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. 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.

**8. LEASES**

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 expires 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 three and six months ended June 30, 2023 and 2022 (dollars in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating cash flows from operating leases	\$ 212	\$ 158	\$ 327	\$ 313
Right-of-use assets exchanged for operating lease liabilities	\$ 483	\$ 15	\$ 483	\$ 624
Weighted average remaining lease term – operating leases (in years)	1.5	0.7	1.5	0.7
Weighted average discount rate – operating leases	8.5%	6.7%	8.5%	6.7%

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**8. LEASES (cont.)**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating leases				
Operating lease cost	\$ 198	\$ 132	\$ 392	\$ 264
Variable lease cost	133	49	192	93
Total rent expense	<u>\$ 331</u>	<u>\$ 181</u>	<u>\$ 584</u>	<u>\$ 357</u>

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

As of June 30, 2023, future minimum payments under the non-cancelable operating leases under ASC 842 were as follows (in thousands):

Six months ending December 31, 2023	\$ 417
Year ending December 31, 2024	894
Total	<u>1,311</u>
Less: imputed interest	<u>(86)</u>
Operating lease liabilities	<u>\$ 1,225</u>

**9. STOCKHOLDERS’ EQUITY**

The Company was authorized to issue 400,000,000 shares of common stock, par value \$0.001 per share as of June 30, 2023 and December 31, 2022. The Company had 136,261,515 and 135,409,564 shares of common stock issued and outstanding as of June 30, 2023 and December 31, 2022, respectively.

**10. STOCK-BASED COMPENSATION**

**2018 Long Term Incentive Plan**

On July 24, 2018, the Company’s Board adopted the 2018 Long Term Incentive Plan (the “2018 Plan”) which permits granting of incentive stock options (they must meet all statutory requirements), non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, and other cash-based or stock-based awards. In June 2021, in connection with the IPO, the 2018 Plan was amended so that stock issued pursuant to the 2018 Plan would be the common stock of the Company. Pursuant to the 2018 Plan, stock options must expire within 10 years and must be granted with exercise prices of no less than the fair value of the common stock on the grant date, as determined by the Board of Directors. As of June 30, 2023, 38,354,118 shares of common stock were authorized for issuance under the 2018 Plan, of which 584,952 remain available for issuance.

**2022 Long Term Incentive Plan**

On September 27, 2022, the Company’s stockholders approved the adoption of the 2022 Long Term Incentive Plan (the “2022 Plan”) which permits granting of incentive stock options (they must meet all statutory requirements), non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, and other cash-based or stock-based awards. Pursuant to the 2022 Plan, stock options must expire within 10 years and must be granted with exercise prices of no less than the fair value of the common stock on the grant date, as determined by the Board of Directors. As of June 30, 2023, 20,000,000 shares of common stock were authorized for issuance under the 2022 Plan, of which 18,485,000 remain available for issuance.

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**10. STOCK-BASED COMPENSATION (cont.)**

**Restricted Stock Awards**

The RSAs generally vest over four years. A summary of RSA activities for the six months ended June 30, 2023 are presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share US\$
Nonvested as of January 1, 2023	312,502	\$ 0.10
Vested	(312,502)	\$ 0.10
Nonvested as of June 30, 2023	<u>—</u>	<u>\$ —</u>

**Restricted Stock Units**

The RSUs generally vest over three years. A summary of RSU activities for the six months ended June 30, 2023 are presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share US\$
Nonvested as of January 1, 2023	—	\$ —
Granted	600,000	\$ 0.45
Nonvested as of June 30, 2023	<u>600,000</u>	<u>\$ 0.45</u>

**Stock Options**

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company's common stock became publicly traded on July 22, 2021 and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options for employees has been determined utilizing the simplified method 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 the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

In applying the Black Scholes option pricing model, the Company used the following assumptions for stock options granted in the six months ended June 30, 2023:

	Six Months Ended June 30, 2023
Exercise price (per share)	\$ 0.44
Expected term (years)	6.0
Volatility (annual)	72%
Risk-free rate	3.5%
Dividend yield (per share)	0%



**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**10. STOCK-BASED COMPENSATION (cont.)**

A summary of stock options activity for the six months ended June 30, 2023 is presented below:

	<i>Stock Options</i>	<i>Weighted Average Exercise Price US\$</i>	<i>Weighted Average Remaining Contractual Life (in years)</i>	<i>Aggregate Intrinsic Value (in thousands)</i>
Outstanding at January 1, 2023	36,124,000	\$ 0.20	7.3	\$ 6,831
Options granted	2,511,000	\$ 0.44		
Options forfeited	(163,334)	\$ 0.35		
Options exercised	(220,000)	\$ 0.17		
Options cancelled	(210,000)	\$ 0.19		
Outstanding as of June 30, 2023	<u>38,041,666</u>	\$ 0.21	7.0	\$ 12,426
Options vested and exercisable as of June 30, 2023	<u>30,265,209</u>	\$ 0.17	6.6	\$ 11,244

The Company recorded stock-based compensation expense for stock options and restricted stock of \$0.3 million and \$0.7 million for the three and six months ended June 30, 2023, respectively, and \$0.3 million and \$0.6 million for the three and six months ended June 30, 2022, respectively, in general and administrative expenses in the condensed consolidated statements of operations.

As of June 30, 2023, there was approximately \$1.7 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 1.2 years and 1.3 years, respectively.

During the year ended December 31, 2018, the Company granted of 10,039,926 stock options to investors (the "Investor Options") that were approved by the Board of Directors outside of the 2018 Plan. As of June 30, 2023, 9,681,354 Investor Options are outstanding and will expire in November 2023. The Investor Options have an exercise price of \$0.20 per share. As of June 30, 2023, there is no unrecognized stock-based compensation expense related to the Investor Options.

As of June 30, 2023, the Company has outstanding stock options, issued to an investor, to purchase 210,000 shares of the Company's common stock (the "ASC 815 Options") at a price of \$0.19 per share that expire in December 2023. The ASC 815 Options have a grant date fair value of \$0.21 per share and are equity-classified stock options in accordance with ASC 815.

**11. INCOME TAXES**

The Company recorded a provision for income taxes of approximately \$40,000 and \$86,000 for the three and six months ended June 30, 2023, respectively, and \$11,000 and \$6,000 for the three and six months ended June 30, 2022, respectively. The effective tax rate was 1.3% for the three and six months ended June 30, 2023, and 4.3% and 0.8% for the three and six months ended June 30, 2022, respectively.

The tax provision for interim periods is determined using an estimate of the Company's annual effective tax rate, adjusted for discrete items arising in that quarter. The Company's effective tax rate differs from the U.S. statutory tax rate in the three and six months ended June 30, 2023 primarily due to changes in valuation allowances on deferred tax assets as it is more likely than not that some or all of the Company's deferred tax assets will not be realized.

The Company evaluates its tax positions on a quarterly basis and revises its estimate accordingly. The Company recorded immaterial interest and penalties during the three and six months ended June 30, 2023.

**Spectral MD Holdings, Ltd.**  
**Notes to Unaudited Financial Statements**

**12. NET LOSS PER COMMON SHARE**

Basic and diluted net loss per common share attributable to common stockholders are the same for the three and six months ended June 30, 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	47,933,020	46,163,926
Common stock warrants	762,712	762,712
Unvested restricted stock units	600,000	—
Unvested restricted stock	—	687,502
Potentially dilutive securities	<u>49,295,732</u>	<u>47,614,140</u>

**13. RELATED PARTY TRANSACTIONS**

For the three and six months ended June 30, 2023 and 2022, the Company did not have any transactions with related parties.

**14. SUBSEQUENT EVENTS*****Share Issuances and Business Combination***

In September 2023, prior to the closing of the Business Combination, the Company completed the Equity Raise.

On September 11, 2023 (the "Closing"), the Company consummated the Business Combination with Rosecliff, whereby all of the Company's 137,701,673 shares of common stock and the Equity Issuance common stock were exchanged by Rosecliff for 13,316,464 and 744,667, respectively, ordinary shares of Rosecliff, at an exchange ratio of 10.31.

Pursuant to the Business Combination Agreement, on the Closing, in sequential order: (a) Ghost Merger Sub I merged with and into the Company, with the Company continuing as the surviving company as a wholly owned subsidiary of Rosecliff (the "Spectral Merger") and then, (b) the Company merged with and into Ghost Merger Sub II (the "SPAC Merger", together with the Spectral Merger (the "Merger")), with Ghost Merger Sub II surviving the SPAC Merger as a direct wholly-owned subsidiary of Rosecliff. Rosecliff was renamed Spectral AI, Inc. ("Spectral AI" or the "Combined Company").

In conjunction with the closing, options to purchase 46,592,862 shares of the Company's common stock and 600,000 RSUs were exchanged for options to purchase 4,519,191 shares of Spectral AI's ordinary shares and 58,196 RSUs of Spectral AI. Additionally, the warrants to purchase 762,712 of the Company's common stock were exchanged for warrants to purchase 73,978 ordinary shares of Spectral AI's common stock.

On September 12, 2023, Spectral AI began trading its shares on the NASDAQ stock exchange after delisting its shares from the AIM market of the London Stock Exchange on September 7, 2023.

**UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION**

Defined terms included below and not otherwise defined in this Section have the same meaning as terms defined and included elsewhere in this Current Report on Form 8-K (the “Form 8-K”) filed with the Securities and Exchange Commission (the “SEC”) on September 15, 2023. Unless the context otherwise requires, the “Combined Company” refers to Spectral AI, Inc. (f/k/a Rosecliff Acquisition Corp I, a Delaware corporation) and its consolidated subsidiaries after the Closing, “Spectral” refers to Spectral MD Holdings, Ltd., a Delaware corporation, and “Rosecliff” refers to Rosecliff Acquisition Corp I prior to the Closing.

The following unaudited pro forma condensed combined financial information presents the combination of the financial information of Spectral and Rosecliff adjusted to give effect to the Business Combination and the other events contemplated by the Business Combination Agreement. The following unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X.

The unaudited pro forma condensed combined balance sheet as of June 30, 2023 combines the historical balance sheet of Rosecliff and the historical balance sheet of Spectral, as adjusted for the Pre-Closing Financing further described in Note 2 to the unaudited pro forma condensed combined financial information, on a pro forma basis as if the Business Combination and the other events contemplated by the Business Combination Agreement had been consummated on June 30, 2023. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2023 and the year ended December 31, 2022, combines the historical statement of operations of Rosecliff and Spectral, as adjusted for the Pre-Closing Financing further described in Note 2 to the unaudited pro forma condensed combined financial information, for such periods on a pro forma basis as if the Business Combination and the other events contemplated by the Business Combination Agreement had been consummated on January 1, 2022, the beginning of the earliest period presented.

The pro forma condensed combined financial information may not be useful in predicting the future financial condition and results of operations of the Combined Company. The actual financial position and results of operations may differ significantly from the pro forma amounts reflected herein due to a variety of factors.

Prior to the closing of the Business Combination, Rosecliff public shareholders were offered the opportunity to redeem all or a portion of such shareholder’s public shares for cash equal to their pro rata share of the aggregate amount on deposit (as of two business days prior to the Closing) in the Rosecliff trust account. The unaudited condensed combined pro forma financial information reflects actual redemptions of 178,231 shares of Rosecliff’s Common Stock at approximately \$10.39 per share, or \$1.85 million in the aggregate.

The following summarizes the pro forma ownership interest in the Combined Company immediately after the Business Combination on a fully diluted basis:

	Shares	%
RCLF Public shareholders	280,485	1.0%
RCLF Founders	880,000	3.0%
Spectral common shareholders	14,961,131	51.2%
Other Spectral equityholders	4,651,365	15.9%
RCLF Public Warrants	8,433,333	28.9%
Fully diluted shares outstanding	<u>29,206,314</u>	<u>100.0%</u>

The Business Combination was accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, Rosecliff was treated as the acquired company and Spectral was treated as the acquirer for financial reporting purposes. Accordingly, for accounting purposes, the financial statements of the Combined Company will represent a continuation of the financial statements of Spectral, with the Business Combination treated as the equivalent of Spectral issuing stock for the net assets of Rosecliff, accompanied by a recapitalization. The net assets of Rosecliff will be stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination will be those of Spectral. Spectral was determined to be the accounting acquirer based on an evaluation of the following facts and circumstances:

- Spectral’s existing shareholders have a majority of the voting power of the Combined Company;
- the Combined Company’s board will consist of seven directors, six of whom were designated by Spectral and one of whom was designated by Rosecliff;

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- all of Spectral's existing management will continue in their key positions in the management team of the Combined Company;
- Spectral's relative size of assets and operations compared to Rosecliff; and
- Spectral's operations prior to the Business Combination comprise the ongoing operations.

Assumptions and estimates underlying the unaudited pro forma adjustments set forth in the unaudited pro forma condensed combined financial information are described in the accompanying notes. The unaudited pro forma condensed combined financial information has been presented for illustrative purposes only and is not necessarily indicative of the operating results and financial position that would have been achieved had the Business Combination occurred on the dates indicated, and does not reflect adjustments for any anticipated synergies, operating efficiencies, tax savings or cost savings. Further, the unaudited pro forma condensed combined financial information does not purport to project the future operating results or financial position of the Combined Company following the consummation of the Business Combination. The unaudited pro forma adjustments represent management's estimates based on information available as of the date of the unaudited pro forma condensed combined financial information and are subject to change as additional information becomes available and analyses are performed. Rosecliff and Spectral have not had any historical relationship prior to the transactions discussed in this Form 8-K. Accordingly, no pro forma adjustments were required to eliminate activities between the companies.

**UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET**  
**AS OF JUNE 30, 2023**  
**(In Thousands)**

	Spectral (Historical)	Transaction Accounting Adjustments: Pre-Closing Financing (Note 2)	Spectral (Adjusted)	RCLF (Historical)	Transaction Accounting Adjustments: Business Combination (Note 3)	Pro Forma Combined
<b>ASSETS</b>						
<b>Current assets</b>						
Cash and cash equivalents	\$ 8,166	\$ 3,351	\$ 11,517	\$ 409	\$ 2,874	(a) \$ 7,855
					(750)	(c)
					(3,614)	(d)
					(2,581)	(d)
Accounts receivable, net	1,520	—	1,520	—	—	1,520
Unbilled revenue	91	—	91	—	—	91
Deferred offering costs	1,124	—	1,124	—	(1,124)	(d) —
Prepaid expenses and other current assets	940	—	940	170	—	1,110
<b>Total current assets</b>	<b>11,841</b>	<b>3,351</b>	<b>15,192</b>	<b>579</b>	<b>(5,195)</b>	<b>10,576</b>
Property and equipment, net	16	—	16	—	—	16
Right-of-use assets	1,141	—	1,141	—	—	1,141
Investments held in Trust Account	—	—	—	4,725	(1,851)	(i) —
					(2,874)	(a)
<b>Total assets</b>	<b>\$ 12,998</b>	<b>\$ 3,351</b>	<b>\$ 16,349</b>	<b>\$ 5,304</b>	<b>\$ (9,920)</b>	<b>\$ 11,733</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>						
<b>Current liabilities</b>						
Accounts payable	\$ 2,657	\$ —	\$ 2,657	\$ —	\$ (650)	(d) \$ 2,007
Accrued expenses	2,394	—	2,394	4,995	(168)	(d) 4,307
					(2,914)	(d)
Deferred revenue	509	—	509	—	—	509
Lease liabilities, short-term	773	—	773	—	—	773
Income taxes payable	—	—	—	273	—	273
Due to Sponsor	—	—	—	16	—	16
Warrant liability	194	—	194	—	—	194
<b>Total current liabilities</b>	<b>6,527</b>	<b>—</b>	<b>6,527</b>	<b>5,284</b>	<b>(3,732)</b>	<b>8,079</b>
Lease liabilities, long-term	452	—	452	—	—	452
Deferred underwriting fees payable	—	—	—	8,855	(8,105)	(c) —
					(750)	(c)
Derivative liabilities	—	—	—	788	(282)	(g) 506
<b>Total liabilities</b>	<b>6,979</b>	<b>—</b>	<b>6,979</b>	<b>14,927</b>	<b>(12,869)</b>	<b>9,037</b>
<b>Commitments and contingencies</b>						
Class A ordinary shares subject to possible redemption	—	—	—	4,854	(1,851)	(i) —
					(3,003)	(b)
<b>Stockholders' equity (deficit)</b>						
Common stock	—	—	—	—	—	(b) 1
					—	(d)
					—	(d)
					—	(h)
			—		1	(f)
Class B common stock	—	—	—	1	(1)	(h) —
Common stock, Spectral	136	8	144	—	(144)	(f) —
Additional paid-in capital	24,496	3,343	27,839	—	3,003	(b) 31,021
					8,105	(c)
					(2,874)	(d)
					8,667	(d)
					333	(d)
					(14,478)	(e)
					1	(h)
					143	(f)
					282	(g)

Accumulated deficit	(18,613)	—	(18,613)	(14,478)	(9,713)	<b>(d)</b>	(28,326)
			—		14,478	<b>(e)</b>	
Total stockholders equity (deficit)	6,019	3,351	9,370	(14,477)	7,803		2,696
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 12,998</b>	<b>\$ 3,351</b>	<b>\$ 16,349</b>	<b>\$ 5,304</b>	<b>\$ (9,920)</b>		<b>\$ 11,733</b>

**UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS  
FOR THE SIX MONTHS ENDED JUNE 30, 2023  
(In Thousands, Except Share and Per Share Amounts)**

	Spectral (Historical)	Accounting Adjustments: Pre-Closing Financing (Note 2) (Historical)	Spectral (Adjusted)	RCLF (Historical)	Transaction Accounting Adjustments (Note 3)	Pro Forma Combined
Research and development revenue	\$ 9,329	\$ —	\$ 9,329	\$ —	\$ —	\$ 9,329
Cost of revenue	(5,357)	—	(5,357)	—	—	(5,357)
Gross Profit	3,972	—	3,972	—	—	3,972
<b>Operating costs and expenses:</b>						
General and administrative	9,861	—	9,861	2,003	(60) (aa)	11,804
Total costs and expenses	9,861	—	9,861	2,003	(60)	11,804
<b>Operating loss</b>	(5,889)	—	(5,889)	(2,003)	60	(7,832)
<b>Other income (expense)</b>						
Interest income on investments held in Trust Account	—	—	—	99	(99) (bb)	—
Change in fair value of derivative warrant liabilities	(65)	—	(65)	(394)	141 (cc)	(318)
Interest expense	86	—	86	—	—	86
Foreign exchange transaction loss	13	—	13	—	—	13
Transaction costs	(738)	—	(738)	—	—	(738)
Total other income (expense)	(704)	—	(704)	(295)	42	(957)
<b>Income (loss) before provision for income taxes</b>						
Provision for income taxes	(6,593)	—	(6,593)	(2,298)	102	(8,789)
Provision for income taxes	86	—	86	18	—	104
<b>Net income (loss)</b>	<u>\$ (6,679)</u>	<u>\$ —</u>	<u>\$ (6,679)</u>	<u>\$ (2,316)</u>	<u>\$ 102</u>	<u>\$ (8,893)</u>
<b>Weighted average Spectral common stock outstanding, basic and diluted</b>						
	136,097,641	7,679,198	143,776,839			
<b>Basic and diluted net loss per Spectral common stock</b>						
	\$ (0.05)		\$ (0.05)			
<b>Weighted average Common Stock outstanding, basic and diluted</b>						
						16,121,616
<b>Basic and diluted net loss per Common Stock share</b>						
						\$ (0.55)
<b>Weighted average Class A common stock outstanding, basic and diluted</b>						
						458,716
<b>Basic and diluted net loss per Class A common stock share</b>						
						\$ (0.34)
<b>Weighted average Class B common stock outstanding, basic and diluted</b>						
						6,325,000
<b>Basic and diluted net loss per Class B common stock share</b>						
						\$ (0.34)

**UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS  
FOR THE YEAR ENDED DECEMBER 31, 2022  
(In Thousands, Except Share and Per Share Amounts)**

	Spectral (Historical)	Transaction Accounting Adjustments: Pre-Closing Financing (Note 2) (Historical)	Spectral (Adjusted)	RCLF (Historical)	Transaction Accounting Adjustments (Note 3)	Pro Forma Combined
Research and development revenue	\$ 25,368	\$ —	\$ 25,368	\$ —	\$ —	\$ 25,368
Cost of revenue	(14,531)	—	(14,531)	—	—	(14,531)
Gross Profit	10,837	—	10,837	—	—	10,837
<b>Operating costs and expenses:</b>						
General and administrative	13,484	—	13,484	1,251	(120) (aa)	14,615
Total costs and expenses	13,484	—	13,484	1,251	(120)	14,615
<b>Operating loss</b>	(2,647)	—	(2,647)	(1,251)	120	(3,778)
<b>Other income (expense)</b>						
Interest income on investments held in Trust Account	—	—	—	3,156	(3,156) (bb)	—
Change in fair value of derivative warrant liabilities	57	—	57	9,748	(3,508) (cc)	6,297
Net interest income	21	—	21	—	—	21
Foreign exchange transaction loss	(253)	—	(253)	—	—	(253)
Other income (expense)	16	—	16	—	(9,713) (dd)	(9,697)
Total other income (expense)	(159)	—	(159)	12,904	(16,377)	(3,632)
<b>Income (loss) before provision for income taxes</b>	(2,806)	—	(2,806)	11,653	(16,257)	(7,410)
Provision for income taxes	106	—	106	614	—	720
<b>Net income (loss)</b>	<u>\$ (2,912)</u>	<u>\$ —</u>	<u>\$ (2,912)</u>	<u>\$ 11,039</u>	<u>\$ (16,257)</u>	<u>\$ (8,130)</u>
<b>Weighted average Spectral common stock outstanding, basic and diluted</b>						
	135,442,441	7,679,198	143,121,639			
<b>Basic and diluted net loss per Spectral common stock</b>						
	\$ (0.02)			\$ (0.02)		
<b>Weighted average Class Common Stock outstanding, basic and diluted</b>						
	16,121,616					
<b>Basic and diluted net loss per Common Stock share</b>						
	\$ (0.50)					
<b>Weighted average Class A common stock outstanding, basic and diluted</b>						
	25,095,264					
<b>Basic and diluted net income per Class A common stock share</b>						
	\$ 0.35					
<b>Weighted average Class B common stock outstanding, basic and diluted</b>						
	6,325,000					
<b>Basic and diluted net income per Class B common stock share</b>						
	\$ 0.35					



**NOTES TO UNAUDITED PRO FORMA  
CONDENSED COMBINED FINANCIAL STATEMENTS**

**1. Basis of Presentation**

The Business Combination was accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, Rosecliff was treated as the “acquired” company for financial reporting purposes. Accordingly, for accounting purposes, the financial statements of the Combined Company will represent a continuation of the financial statements of Spectral, and the Business Combination was treated as the equivalent of Spectral issuing stock for the net assets of Rosecliff, accompanied by a recapitalization. The net assets of Rosecliff will be stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination will be those of Spectral.

The unaudited pro forma condensed combined balance sheet as of June 30, 2023 gives pro forma effect to the Business Combination and other events contemplated by the Business Combination Agreement as if they had been consummated on June 30, 2023. The unaudited pro forma condensed combined statements of operations for the six months ended June 30, 2023 and for the year ended December 31, 2022, give pro forma effect to the Business Combination and the other events contemplated by the Business Combination Agreement as if they had been consummated on January 1, 2022.

The unaudited pro forma condensed combined financial information and accompanying notes have been derived from and should be read in conjunction with:

- the historical audited financial statements of Rosecliff as of and for the year ended December 31, 2022 and the related notes, which are included in Rosecliff’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 31, 2023 (the “Rosecliff 2022 10-K”);
- the historical unaudited financial statements of Rosecliff as of and for the six months ended June 30, 2023 and the related notes, which are included in Rosecliff’s Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023 (the “Rosecliff 2023 10-Q”);
- the historical audited financial statements of Spectral as of and for the year ended December 31, 2022 and the related notes, which are included in the Proxy Statement/Prospectus; and
- the historical unaudited financial statements of Spectral as of and for the six months ended June 30, 2023 and the related notes, which are included elsewhere in this Form 8-K.

Management has made significant estimates and assumptions in its determination of the pro forma adjustments. As the unaudited pro forma condensed combined financial information has been prepared based on these preliminary estimates, the final amounts recorded when accounting for the Business Combination may differ materially from the information presented.

The unaudited pro forma condensed combined financial information does not give effect to any synergies, operating efficiencies, tax savings or cost savings that may be associated with the Business Combination.

The pro forma adjustments reflecting the consummation of the Business Combination are based on currently available information as of the date of this Form 8-K and certain assumptions and methodologies that management believes are reasonable under the circumstances. The unaudited condensed pro forma adjustments, which are described in these notes, may be revised when accounting for the Business Combination as additional information becomes available and is evaluated. Therefore, the actual adjustments may materially differ from the pro forma adjustments that appear in this Form 8-K. The unaudited pro forma condensed combined financial information does not reflect the income tax effects of the pro forma adjustments as based on the statutory rate in effect for the historical periods presented, as management believes income tax adjustments to not be meaningful given the combined entity incurred significant losses during the historical periods presented. Management considers this basis of presentation to be reasonable under the circumstances.

**NOTES TO UNAUDITED PRO FORMA  
CONDENSED COMBINED FINANCIAL STATEMENTS**

**2. Transaction Accounting Adjustments to Unaudited Pro Forma Condensed Combined Financial Information Related to the Pre-Closing Financing**

Prior to the closing of the Business Combination Agreement, Spectral entered into Subscription Agreements (the “Subscription Agreements”) with certain “qualified institutional buyers” (as defined in Rule 144A under the Securities Act of 1933, as amended (the “Securities Act”)) and accredited investors (together, the “Spectral Investors”), pursuant to which the Spectral Investors subscribed for and purchased, and Spectral issued and sold to the Spectral Investors, an aggregate of 7,679,198 shares of Spectral common stock that converted into shares of Common Stock at the applicable exchange ratio under the Business Combination Agreement, for aggregate gross proceeds of \$3,351,000 (the “Pre-Closing Financing”). The offer and sale of the shares of Spectral common stock issued in the Pre-Closing Financing pursuant to the Subscription Agreements have not been registered under the Securities Act in reliance upon the exemption provided in Section 4(a)(2) of the Securities Act. Spectral granted the Spectral Investors certain registration rights in connection with the Pre-Closing Financing.

**3. Transaction Accounting Adjustments to Unaudited Pro Forma Condensed Combined Financial Information Related to the Business Combination**

***Transaction Accounting Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet***

The transaction accounting adjustments related to the Business Combination included in the unaudited pro forma condensed combined balance sheet as of June 30, 2023 are as follows:

- (a) Reflects the liquidation and reclassification of cash and investments held in the Trust Account.
- (b) Reflects the transfer of Rosecliff’s Class A common shares subject to possible redemptions to permanent equity.
- (c) Reflects the settlement of \$0.8 million of deferred underwriting fee payable and the reversal of \$8.1 million in deferred underwriting fees as the underwriters have agreed to waive this portion of the fees. The reversal of the deferred underwriting fees was reflected as an increase to additional paid-in capital.
- (d) Represents transaction costs incurred by Spectral and Rosecliff of \$12.6 million and \$2.9 million, respectively, for legal, financial advisory and other professional fees. Rosecliff’s transaction costs exclude the deferred underwriting fees as described in Note 3(c) above.

*For the Spectral transaction costs:*

- \$0.7 million and \$0.2 million were capitalized in deferred offering costs and accrued in accounts payable and accrued expenses, respectively, as of June 30, 2023;
- \$0.3 million was capitalized in deferred offering costs and paid as of June 30, 2023;
- \$3.6 million was reflected as a reduction of cash, which represents Spectral’s transaction costs less amounts previously paid by Spectral as of June 30, 2023 and amounts settled in Common Stock;
- \$8.7 million was settled through the issuance of 866,667 shares of Common Stock and reflected as an increase of Common Stock and additional paid-in capital;
- \$2.9 million was capitalized and offset against the proceeds of the Business Combination and reflected as a reduction to additional paid in capital; and

**NOTES TO UNAUDITED PRO FORMA  
CONDENSED COMBINED FINANCIAL STATEMENTS**

**3. Transaction Accounting Adjustments to Unaudited Pro Forma Condensed Combined Financial Information Related to the Business Combination (cont.)**

- \$9.7 million was not capitalized as part of the Business Combination and reflected as an increase in accumulated deficit. The costs expensed through accumulated deficit, which are in excess of the proceeds of the transaction and are included in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2022 as discussed in Note (dd) below.

*For the Rosecliff transaction costs:*

- \$2.6 million was reflected as a reduction of cash and the settlement of amounts previously expensed and accrued by Rosecliff as of June 30, 2023; and
  - \$0.3 million was reflected as an issuance of 33,333 shares of Common stock and the settlement of amounts previously expensed and accrued by Rosecliff as of June 30, 2023.
- (e) Reflects the elimination of Rosecliff's accumulated deficit after recording the transaction costs incurred by Rosecliff as described in Note 3(d) above.
- (f) Reflects the recapitalization of Spectral's equity as a result of the Business Combination for the issuance of 14,494,964 shares of Common Stock.
- (g) Reflects the forfeiture of 4,706,667 Private Placement Warrants held by the Sponsor immediately prior to the Business Combination pursuant to the Sponsor Letter Agreement.
- (h) Reflects the forfeiture of 5,445,000 Class B shares, with a par value of \$0.0001, held by the Sponsor immediately prior to the Business Combination in accordance with the Sponsor Agreement, and the conversion of the remaining 880,000 Class B common stock to Common Stock.
- (i) Reflects the actual redemptions prior to the Closing of 178,231 shares of Rosecliff's Common Stock at \$10.39 per share, or \$1.9 million in the aggregate.

***Transaction Accounting Adjustments to Unaudited Pro Forma Condensed Combined Statements of Operations***

The transaction accounting adjustments related to the Business Combination are included in the unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2023 and the year ended December 31, 2022 are as follows:

- (aa) Represents pro forma adjustment to eliminate historical expenses related to Rosecliff's administrative service agreement with the Sponsor, which was terminated upon consummation of the Business Combination.
- (bb) Reflects an adjustment to eliminate interest and investment income related to the Rosecliff trust account.
- (cc) Reflects the change in fair value of \$0.1 million for the six months ended June 30, 2023 and \$3.5 million for the year ended December 31, 2022 related to the Private Placement Warrants that were forfeited by the Sponsor upon the consummation of the Business Combination.
- (dd) Represents Spectral transaction costs expensed as part of the Business Combination, which includes transaction costs in excess of the proceeds received in the Business Combination and amounts allocated to the Rosecliff Public Warrants assumed as part of the Business Combination. These costs are reflected as if incurred on January 1, 2022, the date the Business Combination is deemed to have occurred for the purposes of the unaudited pro forma condensed combined statements of operations. This is a non-recurring item.

**NOTES TO UNAUDITED PRO FORMA  
CONDENSED COMBINED FINANCIAL STATEMENTS**

**4. Net Tangible Assets**

The computation of the pro forma net tangible assets is as follows:

Stockholders' deficit	\$ 2,696
Proforma net tangible assets	<u>\$ 2,696</u>

Although net tangible assets are less than the \$5,000,001 threshold, the Company completed the Business Combination.

**5. Net Loss per Share**

Represents the net loss per share calculated using the historical basic and diluted weighted average shares of Spectral exchanged common shares outstanding, and the issuance of additional shares in connection with the Business Combination and other related events, assuming the shares were outstanding since January 1, 2022. As the Business Combination and other related events are being reflected as if they had occurred at the beginning of the period presented, the calculation of weighted average shares outstanding for basic and diluted net loss per share assumes that the shares issuable in connection with the Business Combination have been outstanding for the entire period presented. No warrants stock options or unvested restricted stock units were included in the earnings per share calculation as they would be anti-dilutive.

	<b>Six Months Ended June 30, 2023</b>	<b>Year Ended December 31, 2022</b>
<b>Numerator</b>		
Pro forma net loss	\$ (8,893)	\$ (8,130)
<b>Denominator</b>		
<b>Pro forma weighted-average Common Stock outstanding – basic and diluted</b>	<u>16,121,616</u>	<u>16,121,616</u>
Basic and diluted net loss per share of Common Stock	<u>\$ (0.55)</u>	<u>\$ (0.50)</u>

Basic and diluted loss per share are the same for both the six months ended June 30, 2023 and the year ended December 31, 2022 as the Combined Company had a loss for those periods.

The following outstanding shares of common stock equivalents are excluded from the computation of pro forma diluted net loss per share for all the periods and scenarios presented because including them would have an anti-dilutive effect.

	<b>Six Months Ended June 30, 2023</b>	<b>Year Ended December 31, 2022</b>
Rosecliff public warrants	8,433,333	8,433,333
Spectral warrants	73,978	73,978
Spectral stock options	4,519,191	4,519,191
Spectral unvested restricted stock units	58,196	58,196
<b>Total</b>	<u>13,084,698</u>	<u>13,084,698</u>

**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions.

	<b>Amount</b>
Securities and Exchange Commission registration fee	\$ 5,444.20
Accountants' fees and expenses	\$ 5,000
Legal fees and expenses	\$ 25,000
Miscellaneous	\$ 2,500
Total expenses	<u>\$ 37,944.20</u>

**Item 14. Indemnification of Directors and Officers.**

Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our Charter provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

Our Charter provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our Charter provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit

or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of Common Stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

#### **Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

##### ***(a) Issuance of Capital Stock.***

On February 17, 2021, simultaneously with the consummation of the RCLF IPO, RCLF completed a private placement of warrants to the Sponsor at a price of \$1.50 per warrant, raising total gross proceeds of \$7.06 million. In connection with the Business Combination and pursuant to that certain Sponsor Letter Agreement dated September 11, 2023, the Sponsor agreed to forfeit all of the Private Placement Warrants for no consideration.

Prior to the Closing, Legacy Spectral entered into Subscription Agreements with certain "qualified institutional buyers" (as defined in Rule 144A under the Securities Act and accredited investors (together, the "Legacy Spectral Investors"), pursuant to which the Legacy Spectral Investors subscribed for and purchased, and Legacy Spectral issued and sold to the Legacy Spectral Investors, shares of Legacy Spectral common stock that converted into shares of Common Stock at the applicable exchange ratio under the Business Combination Agreement, for aggregate gross proceeds of \$3,351,000.

**Item 16. Exhibits and Financial Statement Schedules.**

**Exhibits and Financial Statement Schedules**

**Exhibit Index**

<b>Exhibit Number</b>	<b>Description</b>
2.1†**	<a href="#">Business Combination Agreement, by and among Rosecliff Acquisition Corp I, Merger Sub I, Merger Sub II and Spectral MD Holdings, Ltd., dated as of April 11, 2023 (incorporated by reference to Annex A of the Registration Statement on Form S-4 (File No. 333-271566)).</a>
3.1**	<a href="#">Second Amended and Restated Certificate of Incorporation of Spectral AI, Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).</a>
3.2**	<a href="#">Amended and Restated Bylaws of Spectral AI, Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).</a>
4.1**	<a href="#">Warrant Agreement, dated February 11, 2021, between Rosecliff Acquisition Corp I and Continental Stock Transfer &amp; Trust Company, as warrant agent (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 17, 2021)</a>
4.2**	<a href="#">Description of the Registrant's Securities (incorporated by reference to the Registrant's Annual Report on Form 10-K filed on March 31, 2022)</a>
4.3**	<a href="#">Amended and Restated Registration Rights &amp; Lock-up Agreement (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).</a>
5.1	<a href="#">Opinion of Reed Smith LLP</a>
10.1**	<a href="#">Form of Indemnification Agreement (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on September 15, 2023).</a>
10.2**	<a href="#">Sponsor Warrants Purchase Agreement, dated February 11, 2021, between the Company and the Sponsor (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 17, 2021)</a>
10.3**	<a href="#">BARDA Award/Contract, July 1, 2019, by and between Spectral MD, Inc. and ASPR-BARDA (incorporated by reference to Exhibit 10.14 of the Registration Statement on Form S-4 (File No. 333-271566)).</a>
10.4**	<a href="#">Amendment of the Solicitation/Modification of the BARDA Contract, dated August 26, 2023, by and between Spectral MD, Inc. and ASPR-BARDA (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form S-4 (File No. 333-271566)).</a>
10.5**	<a href="#">Award/Contract for DHA, dated July 1, 2021, by and between Spectral MD, Inc. and U.S. Army Medical Materiel Development Activity (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form S-4 (File No. 333-271566)).</a>
10.6**	<a href="#">Amendment of the Solicitation/Modification of the DHA Contract, dated July 1, 2021, by and between Spectral MD, Inc. and U.S. Army medical Materiel Development Activity (incorporated by reference to Exhibit 10.17 of the Registration Statement on Form S-4 (File No. 333-271566)).</a>
10.7**	<a href="#">MTEC Research Project Award, dated April 12, 2023, by and between Spectral MD, Inc. and Advanced Technology International MTEC Consortium Manager (incorporated by reference to Exhibit 10.18 of the Registration Statement on Form S-4 (File No. 333-271566)).</a>
10.8**	<a href="#">Sponsor Letter Agreement, dated April 11, 2023, by and among Rosecliff Acquisition I Sponsor LLC, Spectral MD Holdings, Ltd., and Rosecliff Acquisition Corp I (incorporated by reference to Annex F of the Registration Statement on Form S-4 (File No. 333-271566)).</a>
23.1	<a href="#">Consent of Reed Smith LLP (included in Exhibit 5.1)</a>
24.1	<a href="#">Power of Attorney (included on signature page to this registration statement)</a>
107	<a href="#">Calculation of Filing Fee Table</a>

\*\* Previously filed.

† Schedules to this Exhibit have been omitted pursuant to Regulation S-K Item 601(a)(5) promulgated under the Exchange Act. The Registrant agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes:

- (1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act; (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (i), (ii) and (iii) do not apply if the registration statement is on Form S-1 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement;
- (2) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;
- (3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;
- (4) that, for the purpose of determining liability under the Securities Act to any purchaser:

Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use; and
- (5) that, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (a) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;



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- (b) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (c) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of an undersigned registrant; and
- (d) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Dallas, Texas, on the 30<sup>th</sup> day of October, 2023.

**SPECTRAL AI, INC.**

By: /s/ Wensheng Fan

Name: Wensheng Fan

Title: Chief Executive Officer

**POWER OF ATTORNEY**

Each person whose signature appears below hereby constitutes and appoints Wensheng Fan and Nils Windler his, her or their true and lawful attorney-in-fact, with full power of substitution and resubstitution for such person and in his name, place and stead, in any and all capacities to sign any and all amendments including post-effective amendments to this registration statement and any and all registration statements filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following person in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Wensheng Fan</u> Wensheng Fan	Director and Chief Executive Officer <i>(Principal Executive Officer)</i>	October 30, 2023
<u>/s/ Nils Windler</u> Nils Windler	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	October 30, 2023
<u>Michael P. Murphy</u>	Director	October 30, 2023
<u>/s/ Cynthia Cai</u> Cynthia Cai	Director	October 30, 2023
<u>/s/ Richard Cotton</u> Richard Cotton	Chairman of the Board of Directors	October 30, 2023
<u>/s/ Martin Mellish</u> Martin Mellish	Director	October 30, 2023
<u>/s/ Deepak Sadagopan</u> Deepak Sadagopan	Director	October 30, 2023

Reed Smith LLP  
599 Lexington Avenue  
New York, NY 10022-7650  
+1 212 521 5400  
Fax +1 212 521 5450  
reedsmith.com



October 27, 2023

Spectral AI, Inc.  
2515 McKinney Avenue  
Suite 1000  
Dallas, TX 75201

Ladies and Gentlemen:

We have acted as counsel to Spectral AI, Inc. (f/k/a Rosecliff Acquisition Corp I), a Delaware corporation (the “**Company**”), in connection with the preparation and filing by the Company with the Securities and Exchange Commission (the “**Commission**”) of a registration statement on Form S-1 (the “**Registration Statement**”) and the related prospectus relating to the registration under the Securities Act of 1933, as amended (the “**Securities Act**”) of (A) the issuance of up to 8,433,231 shares of our Class A common stock, par value \$0.0001 per share (the “**Common Stock**”) that are issuable upon the exercise of 8,433,231 warrants (the “**Warrants**,” and such shares issuable upon exercise of the Warrants, the “**Warrant Shares**”), which were originally issued in connection with Rosecliff Acquisition Corp I’s (“**RCLF**”) initial public offering and (B) the offer and resale from time to time by the selling stockholders named in the Registration Statement or their permitted transferees of (i) up to 10,069,748 shares of Common Stock (the “**Selling Stockholder Shares**”), which consists of (a) up to 8,623,081 shares of Common Stock issued in connection with closing of the business combination between the Company and RCLF described in the prospectus included in the Registration Statement (the “**Business Combination**”), (b) up to 880,000 shares of Common Stock that were originally issued to Rosecliff Acquisition Sponsor I LLC (the “**Sponsor**”) and each independent director of RCLF (together with the Sponsor, the “**Initial Holders**”), and (c) up to 566,667 shares of Common Stock that were issued to certain service providers of the Company in connection with the closing of the Business Combination.

This opinion letter is being furnished in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act.

We have reviewed originals or copies of (a) the Registration Statement, (b) the Company’s certificate of incorporation and bylaws, each as currently in effect, (c) that certain Warrant Agreement, dated February 17, 2021, by and between Continental Stock Transfer & Trust Company (the “**Warrant Agent**”) and the Company (the “**Warrant Agreement**”), (d) the Amended and Restated Registration Rights & Lock-Up Agreement, dated September 11, 2023, by and between the Sponsor, the Company, and each holder thereto (the “**Registration Rights Agreement**”), (e) the Sponsor Letter Agreement, dated April 11, 2023, by and between the Sponsor, Spectral MD Holdings, Ltd. and RCLF (the Warrant Agreement, Registration Rights Agreement, and Sponsor Letter Agreement collectively referred to herein as the “**Transaction Documents**”), and such other corporate records, agreements and documents of the Company, certificates or comparable documents of public officials and officers of the Company and have made such other investigations as we have deemed necessary as a basis for the opinions set forth below.

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In rendering the opinion set forth below, we have assumed:

- a. the genuineness of all signatures;
- b. the legal capacity of natural persons;
- c. the authenticity of all documents submitted to us as originals;
- d. the conformity to original documents of all documents submitted to us as duplicates or conformed copies; and
- e. as to matters of fact, the truthfulness of the representations and warranties made or to be made (as applicable) by the parties to the Transaction Documents and the truthfulness of the representations made in certificates or comparable documents of public officials and officers of the Company.

We have not independently established the validity of the foregoing assumptions.

Based upon the foregoing, and subject to the qualifications, assumptions and limitations stated herein, we are of the opinion that:

1. The Warrants, assuming the due authorization, execution and delivery of the Warrant Agreement and the Warrants by the Warrant Agent, constitute the legal, valid, and binding obligations of the Company, enforceable against the Company in accordance with their terms, under the laws of the State of New York, subject to applicable bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally, and subject, as to enforceability, to general principles of equity, including principles of commercial reasonableness, good faith and fair dealing (regardless of whether enforcement is sought in a proceeding at law or in equity).
2. The Warrant Shares, when issued and paid for upon exercise of the Warrants in accordance with the terms of the Warrants, will be validly issued, fully paid, and nonassessable.
3. The Selling Stockholder Shares, other than the Warrant Shares, are validly issued, fully paid and non-assessable.

The opinions stated herein are subject to the qualifications that we express no opinion as to the applicability of, compliance with, or effect of (i) public policy considerations which may limit the rights of parties to obtain certain remedies, (ii) any provision waiving the right to object to venue in any court; and (iii) any agreement to submit to the jurisdiction of any federal court.

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Our opinion is limited to the General Corporation Law of the State of Delaware and the laws of the State of New York (the “**Opined-on Law**”) and we do not express any opinion herein concerning any other law. We advise you that issues addressed by this letter may be governed in whole or in part by other laws, but we express no opinion as to whether any relevant difference exists between the laws upon which our opinions are based and any other laws which may actually govern. This opinion letter speaks only as of its date.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Registration Statement and to the use of our name under the caption “Legal Matters” in the prospectus forming part of the Registration Statement and any amendments thereto. In giving such consent, we do not hereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act, and the rules and regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ REED SMITH LLP

Reed Smith LLP

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## Calculation of Filing Fee Table

Form S-1  
(Form Type)Spectral AI, Inc.  
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered (1)	Proposed Maximum Offering Price Per Share	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial effective date	Filing Fee Previously Paid In Connection with
											Unsold Securities to be Carried Forward
<b>Newly Registered Securities</b>											
<b>Primary Offering</b>											
Fees to be Paid	Equity	Common Stock Underlying Warrants	457(c)	8,433,231 <sup>(2)</sup>	\$ 2.67 <sup>(3)</sup>	\$22,616,726.80	0.00014760	\$ 3,338.29 <sup>(4)</sup>			
<b>Secondary Offering</b>											
	Equity	Common Stock	457(c)	10,069,748 <sup>(2)</sup>	\$ 2.67 <sup>(3)</sup>	\$26,886,227.20	0.00014760	\$ 3,968.41 <sup>(4)</sup>			
Fees Previously Paid	-	-	-	-	-	-	-	-			
<b>Carry Forward Securities</b>											
Carry Forward Securities	-	-	-	-	-	-	-	-			
<b>Total Offering Amounts</b>							\$ 7,306.70				
<b>Total Fees Previously Paid</b>							-				
<b>Total Fee Offsets</b>							-				
<b>Net Fee Due</b>							<u>\$ 7,306.70</u>				

(1) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended (the "Securities Act"), there are also being registered an indeterminable number of additional securities as may be issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Represents the sum of (a) up to 8,623,081 shares of Class A common stock, par value \$0.0001 per share ("Common Stock") issued in connection with the closing (the "Closing") of the Business Combination (the "Business Combination"), (b) up to 880,000 shares of Common Stock that were originally issued to Rosecliff Acquisition Sponsor I LLC (the "Sponsor") and the independent directors of Rosecliff Acquisition Corp I ("RCLF," and together with the Sponsor, the "Initial Holders") in the form of founder shares prior to the RCLF's initial public offering (the "RCLF IPO"), and (c) up to 566,667 shares of Common Stock that were issued to certain service providers of the Company in connection with the Closing, in each case, as further described in the prospectus forming part of this registration statement.

(3) Estimated solely for the purpose of calculating the registration fee, based on the average of the high and low prices of the Common Stock on the Nasdaq Stock Market LLC ("Nasdaq") on October 24, 2023 (\$2.67 per share), in accordance with Rule 457(c) of the Securities Act.

(4) Calculated pursuant to Rule 457 of the Securities Act by multiplying the proposed maximum aggregate offering price of securities to be registered by 0.00014760.