APPENDIX 4E (RULE 4.3A)

FINAL REPORT FOR THE YEAR ENDED 31 DECEMBER 2024

31 DECEMBER 2024 RESULTS FOR ANNOUNCEMENT TO THE MARKET

(All comparisons to year ended 31 December 2023)

	$USD	up/down	% movement
Revenue from ordinary activities	Nil	Nil	Nil
Loss after tax from ordinary activities attributable to members	($40,798,272)	Up	16.4%
Loss after tax attributable to members	($40,798,272)	Up	16.4%

Dividend information

	Amount per security $USD	Franked amount per security $USD	Tax rate for franking credit
Dividend	Nil	Nil	N/A
Previous corresponding dividend	Nil	Nil	N/A

Net tangible asset backing

	31 Dec 2024 $USD	31 Dec 2023 $USD
Net tangible asset per share of common stock	$0.07	$0.10
Net tangible asset per CDI	$0.07	$0.10

- **Annual financial results:**
  This report is based on the accompanying Consolidated Financial Statements for the twelve-month period ended 31 December 2024, which have been audited by Deloitte & Touche LLP with the Independent Auditor's Report included in the Consolidated Financial Statements.

- **Changes in control over entities:**
  There were no entities over which control has been gained or lost during 2024.

- **Details of dividends and dividend reinvestment plans:**
  No dividends have been declared or proposed.

- **Details of associates or joint ventures:**
  N/A

- **Set of accounting standards used in compiling the report:**
  The audited consolidated financial statement have been prepared in accordance with accounting principles generally accepted in the U.S. (US GAAP) and are denominated in U.S. dollars.

- **Details of audit disputes or audit qualification:**
  None.

A commentary on the results for the period:

The net loss for the twelve-month period ended 31 December 2024 increased to $40,798,272 compared to $35,036,888 for the previous corresponding period. The increase was primarily due to an increase in general and administrative expenses and interest expense in 2024. General and administrative expenses increased by $3,850,68 primarily due to an increase in professional fees resulting from higher audit, legal, regulatory, and tax-related services in connection with preparation for our filing of a registration statement on Form 10, as well as due to an increase in personnel-related expenses, as a result of the expansion of our workforce to support our business needs. Interest expense increased by $1,545,937 million, which resulted from an additional $20.0 million in borrowings during the twelve-month period ended 31 December 2023.

The Company had cash, cash equivalents, and marketable securities of $65,967,907 at 31 December 2024 compared to $73,440,580 at 31 December 2023.

The Company operated in one segment only during the period and there were no returns to shareholders or share buy backs.

Please refer to our audited consolidated financial statements, with accompanying notes, which are attached hereto.

Annual Meeting of Stockholders:

The Annual General Meeting of stockholders will be held as a virtual meeting on Thursday, 22 May 2025 at 9:00am Australian Eastern Standard Time (Wednesday, 21 May 2025 at 4:00pm U.S. Pacific Daylight Time).

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

FORM 10-K

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from____to

Commission file number: 000-56671

EBR SYSTEMS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**51-1164669**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
480 Oakmead Parkway Sunnyvale, CA	**94085**
(Address of Principal Executive Offices)	(Zip Code)

(408) 720-1906
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None.	None.	None.

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value $0.0001 per share

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was approximately $143 million, based on the closing price per share of the Registrant's common stock on the Australian Securities Exchange ("ASX") and the daily exchange rate reported by Oanda for conversion of Australian dollars into U.S. dollars on June 30, 2024.

As of March 15, 2025, the registrant had 372,851,324 shares of common stock, par value $0.0001 per share, including shares underlying all issued and outstanding Chess Depository Interests ("CDIs"), outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the 2025 Annual Meeting of Stockholders of the Registrant (the "Proxy Statement"), are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2024.

EBR SYSTEMS, INC.
ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2024

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In this report, unless otherwise stated or the context otherwise indicates, the terms "EBR Systems," "EBR," "the Company," "we," "us," "our" and similar references refer to EBR Systems, Inc. and its consolidated subsidiaries. The EBR logo, and other trademarks, trade names or service marks of EBR Systems, Inc. appearing in this Annual Report on Form 10-K are the property of EBR Systems, Inc. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Some of the statements under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this Annual Report contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "seek," "believe," "estimate," "predict," "potential," "continue," "contemplate," "possible" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us as of the date of this Annual Report and our projections of the future, about which we cannot be certain. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and effectiveness of our WiSE system, our ability to obtain the U.S. Food and Drug Administration ("FDA") approval of our WiSE system, and the timing of such FDA approval;
- the timing of commencement and focus of our ongoing and future studies and clinical trials, and the reporting of data from those clinical trials;
- our expectations regarding the results of our clinical studies and research and development programs, including the timing for patient enrollment and the timing and availability of data from such clinical trials;
- the size of the market opportunity for our WiSE system, including our estimates of the number of patients who suffer from the diseases we are targeting and the overall size of our target market;
- our ability to develop, and advance our WiSE system into, and successfully complete, clinical trials;
- developments and projections relating to our competitors and our industry and the success of competing products that are or may become available;
- the beneficial characteristics, safety, and effectiveness of our products;
- our ability to obtain and maintain regulatory approval of or Conformité Européene ("CE mark") Certificates of Conformity for our products;
- our plans relating to the further development and commercialization of our products, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available and our ability to avoid infringing the intellectual property rights of others;
- our ability to effectively manage our growth, including the need to hire additional personnel and our ability to attract, recruit and retain such personnel, and maintain our culture;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the performance of our third-party suppliers, contract research organizations ("CROs") and manufacturers;
- our financial performance; and
- the period over which we estimate our existing cash will be sufficient to fund our future operating expenses and capital expenditure requirements.

You should refer to the "Item 1A. Risk Factors" section of this Annual Report for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time and existing risks and uncertainties may become more material, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and although

we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Part I

Item 1. Business

Overview

EBR Systems, Inc., a Delaware corporation incorporated in 2003, is a U.S. based medical device company that is developing the WiSE CRT System, an implantable cardiac pacing system able to provide stimulation to endocardial heart tissue for the correction of heart rhythm conditions without requiring the use of wires or leads. This implantable, investigational device delivers left-ventricle endocardial pacing for cardiac resynchronization therapy ("CRT"), without the use of wires or leads going into the heart. An investigational device is one that has not been cleared or approved for commercial use by the U.S. Food and Drug Administration (the "FDA"). The left ventricle ("LV") is a chamber of the heart responsible for pumping blood through the aorta to the rest of the body, such that 'left-ventricle endocardial' pacing refers to electrical pacing delivered inside the left ventricle of the heart. Conventional cardiac rhythm management ("CRM") systems use leads to conduct electricity from an implantable pulse generator ("IPG") to electrodes that deliver therapeutic electric pulses to heart tissue. While leads are a critical part of most CRM systems, they have long been recognized as a primary shortcoming of these systems and are a leading cause of device failure. Our leadless system is designed to address this shortcoming.

Our proprietary WiSE CRT technology is engineered to benefit patients who have not seen success with conventional CRT or face high complication risks. Conventional CRT has limitations related to the need for lead placement and complication risks of occlusion, infection or concurrent illness. By eliminating lead requirements for left ventricular pacing, WiSE CRT introduces a novel approach to cardiac pacing, with the potential to transform CRT delivery. If approved by the FDA, our system would allow clinicians to provide CRT for patients where a LV lead has failed or is deemed high-risk by their doctor. A patient in whom standard CRT upgrade is not advisable due to known relative contraindication to coronary sinus ("CS") lead implant would be deemed high-risk by their doctor.

The initial focus of our WiSE CRT technology is to serve as an adjunct to existing implanted cardiac devices, providing CRT to those for whom traditional methods have failed or are not viable. In support of capturing this opportunity, WiSE CRT has been granted a Breakthrough Device Designation ("BDD") by the FDA, which provides us with greater access to the FDA during the premarket review phase, a prioritized review process, and potentially up to three years of favorable reimbursement coverage in the U.S. following such approval. We completed a pivotal clinical study, SOLVE-CRT (Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy) and submitted the final module of our modular pre-market approval ("PMA") submission on August 28, 2024. For a more comprehensive discussion of the SOLVE-CRT study, see "SOLVE-CRT Clinical Trial" below.

Products

The WiSE CRT System, the Company's only product candidate, is an implantable cardiac pacing system capable of delivering pacing level energy to the heart without using a lead/ wire. The technology used to achieve this leadless pacing is based on converting ultrasound energy to electrical energy. The system consists of a battery connected to an ultrasound transmitter that is implanted subcutaneously and the electrode implanted in the LV endocardium. The system requires a co-implant (e.g., pacemaker, defibrillator, or CRT) capable of right ventricular ("RV") pacing. The transmitter senses the RV pacing spike of the co-implant and within approximately five milliseconds emits an ultrasonic pulse to the electrode, which converts the ultrasound energy received to electrical energy at sufficient amplitudes to pace/ stimulate cardiac tissue. The intensity of the ultrasound energy used is very low, even in comparison to levels used for echocardiographic imaging.

The leadless WiSE Electrode essentially replaces the pacing function of a traditional LV lead. The WiSE CRT System is used in conjunction with a typical, commercially available implanted pacemaker, implantable cardioverter defibrillator ("ICD"), or CRT device with an RV pacing function. Immediately after sensing an RV pacing output from the co-implanted device, the WiSE CRT System triggers an ultrasound pulse targeted at the Electrode to pace the left ventricle. The sequence of sensing, transmitting, receiving, and stimulating the left ventricle is essentially simultaneous with the co-implanted device's RV pacing output and thus provides biventricular ("BiV") pacing analogous to CRT pacing devices.

Components of the WiSE CRT System include the Delivery Sheath and Electrode Catheter which delivers the Electrode, the Pulse Generator (Transmitter and Battery), and the Programmer (**Figure 1.1**).

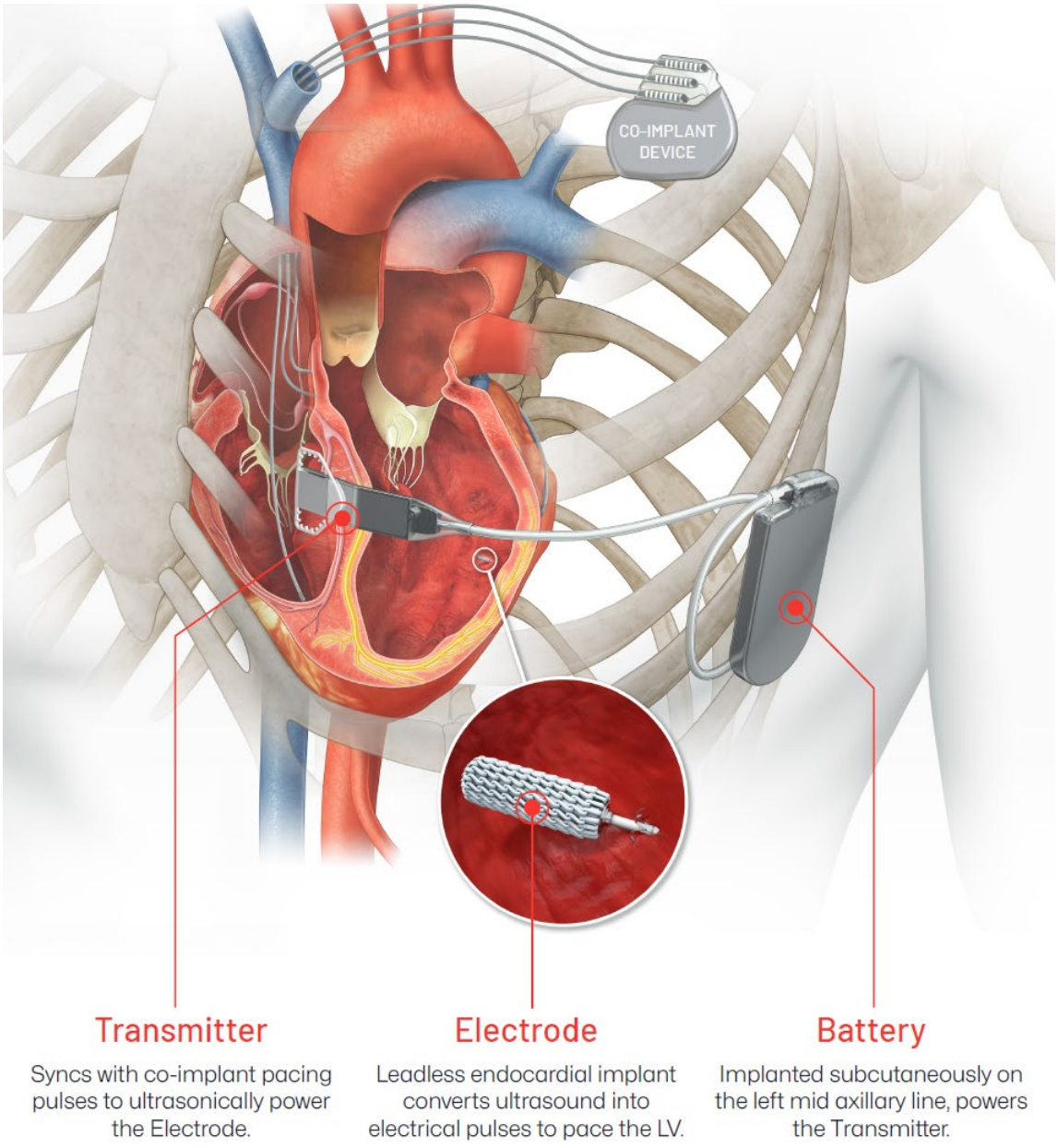

Figure 1.1 How WiSE CRT System Provides Leadless Cardiac Pacing

SOLVE-CRT Clinical Trial

The SOLVE-CRT investigational device exemption ("IDE") study is a prospective, multicenter trial consisting of an initial randomized, double-blind part and a subsequent single-arm part. It was originally designed as a randomized, multinational, double-blind study to enroll 350 patients from up to 45 centers. Patients were enrolled if they received right ventricular ("RV") pacing from a prior pacing implant and either did not have a fully functioning CRT system because of lead issues (Previously Untreatable ["PU"]), did not respond to CRT therapy (Non-Responders ["NR"]), or were considered high risk for a standard CRT upgrade (High-Risk Upgrade ["HRU"]), which included those with a cardiac pacemaker or intracardiac defibrillator ("ICD") requiring upgrade to CRT.

The first patient was enrolled in the SOLVE-CRT study in January 2018. Enrollment was severely impacted by the COVID-19 pandemic and was paused in March 2020 after 108 patients were enrolled. At that time, the investigators worked with the FDA to revise the clinical protocol, implementing a single-arm, non-randomized part to complete the study. Central to this strategy was a differentiation of the three original patient groups and the requirements for demonstration of safety and efficacy. For the patients in the PU and HRU groups, CRT was an approved therapy, and the WiSE CRT System could be viewed as an alternate method of providing CRT when conventional CRT was not possible, so a Single-Arm study with pre-specified objective performance goals was appropriate. In contrast, the NR group had suboptimal responses to conventional CRT due to a diverse set of pathophysiologic mechanisms. Thus, there was a different threshold for scientifically acceptable evidence for safety and effectiveness, and this group was excluded from the study continuation.

The modified study was designed to enroll up to 300 patients with a pre-specified interim analysis with early stopping rules after enrolling 183 patients. All 183 patients (PU/HRU/NR) were included in the safety analysis while only the PU and HRU patients (n = 100) were included in the efficacy analysis. The primary safety endpoint was the freedom from device- or procedure-related complications (Type I). The primary efficacy endpoint was the reduction in left ventricular systolic volume ("LVESV"). LVESV is a key marker of advanced heart failure and goes up as the HF progresses. All versions of the study protocol were approved by relevant institutional review boards and the FDA under an IDE application. All patients provided written informed consent.

At the interim analysis, the primary 6-month efficacy endpoint was met with a 16.4% (95% confidence interval ["CI"], 11.7% to 21.0%) reduction in mean LVESV, significantly favorable to the 9.3% performance goal ($p = 0.003$). The primary 6-month safety endpoint was met with an 80.9% (148/183 participants) (lower boundary of the one-sided 98.8% CI, 73.4%) rate of freedom from device- or procedure-related (Type I) complications, significantly favorable to the 70% performance goal ($p < 0.001$). Since both the primary efficacy and safety endpoints met the pre-specified stopping rules for interim analysis, the trial was concluded early for success.

Secondary endpoints included an acoustic pacing capture threshold ("APCT") of < 2.9 mJ achieved in 95.2% of participants and APCT stability achieved in 81.3% of participants, indicating that the WiSE CRT System was capable of delivering CRT in the majority of patients enrolled in the study and that the energy required to deliver CRT remained stable. In addition, 93.1% of participants achieved a mean percent BiV pacing, 46.1% achieved an increase in Left ventricular ejection fraction ("LVEF") ≥ 5%, and 65.5% achieved an increase of ≥ 5 points in Kansas City Cardiomyopathy Questionnaire.

We are seeking to demonstrate with the SOLVE-CRT study that leadless left ventricular endocardial pacing ("LVEP") with the novel WiSE CRT System is feasible, safe, and effective for delivering CRT in patients with advanced HF.

Clinical Conclusion

Subject to the review and determination by the FDA, we believe the performance and safety of the WiSE CRT System is supported by results of the SOLVE-CRT pivotal clinical trial, and peer-reviewed clinical literature. The System has a high implant success rate and delivers significant benefit to moderate to severe HF patients, including improved clinical and functional status and reverse remodeling. Further, complication rates observed with the WiSE CRT System are similar to those observed with other approaches to delivering CRT. The risks associated with the use of the System are acceptable when weighed against the potential benefits to the indicated patient populations. This is of particular importance as the patient populations treated in the EBR-sponsored studies have failed or not responded to conventional CRT and have a poor prognosis. Providing clinical benefit to these high-risk patients shows that the WiSE CRT System can meet the identified unmet clinical need for novel approaches to delivering CRT for the treatment of HF.

Further, we believe the design strategy for the WiSE CRT System results in a leadless device that is 95% smaller by volume compared to commercially available leadless pacemakers, such as Medtronic's Micra or Abbott's Aveir. Consequently, subject to approval by the FDA, we believe WiSE CRT will be the only therapy demonstrated in clinical study that can deliver LVEP and potentially broaden the spectrum of patients who could benefit from CRT.

Status of the FDA Review

We submitted the final module of our PMA submission on August 28, 2024. Under standard review, the FDA has 180 days to review the PMA. In January 2025, the FDA completed the manufacturing site Pre-Approval Inspection ("PAI") with no Form FDA 483 observations. Thus, subject to FDA review and approval, and pre-commercial activities described under "Markets and Distribution" below, we expect to commercially launch the WiSE CRT System in the U.S. in 2025.

Markets and Distribution

If approved by the FDA and other regulatory authorities, we intend to commercially launch WiSE with the focus on driving adoption of WiSE at key, high-volume, luminary sites within the U.S. to be followed by select, high-volume sites in markets outside the U.S. ("OUS") that we are targeting after evaluating regulatory and reimbursement considerations.

a) U.S. Strategy

We plan to implement a phased Limited Market Release ("LMR"), with the following phases:

LMR Phase 1: Initial Target Accounts

- Launch in target accounts from the SOLVE-CRT (Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy) pivotal trial.
- Leverage existing relationships with trial sites to streamline patient identification and device implantation.

LMR Phase 2: Expansion and Optimization

- Strategically expand our field team to broaden our market presence into additional high-volume sites.
- Focus on optimizing the customer training programs and enhancing EBR's business operations.

LMR Phase 3: Increase Implants Per Site

- The field team will focus on increasing the number of cases per month per site by improving hospital implant workflows and familiarity with the technology.

Full Market Release

- Expand market presence and maximize product adoption.
- Utilize refined business operations and continue scaling the field team.
- Focus on expanding into additional sites, leveraging the experience and efficiency gained from the LMR.

If approved, we anticipate our average selling price ("ASP") in the U.S. will be approximately $45,000 per WiSE CRT system. As a result of its breakthrough device designation ("BDD"), our WiSE CRT technology is expected to be eligible for incremental payment coverage in the U.S. for up to three years following potential FDA approval.

b) OUS Strategy

Our OUS commercial activities will not commence until we obtain regulatory approvals and certification in select, target markets. Regulatory submissions in these markets will not likely commence until sometime after FDA approval, if received. These initial target markets include Australia, the United Kingdom, and the European Union. The timing of launch in each of these OUS markets thus depends on meeting additional regulatory requirements, as well as on securing the appropriate payment coverage for WiSE in each market.

Competitive Environment

Significant advances in pacing technology have been made in pacing technology have been made over the last 50 years including: multi-chamber pacing, improved rate of responsiveness, devise size reduction, internet-based remote monitoring, and market increases in battery longevity. However, the basic system format of using an implantable pulse generator ("IPG") connected to one or more leads to stimulate the heart muscle tissue, has remained unchanged over this time.

The most recent advance in the evolution of pacemakers has been the advent of leadless cardiac pacing systems, as most complications associated with pacemakers have been due to leads. To overcome this, leadless pacing systems have been developed in which the IPG and stimulating electrode are combined into a single unit that can be fully implanted inside the heart chamber. Advantages of this approach over lead-based systems include greater efficiency, system simplicity, and ease of implantation. However, these systems also have certain limitation, including the need to retrieve the device in future years due to battery depletion, risk of cardiac perforation and thrombus, and infection risk. Additionally, because of their size and thrombogenicity (tendency to generate and release clots that might cause heart attack or stroke) they cannot be used within the left ventricle.

The three major CRM device companies (Medtronic plc, Boston Scientific, and Abbott) have each developed leadless cardiac pacemakers that can be implanted in the right ventricle, with Abbott having an approved device that can be used in the right atrium. Leadless devices are expected to play an increasingly important role in the future pacemaker market.

Leadless Cardiac Rhythm Management Landscape

Figure 1.2: Current Leadless Pacemakers for Cardiac Pacing*

*CAUTION: The WiSE CRT System is an investigational device. Limited by Federal (US) law to investigational use only.

Opportunity for WiSE

While the leadless pacemakers currently on the market are for bradycardia indication, it is anticipated that the entry of Abbott's Aveir DR dual chamber device could further increase the adoption of leadless pacemakers.

It has been reported that up to 30% of patients with pacemakers develop pacing induced heart failure within four years. Thus, many of the patients implanted with leadless pacemakers may require an upgrade to CRT at a later date. The WiSE CRT System is the only device able to upgrade these patients to CRT.

A 14-patient clinical study, presented during Asia-Pacific Heart Rhythm Society meeting in 2022, demonstrated that WiSE is able to work in conjunction with Medtronic's Micra to provide BiV pacing and an entirely leadless option for upgrading these patients. Only WiSE can provide these patients with an entirely leadless upgrade solution.

Supply of Components

EBR's WiSE CRT System is comprised of five key components:

- an implantable endocardial electrode (Electrode);
- a catheter delivery system (used to implant the Electrode);
- a transmitter that operates the system (Transmitter);
- a battery that powers the Transmitter; and
- a programmer (device that programs the WiSE CRT System).

We source components and sub-assemblies for components from external suppliers and contract manufacturers. We require our suppliers and contract manufacturers to be compliant with the relevant quality standards and certifications required to manufacture medical device products such as the WiSE CRT System.

We conduct our own quality assessment and performance testing of components and subassemblies that we receive from our suppliers. We have developed and maintain the software that runs the WiSE CRT System which is uploaded into the transmitter and programmer. We inspect and evaluate the entire system prior to supplying it for use in patients.

To date, production of our WiSE CRT System has been conducted on a small scale due to the low volumes required for clinical and product optimization studies. We believe that our existing suppliers have the capacity and capability to manufacture at volumes sufficient to meet the anticipated initial commercial demand for WiSE. We will likely seek to bring certain manufacturing processes in-house over time as we seek to reduce the cost of production. Many of the components or sub-assemblies used in the WiSE CRT System are custom built but use standard raw materials that can be provided by a variety of suppliers. Certain components within our sensor/transmitter and the receiver/transducer are unique to the WiSE CRT System design and functionality and would require redesign efforts if we need to change vendors arise. For instance**,** our piezo electric crystal is a single source component purchased from CTS Advanced Materials. We do not currently have a formal master supplier agreement in place with CTS as we generally procure on a purchase order basis. We work closely with our suppliers and have plans and measures in place to help ensure continuity of supply while maintaining high quality and reliability. Generally, we have been able to obtain adequate supplies of such raw materials and components. However, due to the U.S. FDA's manufacturing requirements and those of other regulatory authorities, we may not be able to quickly establish additional or replacement sources for certain components or materials if we experience a sudden or unexpected reduction or interruption in supply and are unable to develop alternative sources.

Intellectual Property

The generation and protection of intellectual property, including patents, trade secrets, trademarks, proprietary technology, proprietary manufacturing techniques, and know-how, is of critical importance in our field and in biotechnology generally. We rely on a combination of trade secrets, patent filings and other intellectual property protections in an effort to protect our WiSE CRT System as well as related methods of use. We will be able to protect our WiSE CRT System and methods of use from unauthorized use by third parties only to the extent that our technology is effectively and diligently maintained as trade secrets or where applicable, covered by valid and enforceable patents. Our commercial success may also depend on whether we can defend our patents against third-party challenges and on operating without infringing on the intellectual property rights of others.

As of December 31, 2024, our WiSE CRT System and related technologies are covered by an extensive portfolio of patents which includes 63 granted U.S. patents, 55 granted non-U.S. patents, and 17 pending patent applications that cover different aspects of the WiSE CRT System including the technological inventions incorporated in:

- leadless cardiac pacing using ultrasound transduction;
- the sensor/transmitter;
- the receiver/stimulator electrode;
- the programmer;
- the delivery system; and
- mechanisms for detecting the location of the receiver/transducer electrode.

Our patents provide protection of the technology incorporated in the WiSE CRT System and a subset of these patents have expiry dates between 2025 and 2029. One pertinent patent related to the method of using an isotropic receiver-stimulator expires December 2025. However, other active patents (including patents in the same family) with device claims that provide similar coverage of the isotropic receiver-stimulator concepts and those directed to the overarching system

and method are not expiring until 2032. Other patents directed to the technology incorporated in the WiSE CRT System expire 2030 and later. The United States has a mechanism, referred to as a patent term extension ("PTE"), for patent holders to extend the period of protection provided by their patents to compensate for time involved in conducting clinical studies and securing regulatory approval from the FDA. PTE is granted by the United States Patent and Trademark Office ("USPTO") based on a formula and can extend the term of a patent by a maximum of five years. In view of the current timeline projected by us, PTE is expected to extend the expiry date for one of our key patents by four to five years depending on the timing of the FDA approval process. We will be able to file for PTE when and if the WiSE CRT System has been approved by the FDA.

We continue to conduct research and development activities directed at improving the use and performance of the WiSE CRT System and related technologies. This has resulted in the recent filing of new patent applications and may result in new inventions that potentially could provide opportunities to file additional patent applications. In addition, we have experience over many years with the WiSE CRT System and the underlying technology for providing leadless cardiac stimulation using ultrasound transduction. This has resulted in extensive know-how and trade secrets that are likely to represent significant barriers to any emerging competitors considering the development of a similar product.

Trade Secrets

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information with respect to our employees and collaborators by obtaining executed agreements requiring protection of our trade secrets and assignment of patents to us. Internal processes around the production of such things as the receiver electrode are complex and require extensive training and fixturing, lending credence to our technical know-how reliance.

Trade secrets are only beneficial if the trade secret can be protected, which in turn requires certain internal record keeping and security measures. Further, third parties are not precluded from practicing such trade secret methods developed on their own because there is no right to prevent others from this innovation. Trade secrets are difficult to protect and enforce and therefore provide us with only limited protection. Trade secrets must be protected within the company. Those employees and former employees with knowledge of our trade secrets must not share them with a third party. It is difficult to ensure that our trade secrets will be kept secret and not shared with a third party, such as a third-party competitor. For this and more comprehensive risks related to our intellectual property, please see "*Item 1A. Risk Factors—Risks Related to Intellectual Property*."

Trademarks

We also have applied for and been awarded certain trademarks as shown in the table below. We intend to maintain and protect our trademarks from unauthorized use.

Country	Trademark	Status	Reg. Date	Reg. No
Australia	EBR SYSTEMS	Registered	Dec 20 2021	2212887
Australia	WISE	Registered	Nov 20 2019	1951115
China	EBR SYSTEMS	Registered	Mar 28 2022	59571858
European Union	EBR SYSTEMS	Registered	Feb 22 2022	18564067
European Union	WISE	Registered	Feb 5 2021	18169605
Japan	EBR SYSTEMS	Registered	Jan 24 2022	6503797
Japan	WISE	Registered	Aug 11 2021	6427134
United Kingdom	EBR SYSTEMS	Registered	Dec 24 2021	UK00003698958
United Kingdom	WISE	Registered	Feb 8 2021	UK00003592127
United States of America	EBR SYSTEMS	Registered	Nov 22 2022	6908275
United States of America	WICS	Registered	Oct 6 2009	3692984
United States of America	WICS WIRELESS CARDIAC STIMULATION	Registered	Jan 10 2017	5118101
United States of America	WISE	Registered	Dec 13 2022	6925121
United States of America	WISE	Registered	Sep 19 2023	7169926

Government Regulation of Medical Devices

We intend to seek regulatory approval and certification for the WiSE CRT System in Australia, UK, and EU after initial commercialization in the U.S., pending FDA approval, and securing adequate reimbursement. We will evaluate the regulatory cost associated with securing CE Mark approval, which would allow it to be sold and used in countries within the E.U. and, potentially although not certainly, the U.K.

United States

Regulation of Medical Devices in the United States

The U.S. Food, Drug and Cosmetic Act ("FDCA") classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control and premarket approval to provide reasonable assurance of the device's safety and effectiveness.

Establishments that manufacture and/or distribute devices, including manufacturers, contract manufacturers, sterilizers, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, initial importers, manufacturers of accessories and components sold directly to the end user, and U.S. manufacturers of export-only devices, are required to register their establishments with the FDA and provide the FDA a list of the devices that they handle at their facilities.

Pre-market Authorization and Notification

While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a premarket approval application, or PMA, prior to marketing, generally applicable to Class III devices; or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because the FDA has not yet called for PMAs for these devices. Other less common regulatory pathways to market for certain devices include the de novo classification process, the humanitarian device exception, or a product development protocol.

The 510(k) Clearance Process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the 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, often referred to as a preamendment 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 previously found substantially equivalent through the 510(k) process. 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 is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA has a performance goal to complete its review of 95% of 510(k) submissions within 90 days of receipt. As a practical matter, clearance often takes longer, because the FDA can request additional dates and information, which pauses the review clock for up to 180 days, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing

requirements of the PMA approval process or seek reclassification of the device through the de novo process. A manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or de novo classification. 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. Many minor modifications are accomplished by a letter-to-file in which the manufacturer documents the change in an internal letter-to-file. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite PMA application(s).

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute , has a performance goal to review 90% of PMA applications within 180 days, if advisory committee input is not required, and within 320 days, if advisory committee input is required, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (i.e., major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit, or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require requisite data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials, or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the

proposed change. In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices , such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution, and use.

Breakthrough Device Designation (BDD)

FDA grants BDD to those devices that are intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

The BDD program provides more interactive and timely access to the FDA during the premarket development phase and submission process. This designation includes a prioritized review of regulatory filings and enhanced FDA guidance during the process. It also provides positive implications for incremental hospital payment from the Centers for Medicare and Medicaid Services ("CMS").

Post-market Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: Quality System Regulation ("QSR"), labeling regulations, the FDA's general prohibition against promoting products for unapproved or off-label uses, the Medical Device Reporting ("MDR") regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA.

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

OUS

On May 26, 2021, Regulation (EU) 2017/745 on Medical Devices, entered into application, repealing and replacing both Directive 93/42/EEC concerning medical devices, and Directive 90/385/EEC concerning active implantable medical devices. The Regulation and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. Medical devices must comply with the General Safety and Performance Requirements, or GSPRs, set out in Annex I of the Medical Devices Regulation. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the European Economic Area ("EEA"). To demonstrate compliance with the GSPRs provided in the MDR and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body will audit and examine the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity

with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EU Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming. After a device is placed on the market in the EEA, it remains subject to significant regulatory requirements.

The changes to the regulatory system implemented in the EU by the Medical Devices Regulation include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well as a refined responsibility of economic operators, and the requirement to provide clinical data in the form of a clinical evaluation report.

The UK has devised a new route to market culminating in a United Kingdom Conformity Assessment ("UKCA") Mark to replace the CE Mark. Northern Ireland will, however, continue to be covered by the EU regulations governing CE Marks.

For a medical device to be sold and marketed in Australia, it must be included in the Australian Register of Therapeutic Goods ("ARTG"). For an active implantable medical device ("AIMD")/Class III device, this is a two-stage process. The first stage involves an application to the Therapeutic Goods Administration ("TGA") for a Declaration of Conformity. The second stage is an application for inclusion on the ARTG.

Other Healthcare Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback laws, false claims laws, data privacy and security laws, and other healthcare fraud and abuse laws, such as transparency laws regarding payments or other items of value provided to healthcare providers.

- The Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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 the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. 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 certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants, or charitable donations. Practices that involve remuneration to those who prescribe, purchase, or recommend medical devices, including discounts, providing items or services for free

or engaging such individuals as consultants, advisors, or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute.

- Federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil 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. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil False Claims Act for a variety 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 interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings.

- Health Insurance Portability and Accountability Act ("HIPAA"), which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates and their subcontractors that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions, to the 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 (such as physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and foreign laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign beneficiary inducement laws, which are laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information

in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were 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, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. For example, implementation of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA) substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry.

Since its enactment, there have been judicial, administrative, executive, and Congressional legislative challenges and amendments to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may, for example, include directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation ("CMMI") to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical and medical device product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which products and supplies

will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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.

Reimbursement

Potential reimbursement pathways vary by target markets.

United States

In the United States, sales of our products will depend substantially on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health care programs, private health coverage insurers and other third-party payors. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Our products are purchased by hospitals and other providers who will then seek reimbursement from third-party payors for the procedures performed using our products. Private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement under the Medicare program. If sufficient coverage and reimbursement is not available for the procedures using our products, the demand for our products and our revenue will be adversely affected.

Current Procedural Terminology (CPT) codes are utilized to report services provided by physicians and other qualified healthcare professionals. Other providers may also utilize CPT codes to report services, including hospital outpatient departments and ambulatory surgery centers. Currently, there are eight Category III CPT codes that describe the various procedures related to WiSE. We will coordinate with relevant professional physician societies to convert the Category III CPT codes to Category I CPT codes when appropriate. Category I CPT codes are utilized to establish a Medicare national payment level for physician services.

For hospital payment for Medicare patients, WiSE currently maps to existing Medicare Severity Diagnosis Related Groups (MS-DRGs) for hospital inpatient procedures, and Ambulatory Payment Classifications (APCs) for hospital outpatient procedures. It is expected that the vast majority of Medicare patients receiving WiSE will be implanted in the hospital inpatient or outpatient setting.

Additionally, CMS (Medicare) provides an opportunity for select new technologies that meet pre-specified criteria to receive incremental payment in the hospital setting. For hospital inpatient procedures, the New Technology Add-On Payment (NTAP) provides incremental payment to hospitals for 2-3 years in addition to the MS-DRG payment. For hospital outpatient procedures, the Transitional Pass-Through (TPT) provides incremental payment to hospitals for 3 years in addition to the APC payment. Once the NTAP and TPT expire, CMS utilizes the claims data from WiSE CRT procedures to update MS-DRG and APC payment rates based on standard payment policy.

As stated above, the WiSE CRT System has received a BDD from the FDA. CMS has established policies that for technologies with BDD, two of the three qualifying criteria for NTAP are automatically deemed to be met. Thus, the probability of the WiSE CRT System securing NTAP, and incremental payment for 2-3 years is high. For TPT, technologies with BDD are deemed to automatically meet the "substantial clinical improvement" criterion, which significantly increases the probability of securing TPT.

Third-party payors are also increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction.

Jurisdiction of Incorporation

We are incorporated in the State of Delaware, United States of America, and are a registered foreign company in Australia. As a foreign company registered in Australia, we are subject to different reporting and regulatory regimes than Australian companies. As a foreign company registered in Australia, we are not subject to Chapters 6, 6A, 6B and 6C of the Corporations Act 2001 (Cth) of Australia ("Corporations Act") dealing with the acquisition of shares (including substantial shareholdings and takeovers).

Employees

As of December 31, 2024, we had 89 full-time employees including 79 in research and development and 10 in general and administrative. As of December 31, 2024, we had 79 employees located in the U.S., six in Europe, and four in Australia. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relations with our employees to be good.

Available Information

Copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements as well as any amendments to those reports, are filed or furnished with the Securities and Exchange Commission (the "SEC"). Such reports and other information filed by the Company with the SEC are available on our website at https://www.ebrsystemsinc.com/ as soon as reasonably practicable after it is electronically filed with the SEC. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors

Summary of Risk Factors

Our business and operations are subject to a number of risks, which you should be aware of prior to deciding to invest in our common stock. Listed below is a summary of these risks, which are discussed more fully immediately following this summary.

Risks Related to Our Business and the Development, Manufacturing and Commercialization of Our Products

- If we are unable to obtain regulatory approval and ultimately commercialize our WiSE CRT technology, or experience significant delays in doing so, our business will be materially harmed;
- Coverage and adequate reimbursement may not be available for our products or the procedures that utilize our products, which could diminish our sales or affect our ability to sell our products profitably;
- We depend upon third-party suppliers, including single-source suppliers, making us vulnerable to supply disruptions and price fluctuations;
- The commercial success of our products will depend upon attaining significant market acceptance of these products among hospitals, physicians, patients, and payors;
- Adoption of our products depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of our products and adversely affect our business;
- We have limited sales and marketing resources. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our CRT products, we may not be able to effectively market and sell our CRT products or generate product revenue; and
- We have limited experience manufacturing our products in commercial quantities, which could harm our business.

Risks Related to Our Industry

- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customers' patients or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation;
- Litigation and other legal proceedings may adversely affect our business; and
- We may face difficulties encountered by many medical technology companies early in their commercialization.

Risks Related to Our Financial Position and Need for Additional Capital

- Our existing indebtedness contains restrictions that limit our flexibility in operating our business. In addition, we may be required to make a prepayment or repay our outstanding indebtedness earlier than we expect;
- We have a history of net losses, and we expect to continue to incur losses for at least the next several years. We may never generate any revenue from commercial products or become profitable or, if we ever achieve profitability, we may not be able to sustain it;
- In order to support our continued operations and the growth of our business, we may seek to raise additional capital, which may not be available to us on acceptable terms, or at all;
- The issuance of additional shares of our common stock in connection with financings, acquisitions, investments, and share incentive plans or otherwise will dilute all other stockholders;
- Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business;
- Our current capital reserves may not be adequate;
- We have capitalized pre-launch inventories prior to receiving FDA approval. If either FDA approval or market acceptance post-approval do not occur at all or on a timely basis, we will be required to write-off pre-launch inventories which would materially and adversely affect our business, financial condition and stock price;
- Our disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors; and
- Our results may be impacted by changes in foreign currency exchange rates.

Risks Related to Government Regulation

- Regulatory compliance is expensive, complex, and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business;
- Our operations are subject to pervasive and continuing FDA regulatory requirements;
- Even if our products are cleared or approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market;
- Our products may be subject to recalls after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business;
- If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected.
- Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the Foreign Corrupt Practices Act ("FCPA"), as well as export control laws, customs laws, sanctions laws and other laws governing our operations could result in civil or criminal penalties, other remedial measures, and legal expenses; and
- The impact of the new E.U. Medical Device Regulation may be costly and disruptive to our business.

Risks Related to Our Intellectual Property

- We are dependent on the protection and enforcement of our intellectual property rights;
- We may be subject to future third party intellectual property rights disputes;
- If we are unable to obtain and maintain patent protection or freedom to operate for any products we develop and for our technology, or if the scope of the patent 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 adversely affected; and
- Obtaining and maintaining patient protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Risks Related to Our CDIs and Common Stock

- Our common stock may never be listed on a major U.S. stock exchange;

- The issuance of additional securities in connection with financings, acquisitions, investments, our share incentive plans or otherwise may adversely affect the value of and rights associated with our common stock;
- The market price of our CDIs and common stock may be volatile, which could cause the value of our common stock to decline;
- The requirements of being an SEC registrant may strain our resources, divert management's attention and affect our ability to attract and retain qualified Board of Directors (the "Board") members;
- Investors may have difficulty in reselling their shares due to the lack of market or state Blue Sky laws;
- The different characteristics of the capital markets in Australia and the United States may negatively affect the trading prices of our CDIs and common stock and may limit our ability to take certain actions typically performed by a U.S. company; and
- Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums 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.

Risks Related to Our Business and the Development, Manufacturing and Commercialization of Our Products

If we are unable to complete clinical trials, obtain regulatory approval and ultimately commercialize our WiSE technology, or experience significant delays in doing so, our business will be materially harmed.

Our business is dependent on successful approval and marketing of our WiSE CRT technology that is still under development and subject to FDA approval. While our WiSE CRT System and has been granted Breakthrough Device Designation by the FDA, the premarket review of our WiSE CRT System by the FDA is still subject to final review and approval of our submission of information garnered from our pivotal trial, SOLVE-CRT, which is intended to assess the safety and efficacy of our WiSE technology.

Until FDA approval is received, we do not have regulatory approval to market WiSE in the United States, and we will be unable to generate revenue in the United States. Our business model and growth strategy is dependent on obtaining FDA approval as well as approvals from regulatory bodies in other key jurisdictions, including the Australian market. If FDA approval is not received within the expected timeframe, or not received at all, we will be unable to implement our business model, and our business and financial condition will be harmed.

Furthermore, even if we receive FDA approval, we are not assured of receiving future regulatory approvals for other indications or approval or notified body certification in other jurisdictions and cannot predict with certainty the timelines for such approvals or certifications, or other requirements that may be imposed by regulatory authorities (e.g. further clinical trials or other requirements to prove the safety and effectiveness of its products). In addition, future changes or updates to our products, which affect their safety or efficacy, may require new regulatory approvals or notified body certification in some jurisdictions before we may sell the revised product.

Coverage and adequate reimbursement may not be available for the procedures that utilize our products, which could diminish our sales or affect our ability to sell our products profitably.

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Our products are purchased by hospitals and other providers who will then seek reimbursement from third-party payors for the procedures performed using our products. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain non-U.S. markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many non-U.S. markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems.

We can give no assurance that these third-party payors will provide coverage and adequate reimbursement for procedures using our products, permit hospitals and doctors to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using our products will continue. If sufficient coverage and

reimbursement is not available for the procedures using our products, in either the United States or non-U.S. markets, the demand for our products and our revenue will be adversely affected. Furthermore, although we believe there is potential to improve on the current reimbursement profile for our products in the future, the overall amount of reimbursement available for procedures intended to diagnose and treat complex heart arrhythmias could remain at current levels or decrease in the future. Failure by hospitals and other users of our products to obtain and maintain coverage and adequate reimbursement for the procedures using our products would materially adversely affect our business, financial condition, and results of operations.

Third-party payors are also increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates but also have their own methods and approval process apart from Medicare determinations. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction. Similar inconsistency exists on non-U.S. markets.

We depend upon third-party suppliers, including single-source suppliers, making us vulnerable to supply disruptions and price fluctuations.

Our products include components that are manufactured and supplied by third parties, some of which are single-source suppliers. The products are then assembled, validated, and tested by these third parties or at our headquarters in California. There are inherent risks in relying on third-party suppliers for our product components, especially since any change to the manufacturing process of an approved medical device requires significant documentation and, in many cases, supplemental testing. A disruption at a key supplier could cause a substantial delay in the availability of our products, leading to a potential loss of sales. In general, we do not have long-term supply agreements with our suppliers as we generally order on a purchase order basis. We depend on our suppliers to provide us and our customers with materials in a timely manner that meets our quality, quantity, and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. Our suppliers may also cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition, and results of operations.

In addition, for reasons of quality assurance, cost effectiveness, or availability, some of the components needed to manufacture our products are obtained from sole suppliers. For instance**,** our piezo electric crystal is a single source component purchased from CTS Advanced Materials. We do not currently have a formal master supplier agreement in place with CTS as we generally procure on a purchase order basis. Although we work closely with our suppliers to try to ensure continuity of supply while maintaining high quality and reliability, the supply of these components may, at times, be interrupted or insufficient. In addition, due to the stringent regulations and requirements of the regulatory agencies like the FDA, we may not be able to quickly establish additional or replacement sources. Further, dependence on a sole source for certain key components of our products may allow such sole source suppliers to command increased leverage in negotiating prices and other terms of sale, which could adversely affect our potential future profitability. As a result, we may be left with little choice but to accept such higher prices or other fees for key components in order to ensure continuity of supply. This could affect our potential profitability or if we choose to push back against more onerous terms, could lead to inadequate supply, which could materially affect our business. It could be difficult, costly and time consuming to obtain alternative sources for these components, or to change product designs to make use of alternative components.

The commercial success of our products will depend upon attaining significant market acceptance of these products among hospitals, physicians, patients, and payors.

Our success will depend, in part, on the acceptance of our products as safe, effective and, with respect to providers, cost-effective. We cannot predict how quickly, if at all, hospitals, physicians, patients, or payors will accept our products or, if accepted, how frequently they will be used. Our products and planned or future products we may develop, or market

may never gain broad market acceptance for some or all of our targeted indications. Hospitals, physicians, patients, and payors must believe that our products offer benefits over alternative treatment methods. Our future growth and profitability largely depend on our ability to increase physician awareness of our system and our products and on the willingness of hospitals, physicians, patients, or payors to adopt them. These parties may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products are safe, effective and, with respect to providers, cost- effective, on a stand-alone basis and relative to competitors' products. Healthcare providers must believe that our products offer benefits over alternative treatment methods. Even if we are able to raise awareness, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to their hospitals or patients for a variety of reasons, including:

- lack of experience with our products and concerns that we are relatively new to market;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting safety or clinical benefits; and
- time commitment and skill development that may be required to gain familiarity and proficiency with our products.

Physicians play a significant role in determining the course of a patient's treatment, and, as a result, the type of treatment that will be utilized and provided to a patient. We focus our sales, marketing, and education efforts primarily on cardiac electrophysiologists, and aim to educate referring physicians regarding the patient population that would benefit from our products. However, we cannot assure you that we will achieve broad market acceptance among these practitioners.

We cannot assure you that our products will achieve broad market acceptance among hospitals and physicians. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products, procedures or technologies are considered safer or more cost-effective or otherwise superior. Any failure of our products to generate sufficient demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

Our reputation among our current or potential customers, as well as among electrophysiologists, could also be negatively affected by safety or customer satisfaction issues involving us or our products, including product recalls. Future product recalls or other safety or customer satisfaction issues relating to our reputation could negatively affect our ability to establish or maintain broad adoption of our products, which would harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

In most cases, before a hospital can purchase our system for the first time, our system must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Such approvals could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition, and results of operations.

Adoption of our products depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of our products and adversely affect our business.

The success of our products depends in part on hospitals and physicians' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by the Company. However, physicians rely on their previous medical training and experience, and we cannot guarantee that all such physicians will have the necessary skills or training to effectively utilize our WiSE CRT System. If physicians use our products in a manner that is inconsistent with their labelled indications, with components that are not compatible with our products or without adhering to or completing the requisite training sessions, their patient outcomes may not be consistent with the outcomes achieved by other physicians or in our clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of our products, which would have a material adverse effect on our business, financial condition, and results of operations.

We have limited sales and marketing resources. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our CRT products, we may not be able to effectively market and sell our CRT products or generate product revenue.

We currently have limited sales and marketing resources. In order to successfully launch our CRT products commercially after we receive marketing approval, we will need to, among other things, build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. We may elect to build a targeted specialty sales force which will be expensive and time-consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our CRT products. If we choose to partner with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into collaborations with third parties for the commercialization of approved products, if any, on acceptable terms or at all, or if any such partner does not devote sufficient resources to the commercialization of our products or otherwise fails in commercialization efforts, we may not be able to successfully commercialize any of our WiSE CRT system that receive regulatory approval. If we are not successful in commercializing our WiSE CRT system, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted.

We have limited experience manufacturing our products in commercial quantities, which could harm our business.

Because we have only limited experience in manufacturing our products in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following:

- our intent to expand our manufacturing capacity, as a result of which our production processes may have to change;
- key components of our products are provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components; if we experience a shortage or quality issues in any of these components, we will need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;
- a delay in completing validation and verification testing for new controlled environment rooms at our manufacturing facility;
- state and federal regulations, including the FDA's Quality System Regulation ("QSR") for the manufacture of our products, noncompliance with which could cause an interruption in our manufacturing; and
- attraction and retention of qualified employees for our operations in order to significantly increase our manufacturing output.

If we are unable to keep up with demand for our products, our growth could be impaired, and market acceptance for our products could be harmed and physicians may instead elect to use our competitors' products. Our inability to successfully manufacture our products in sufficient quantities would materially harm our business.

In addition, our manufacturing facility and processes and those of our third-party suppliers must meet stringent quality standards and are subject to unannounced FDA and state regulatory inspections for compliance with the QSR. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators, could result in enforcement actions against us or our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls, temporary manufacturing shutdowns, and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results. For example, to maintain Notified Body certification permitting us to affix the CE Mark to our devices in the E.U., the Company's Notified Body is expected to regularly audit the Company and its suppliers. In 2018, we received a warning notice from the Company's Notified Body, BSI Group ("BSI") for non-conformance with manufacturing standards. In 2020, we identified manufacturing process issues with our contract manufacturer of the Transmitter Model 4100, which were subsequently ratified in 2021. Although the process improvements were reviewed and approved by BSI and by the FDA, any failure to comply with the applicable regulatory requirements in the future can result in such enforcement actions noted above and a damaged brand name.

We have limited data and experience regarding the safety and efficacy of its WiSE-CRT system.

Even though the preliminary clinical data from SOLVE-CRT met our primary endpoints and has been submitted in support of the Company's application for FDA approval, it may not necessarily be predictive of the results of future clinical trials that will need to be conducted to support regulatory approval in other jurisdictions.

WiSE CRT is a relatively new potential solution for treating heart failure with CRT, so the Company has performed clinical trials only with limited patient populations. The long-term effects of using our WiSE CRT System in a large number of patients have not been studied and the results of short-term clinical use do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. The results of preclinical studies, completed clinical trials, ongoing trials, and future studies of our current, planned, or future technology may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

The interpretation of data and results from the Company's clinical trials do not ensure that it will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and early clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

There is no assurance that future trials will meet their endpoints or that regulatory bodies such as the FDA and TGA will agree that our products are sufficiently safe and effective to support regulatory approval.

The sizes of the markets for our current and future products may be smaller than our estimates.

The Company's estimates of the annual total addressable markets for WiSE CRT are based on internal and third-party estimates, including the number of patients with heart failure requiring Cardiac Resynchronization Therapy and our internally derived average selling price expectations at which we anticipate selling products for but has not been definitively established. While we consider the assumptions and the data underlying our estimates as reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

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

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 products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for procedures involving the use of our products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, 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 prices, or if our costs increase and we are unable to offset such an increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business, financial condition, and results of operations.

Our customers may not be able to achieve adequate reimbursement for using our products in the United States or in key foreign jurisdictions.

Even if we are able to receive approval from the FDA to market our WiSE CRT System technology, we may not be able to achieve adequate reimbursement for our business to succeed. We expect to derive our revenue in the United States from sales to hospital and medical centers, which typically bill all or a portion of the costs and fees associated with a company's products to various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, and then bill patients for any applicable deductibles or co-payments. As a result, access to adequate coverage and reimbursement for our products by third-party payors is essential to the acceptance of our products by its customers.

However, in the United States, there is no uniform policy of coverage and reimbursement for medical device products and services among third-party payors, so coverage and reimbursement can differ significantly from payor to payor, and each coverage decision and level of reimbursement is independent. As a result, third-party reimbursement may not be available or adequate for the Company's products, and there is no guarantee that the Company will be able to achieve adequate reimbursement for using our products.

Further, payors continually review new technologies for possible coverage and can, without notice, deny coverage for products and procedures or delay coverage approval until further clinical data is available. As a result, the coverage determination process is often a time-consuming and costly process that may require the Company to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained. If third-party reimbursement is not available or adequate for the Company's products, or if there is any decline in the amount that payors are willing to reimburse customers, new customers may not adopt, or may reduce their rate of adoption of, the Company's products and we could experience additional pricing pressure, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Internationally, reimbursement systems in foreign markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Additionally, many international markets have government-managed healthcare systems that control reimbursement for products and procedures. In most markets there are both private insurance systems and government-managed systems. If sufficient levels of coverage and reimbursement are not available for our WiSE CRT System, in either the United States or internationally, particularly in key European Union jurisdictions targeted by us, the demand for our products and its revenues will be adversely affected.

We may not realize the benefits from continued research and development costs.

Developing medical devices and related technologies is expensive and the investment in the development of these product offerings often involves an extended period of time to achieve a return on investment. An important element of our business strategy is to continue to make investments in innovation and related product opportunities. We believe that we must continue to dedicate resources to our innovation efforts to develop or enhance product offerings in order to maintain our competitive position and expand the total addressable market opportunity. We may not, however, receive significant revenues from these investments for several years, or may not realize such benefits at all.

We have limited management resources and must attract and retain skilled staff.

Our long-term growth and performance is dependent on attracting and retaining highly skilled staff. Despite having structured incentive programs, there is a risk that we will be unable to attract and retain the necessary staff to pursue our business model. If Mr. John McCutcheon, our Chief Executive Officer ("CEO"), was to leave EBR, we would lose significant technical and business expertise, and we may not be able to find a suitable replacement. This would affect how efficiently we operate our business, and our future financial performance could be impacted.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies, and implementing our business strategy.

In addition, our research and development programs, clinical operations and sales and marketing efforts depend on our ability to attract and retain highly skilled scientists, engineers, and sales professionals. Competition for skilled personnel in our market is intense, and we have from time to time experienced, and we expect to continue to experience difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects will be harmed.

Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity, and adverse competitive pressure. Furthermore, the reporting of product defects or voluntary recalls to the FDA or analogous regulatory bodies outside the United States could result in manufacturing audits, inspections and broader recalls or other disruptions to our manufacturing processes. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition, and results of operations.

During our WiSE CRT Premarket Clinical study, three instances of pericardial effusion were observed associated with the implantation of our system. The study was terminated during March 2012, and procedural changes were enacted to mitigate future risk. The key mitigation was a requirement for real-time echocardiography during the Electrode implant procedure and the mandatory use of fluoroscopy with use of contrast while advancing the delivery catheter. Another key change was the implementation of physician training for Electrode implantation using Electrode Implant Simulator (EIS) prior to the physician implanting any WiSE CRT device in a patient.

During 2020, we notified our SOLVE-CRT study investigators in the US informing them of a transmitter issue resulting in premature battery depletion. Based upon the investigation of the devices in question, the likely failure mode appeared to be a related manufacturing process that led to a conductive breach in the transmitter feedthrough area. Ultimately, the suspect transmitters were replaced. During 2022, similar further failure instances were observed resulting in the same premature battery depletion. Analysis of the impacted devices confirmed that the failure mode was an insulation breach in the transmitter feedthrough. We paused further shipment of the transmitter model for new patient implants effective immediately. The root cause analysis identified manufacturing process and design elements as contributors.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace, or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some, or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery and any recovery from such vendor or supplier may not be adequate.

The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any such claims even if we believe that such injuries were not due to the failure of our products. An adverse outcome of any such claim involving one of our products could result in reduced market acceptance and demand for any or all of our products and could harm our reputation or brand and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition, and results of operations.

Although we carry product liability insurance, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not continue to be available on acceptable terms, if at all. 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, harm our reputation, significantly increase our expenses, and reduce product sales. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in

adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We required to file adverse event reports under Medical Device Reporting, or MDR, regulations with the FDA and analogous regulatory bodies outside the United States, which reports are publicly available on the competent authority's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. See "—Risks Related to Government Regulation—If any of our products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions."

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.

We are experiencing substantial growth in our operations, and we expect to experience continued substantial growth in our business. This growth has placed and will continue to place significant demands on our management and our operational infrastructure. Any growth that we experience in the future could require us to expand our sales and marketing personnel and manufacturing operations and general and administrative infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure and could require significant capital expenditures that may divert financial resources from other projects, such as research and development of potential future products. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, and reporting systems and procedures. If we are unable to manage our growth effectively, including by failing to implement necessary procedures, transition to new processes or hire necessary personnel, it may be difficult for us to execute our business strategy, and our business could be adversely affected.

We may not be able to develop, license or acquire new products, enhance the capabilities of our existing products to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Our success is influenced by our ability to develop new applications for our technologies in existing and new markets, while improving the performance and cost-effectiveness of our existing products, in each case in ways that address current and anticipated customer requirements. We may develop and commercialize additional products through our research and development program and by licensing or acquiring additional products and technologies from third parties. Such success is dependent upon several factors, including functionality, competitive pricing, ease of use, the safety and efficacy of our products and our ability to identify, select and acquire the rights to products and technologies on terms that are acceptable to us.

The medical device industry is characterized by rapid technological change and innovation. New technologies, techniques or products could emerge that might offer better combinations of price and performance, or better address customer requirements as compared to our current or future products. Competitors, who may have greater financial, marketing and sales resources than we do, may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements. Any new product we identify for internal development, licensing or acquisition may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and comparable foreign regulatory authorities. Due to the significant lead time and complexity involved in bringing a new product to market, we are required to make a number of assumptions and estimates regarding the commercial feasibility of a new product. These assumptions and estimates may prove incorrect, resulting in our introduction of a product that is not competitive at the time of launch. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies. Our ability to mitigate downward pressure on our selling

prices will be dependent upon our ability to maintain or increase the value we offer to hospitals, physicians, patients, and payors. All new products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, successfully commercialized, or widely accepted in the marketplace. The expenses or losses associated with unsuccessful product development or launch activities, or a lack of market acceptance of our new products, could adversely affect our business, financial condition, and results of operations.

The typical development cycle of new medical device products can be lengthy and complicated and may require complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work is not performed according to schedule, then such new technologies or products may be adversely impacted, and our business and operating results may be harmed.

The continuing development of our products depends upon it maintaining strong working relationships with physicians.

The research, development, marketing, and sale of our products and potential new and improved products depend upon us maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products. Physicians assist us in clinical trials, marketing, and as researchers, product consultants and public speakers. Our advisory agreements with physicians can typically be terminated by either party upon notice to the other. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General ("OIG"), the U.S. Department of Justice ("DOJ"), U.S. state attorneys general, comparable foreign regulatory authorities, and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into its compliance by the OIG, the DOJ, state attorneys general and/or other government agencies, could have a material adverse effect on our business, financial condition, and results of operations.

Cost-containment efforts of our potential customers, purchasing groups and governmental organizations could have a material adverse effect on future sales and profitability.

Our ability to generate revenue will largely depend on how effectively we can market and sell WiSE to the healthcare industry. Hospitals and healthcare organizations are constantly facing significant budget constraints. The competition for limited capital budgets is intense and the budget allocation process and approvals for spending on medical devices is complex and time consuming.

In an effort to reduce costs, many hospitals in the U.S. have become members of Group Purchasing Organizations ("GPOs"), and Integrated Delivery Networks ("IDNs"). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for its products, thereby reducing our revenue and margins.

Our ability to utilize our net operating loss carryforwards may be limited.

As of December 31, 2024, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately $220.0 million and $217.3 million, respectively. Subject to certain limitations, we may use these NOL carryforwards to offset our taxable income for U.S. federal and state income tax purposes. If not utilized, our U.S. federal NOL carryforwards (and our state NOL carryforwards in conforming states) arising in taxable years beginning before 2018 will begin to expire in 2027. Under current law, U.S. federal NOL carryforwards arising in taxable years beginning after 2017

may be carried forward indefinitely, but their deductibility in any tax year is limited to 80% of our taxable income in such year before the deduction for such NOL carryforwards. Additionally, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOL carryforwards we may use in any year for U.S. federal income tax purposes in the event we undergo an "ownership change." A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not conducted any study with respect to the impact of Section 382 on our NOL carryforwards. We may have previously undergone an "ownership change." In addition, any future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that have occurred in the past or that may occur in the future, could result in the imposition of an annual limit on the amount of pre-ownership change NOL carryforwards and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing certain of those tax attributes to expire unused. Any limitation on our ability to use NOL carryforwards could, depending on the extent of such limitation and the NOL carryforwards previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, than we would retain if such NOL carryforwards were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact operating results.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws, tax treaties or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, the relative amounts of income before taxes in the various jurisdictions in which we operate, new or revised tax laws, or interpretations of tax laws and policies, the outcome of current and future tax audits, examinations or administrative appeals, our ability to realize our deferred tax assets, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Risks Related to Our Industry

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customers' patients or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may collect, store, or otherwise process sensitive data, including procedure-based information and protected health information, insurance information and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive data from unauthorized access or disclosure, our information technology, or IT, and infrastructure, and that of other technology partners, are vulnerable to cyber-attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. We rely on IT systems, networks, and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical

applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure could negatively impact operations. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware, ransomware, failures during the process of upgrading or replacing software, databases, or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, or other cyber-attacks or other interruptions, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. We have been the target of such events in the past and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. Although we are investing in protection and monitoring practices of our data and IT to try to reduce these risks and we monitor our systems on an ongoing basis for any current or potential threats, there can be no assurance that our efforts will prevent breakdowns or breaches of our or our third-party providers' databases or systems that could materially and adversely affect our business, financial condition, and results of operations.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

We could be subject to any number of unintentional events that could involve a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data, or result in the release of our confidential or other sensitive information. Such attacks or interruptions could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition, and results of operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, and the further development and commercialization of our products could be delayed or disrupted.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related data and system disruptions. We cannot be certain that such potential losses will not exceed our policy limits, insurance will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. In addition, we may be subject to changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements.

Litigation and other legal proceedings may adversely affect our business.

From time to time, we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings, or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence, and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

We may face difficulties encountered by many medical technology companies early in their commercialization.

Our company is currently at the pre-commercialization phase. We intend to move into the initial commercial phase if we receive FDA approval of our WiSE CRT System. As is common with companies at the pre-commercialization stage, we have incurred net losses since its inception, have never been profitable and can give no assurance that we will be profitable or cash-flow positive in the future. In assessing our business prospects, you should consider the various risks encountered by companies early in their commercialization, particularly companies that develop and sell medical devices. These risks include our ability to:

- transition into a commercialization-stage company, and implement and execute its business strategy;
- increase awareness of its brand and market acceptance of its products;
- obtain future regulatory registrations and market approvals;
- manage expanding operations; and
- respond effectively to competitive pressures and developments.

Clinical trials may be delayed, suspended, or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our current or new products or seek new indications.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement and completion of clinical trials for current or future products or indications may be delayed, suspended, or terminated as a result of many factors, including:

- the FDA or comparable foreign regulatory authorities other regulators disagreeing as to the design, protocol, or implementation of our clinical trials;
- the delay or refusal of regulators or institutional review boards, or IRBs, or Ethics Committees to authorize us or issue a positive opinion permitting us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies, and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- patient deaths during a clinical trial, even though their death may not be related to the products that are part of the clinical trial;
- patient adverse events;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- regulators or IRBs or Ethics Committees requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;

- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- the quality of the products falling below acceptable standards;
- the inability to manufacture sufficient quantities of our products to commence or complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice ("GCP"), regulations, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate safety and effectiveness, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

In addition, we may encounter delays if the FDA or a comparable foreign regulatory authority concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a trial, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock-based compensation in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the trial result in perceived or actual conflicts of interest, or if the FDA or a comparable foreign regulatory authority concludes that the financial relationship may have affected interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in a delay or rejection by the FDA or a comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

If we experience delays in the commencement or completion of any clinical trial of our products, or if any of our clinical trials are terminated, the commercial prospects of our products may be harmed, and our ability to generate revenue from sales may be delayed or materially diminished.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

Many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for the Company's products. If we reduce our prices because of consolidation in the medical device industry, its future revenue will decrease, which could have a material adverse effect on our business, financial condition, and results of operations.

New or competing technologies or products could emerge which may adversely affect future sales of our products and may cause our products to become obsolete.

We expect to generate the vast majority of our revenue going forward from the sale of our WiSE CRT System, if approved by the FDA. The medical device industry is competitive, subject to rapid change and significantly affected by new product introductions. Although we believe that there are currently no products or technologies that are commercially comparable to the WiSE CRT System, there are a number of other products and devices on the market which are commonly used to perform conventional CRT procedures. If competitors develop new products (which could include devices or drugs) or technologies that offer better combinations of price and performance than we can offer for the treatment of certain types of heart failure, our products or future products may become obsolete or not competitive, which would have a significant negative effect on our business and financial position.

We are subject to stringent privacy laws, rules, regulations, information security and privacy policies, contractual obligations, and other obligations governing the use, processing and cross-border transfer of personal information.

We receive, generate, store, and otherwise process sensitive information, such as health information, insurance information and other potentially personally identifiable information.

We may be subject to a variety of local, state, national and foreign laws, directives, and regulations that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the different jurisdictions in which we operate, including comprehensive regulatory systems in the U.S. and the European Union. For example, California enacted the California Consumer Privacy Act, or CCPA, which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. Other U.S. states have enacted or are considering comprehensive privacy laws. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity, and liability. Legal requirements relating to the collection, storage, handling, and transfer of personal information and personal data continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions, and increased costs of compliance.

The collection and use of personal data in the European Union are governed by the European Union's General Data Protection Regulation, or GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data.

If we or our vendors fail to comply with the GDPR and the applicable national data protection laws of the European Union member states, or if regulators assert, we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs, and the risks associated with non-compliance.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers.

We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we [may] be subject to investigation, enforcement actions by regulators or other adverse consequences.

Compliance with U.S. or foreign data protection laws, regulations, and other obligations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Penalties for violations of these laws vary. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. In addition, we rely on third-party vendors to collect, process and store data on our behalf and we cannot guarantee that such vendors are in compliance with all applicable data protection laws and regulations. Our or our vendors' failure to comply with U.S. or foreign data protection laws, regulations, or other obligations could result in government enforcement actions (which could include civil or criminal penalties), private litigation (including class demands), mass arbitration demands, additional reporting requirements and/or oversight, bans or restrictions on processing personal data, orders to destroy or not use personal data, imprisonment of company officials and/or adverse publicity and could negatively affect our operating results and business. 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, could result in adverse publicity and could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Regulatory registrations or market approvals may be withdrawn, or regulatory requirements may change.

The manufacture, testing, labelling, sale, and marketing of medical devices are subject to extensive regulation in the U.S., Europe, Australia, and other countries. We are pursuing the required regulatory approvals to place our key products on the market in the U.S. and potentially other markets. However, regulatory registrations or market approval of products can subsequently be withdrawn for a variety of reasons, including failure to comply with manufacturing regulatory requirements by the Company or any third-party contractors engaged by us to manufacture our products. Regulators have the power to ban products sold by us as well as to require the recall, repair, replacement, or refund of such products. Further, regulators may change their approval policies or impose additional regulatory requirements on the Company that could increase its compliance costs, restrict its ability to maintain its current regulatory registrations or market approvals, prevent or delay approval of future products under development or impact its ability to modify its currently cleared products. We cannot guarantee that we will successfully maintain the registrations and approvals we currently have or obtain the additional registrations and approvals that we are seeking or may receive in the future, or that we will successfully obtain the registrations and approvals required for future products.

Risks Related to Our Financial Position and Need for Additional Capital

Our existing indebtedness contains restrictions that limit our flexibility in operating our business. In addition, we may be required to make a prepayment or repay our outstanding indebtedness earlier than we expect.

In June 2022, we entered into a loan and security agreement with Runway Growth Finance Corp. for term a loan facility in an aggregate principal amount up to $50 million. The loan agreement provides three term loan tranches. On June 30, 2022, we drew down $20 million under tranche 1. On June 30, 2023, we drew down an additional $20 million under tranche 2. The loan agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur or assume certain debt;
- merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;
- enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;
- change the nature of our business;
- change our organizational structure or type;
- license, transfer, or dispose of certain assets;
- grant certain types of liens on our assets;
- make certain investments;
- pay cash dividends; and
- enter into material transactions with affiliates.
- The restrictive covenants in the Loan Agreement could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the loan agreement. An event of default will also occur if, among other things, a material adverse effect in our business, operations, or condition occurs, which could potentially include a material impairment of the prospect of our repayment of any portion of the amounts we owe under the loan agreement. In the case of a continuing event of default under the loan agreement, the lender could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted the lender a security interest under the loan agreement, or otherwise exercise the rights of a secured creditor. Amounts

outstanding under the loan agreement are secured by substantially all of our existing and future assets, excluding intellectual property, but includes all proceeds from the sale of intellectual property.

The additional $10 million tranche under the loan agreement was only available after receipt of approval from the FDA for the WiSE CRT System and prior to June 30, 2024. Since we were unable to satisfy this condition, we were not able to draw down the remaining tranche of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all, which could adversely impact our business.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financing to repay or refinance our indebtedness at the time any such repayment is required. In such an event, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts. Our business, financial condition, and results of operations could be materially adversely affected as a result.

We have a history of net losses, and we expect to continue to incur losses for at least the next several years. We may never generate any revenue from commercial products or become profitable or, if we ever achieve profitability, we may not be able to sustain it.

We have incurred net losses since our inception in 2003. For the years ended December 31, 2024 and 2023, we had a net loss of $40.8 million and $35.0 million, respectively, and we expect to continue to incur additional net losses for at least the next several years. As a result of these losses, as of December 31, 2024 and 2023, we had an accumulated deficit of $353.5 million and $312.7 million, respectively. Our losses and accumulated deficit have primarily been due to the significant investments we have made in research and development and clinical trials designed to provide clinical evidence of the safety and efficacy of our products and in support appropriate regulatory submissions. We have not yet demonstrated an ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we expand our marketing efforts to establish adoption of our products upon the commencement of commercialization efforts, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, as a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur operating losses and net losses for at least the next several years, 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 would make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition, and results of operations.

In order to support our continued operations and the growth of our business, we may seek to raise additional capital, which may not be available to us on acceptable terms, or at all.

We expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure, commercial operations and research and development activities. Our primary uses of capital are, and we expect will continue to be, investment in our commercial organization and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses, general administrative costs and working capital. In addition, we may in the future seek to acquire or invest in additional businesses, products, or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities, or otherwise offer growth opportunities. For further information regarding our recent strategic transactions, see the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our revenue growth;
- our research and development efforts;

- our sales and marketing activities;
- our success in leveraging strategic partnerships or strategic transactions in the future;
- our ability to raise additional funds to finance our operations;
- the outcome, costs, and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- the availability and amount of reimbursement for procedures using our products;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and sales, scientific and medical personnel;
- the terms and timing of any collaborative, licensing, or other arrangements that we have or may establish;
- debt service requirements;
- the extent to which we acquire or invest in businesses, products, or technologies; and
- the impact adverse worldwide economic conditions.

If we determine to raise additional funds, we may do so through equity or debt financings, which may not be available to us on the timing needed or on terms that we deem to be favorable. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we are unable to maintain sufficient financial resources, our business, financial condition, and results of operations will be materially and adversely affected, including potentially requiring us to delay, limit, reduce or terminate certain of our product discovery and development activities or future commercialization efforts.

Moreover, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to products or technologies we otherwise would seek to develop or commercialize ourselves or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms.

The issuance of additional shares of our common stock in connection with financings, acquisitions, investments, our share incentive plans or otherwise will dilute all other stockholders.

Our current stockholders do not have preemptive rights to any shares that we issue in the future. Under our Certificate of Incorporation, we have authority to issue a total of 610,000,000 shares. Of the total shares authorized, 600,000,000 are classified as shares of common stock and 10,000,000 are classified as shares of preferred stock. Subject to compliance with applicable rules and regulations, we may issue common stock or securities convertible into common stock from time to time in connection with financing, acquisition, investment, our equity incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline, which will negatively impact the value of a stockholder's investment, especially if we sell these securities at prices less than the price paid for shares.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including potential future revenue, profitability or losses, and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- the level of demand for our products, which may vary significantly from period to period;
- expenditures that we may incur to acquire, develop, or commercialize additional products and technologies;

- the timing and cost of clinical trials, including obtaining regulatory approvals or clearances for planned or future products;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials for our current or planned products or any future products we develop or competing products;
- the timing of customer orders or medical procedures, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold and the geographic mix of where products are sold;
- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- natural disasters, or outbreaks of disease or public health crises;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Because our quarterly and annual results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

In addition, this variability and unpredictability could result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it may result in a decrease in the price of our common stock.

Our current capital reserves may not be adequate.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and/or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current stakeholders' interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stakeholders. The incurrence of indebtedness and/or the issuance of certain equity securities could result in fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur debt and/or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our stock to decline. In the event that we enter into collaborations and/or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to our CTR products or our WiSE CRT system that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms. If we require additional funding and are unable to raise these funds, our business could be adversely impacted.

We have capitalized pre-launch inventories prior to receiving FDA approval. If either FDA approval or market acceptance post-approval do not occur at all or on a timely basis, we will be required to write-off pre-launch inventories which could materially and adversely affect our business, financial condition and stock price.

We capitalize costs associated with certain product candidates prior to regulatory approval and product launch ("pre-launch inventories") when it is reasonably certain that the pre-launch inventories will be saleable, based on management's judgment of future commercial use and net realizable value. The determination to capitalize is based on the particular facts and circumstances and based on the judgment of our management relating to the potential FDA approval. We could be required to expense previously capitalized costs related to pre-launch inventories upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential risk factors. Pre-

launch inventories consist of costs of raw materials and components related to our WiSE CRT System, which have been capitalized prior to the date that we anticipate that WiSE CRT System may receive FDA approval. If FDA approval does not occur or will be significantly delayed, we will be required to write-off pre-launch inventories and such amounts could be material. In addition, market acceptance of our WiSE CRT System could fall short of our expectations, as a result of the introduction of a competing product, as a result of physicians', patients', or payors' unwillingness to adopt our WiSE CRT System. If any of these risks were to materialize, or if the launch of our WiSE CRT System is significantly postponed, the salability of our pre-launch inventories would be adversely affected and may require write-off of the carrying value of our pre-launch inventories in amounts that could have a material adverse effect on our results of operations and financial condition.

We expect to be an emerging growth company, and a smaller reporting company should we choose to list on a US exchange, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.235 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending following the fifth anniversary of the date of our first sale of our common stock pursuant to an effective registration statement under the Securities Act.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

Our results may be impacted by changes in foreign currency exchange rates.

Our reporting currency is the U.S. dollar, and our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States, Australia, and Europe. If our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars. In addition, because we conduct business in currencies other than U.S. dollars, but report our results of operations in U.S. dollars, we also face remeasurement exposure to fluctuations in currency exchange rates, which could hinder our ability to predict our future results and earnings and could impact our results of operations. We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies. If we are unable to address these risks effectively, it could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Government Regulation

Regulatory compliance is expensive, complex, and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

Our current products are subject to extensive regulation by the FDA in the United States, and certain other non-U.S. regulatory agencies and supervision by our Notified Body in the European Union. Complying with these regulations is costly, time-consuming, complex, and uncertain. Government regulations specific to medical devices are wide- ranging and include, among other things, oversight of:

- product design, development, manufacture (including suppliers) and testing;
- laboratory, preclinical and clinical trials;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- premarket clearance or approval;
- marketing, advertising, and promotion;
- product sales, distribution, and use of device;
- product modifications;
- product recalls, repairs, replacements, or refunds;
- product tracking;
- reports of corrections, removals, enhancements, recalls and field corrective actions;
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions; and
- product import and export

Before a new medical device or service, or a new intended use for an existing product or service, can be marketed in the United States, a company must first submit and receive either 510(k) clearance or PMA from the FDA, 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, preclinical, 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.

Either the 510(k) or PMA process can be expensive, lengthy, and unpredictable. We may not be able to obtain any necessary clearances or approval or may be unduly delayed in doing so, which will negatively affect our business, financial condition, and results of operations. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although

we have obtained 510(k) clearance to market our products, our clearance can be revoked if safety or efficacy problems develop.

Further, all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing, or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The FDA can also refuse to clear or approve pending applications. Equivalent rules and powers apply outside the U.S.

Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition, and results of operations. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state or comparable foreign regulatory authorities agencies, which may include any of the following actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these events were to occur, it would have a material and adverse effect on our business, financial condition, and results of operations.

The FDA and the Federal Trade Commission ("FTC"), also regulates the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Equivalent rules and powers apply outside the U.S.

Our operations are subject to pervasive and continuing FDA regulatory requirements.

Medical devices regulated by the FDA are subject to "general controls" which include: registration with the FDA; listing commercially distributed products with the FDA; complying with current good manufacturing practice ("cGMP") under quality management system regulation ("QSR"); filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA. As a company, we do not have prior experience in obtaining PMA approval.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state, and comparable foreign regulatory authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving marketing, business practices and product quality management. Such reviews and investigations may result in civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate

integrity agreements, stipulated judgments or other administrative remedies; and could result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may have a material and adverse effect on our business, financial condition and results of operations, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state, and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, Open Payments requires us to annually report to the Centers for Medicare & Medicaid Services("CMS"), payments, and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems, and processes to comply with these legal and regulatory requirements, which may also impact our business, and which could have a material adverse effect on our business, financial condition, and results of operations. Equivalent transparency obligations and related powers and penalties exist outside the U.S.

Even if our products are cleared or approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product that we market will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. Such oversight will cover, among other things, the product's design and manufacturing processes, our quality system and compliance with reporting requirements, our compliance with post-approval clinical data requirements, and our promotional activities related to our products.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR or QMSR, may result in, among other things, changes to labeling, restrictions on such products or manufacturing processes, product corrections, removal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, withdrawal of regulatory clearance or approvals, delays in or refusals of new 510(k)s, de novo requests or PMA applications, untitled letters, warning letters, refusal to grant export certificates for our products, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our products may be subject to recalls after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA and comparable foreign regulatory authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality- related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation, and adversely affect our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies, including comparable foreign regulatory authorities. This report could be classified by the

FDA as a device recall which could lead to increased scrutiny by the FDA, other comparable foreign regulatory authorities and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or comparable foreign regulatory authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the satisfaction of the FDA or a comparable foreign regulatory authority, can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals, and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or comparable foreign regulatory authorities, which could divert managerial and financial resources, harm our reputation, and have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected.

As a public company, we are required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with our second annual report on Form 10-K, we expect we will be required to furnish annual management assessments of the effectiveness of our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include a report by our independent registered public accounting firm addressing these assessments pursuant to Section 404 of the Sarbanes-Oxley Act. These reporting and other obligations may place significant demands on management, and administrative and operational resources, including accounting systems and resources.

The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the applicable requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or to assert that our internal control over financial reporting is effective, or, when applicable, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are then listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the FCPA, as well as export control laws, customs laws, sanctions laws and other laws governing our operations could result in civil or criminal penalties, other remedial measures, and legal expenses.

As we grow our international presence, we are increasingly exposed to anti-corruption, trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving, or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. In addition, the U.K. Bribery Act prohibits both domestic and international bribery, as well as bribery across both private and public sectors. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. Violations of the FCPA, U.K. Bribery Act and anti-corruption laws could result in fines, criminal sanctions against us, our officers or our employees and prohibitions on the conduct of our business. Violations would also negatively affect our business and reputation, financial condition, and results of operations.

In addition, our solutions may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our solutions, or our failure to obtain any required import or export authorization for our solutions, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our solutions may create delays in

the introduction of our solutions in international markets or, in some cases, prevent the export of our solutions to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our solutions by, or in our decreased ability to export our solutions to, existing or potential customers with international operations. Any decreased use of our solutions or limitation on our ability to export or sell access to our solutions would likely adversely affect our business.

We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants, and agents with the FCPA, the U.K. Bribery Act, export control and economic sanctions laws, and other anti-corruption, anti-money-laundering and anti-terrorism laws, and regulations. We cannot assure you, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants, and agents have not engaged and will not engage in prohibited conduct for which we may be held responsible. Violations of the FCPA, the U.K. Bribery Act, export control and economic sanctions laws, or other anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

The impact of the E.U. Medical Device Regulation may be costly and disruptive to our business.

Compliance with the Medical Device Regulation and its associated guidance documents and harmonized standards is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA.

The changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third-party testing by Notified Bodies, additional requirements for the quality management system, traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body, where applicable, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the MDR or continued certification under the MDR. Following the withdrawal of the United Kingdom from the European Union on January 31, 2020, commonly referred to as Brexit, an EU-UK Trade and Cooperation Agreement, or TCA, was concluded. As a result of this Agreement, Northern Ireland will continue to follow many aspects of the European Union regulatory rules, particularly in relation to trade in goods, and including the Medical Devices Regulation. In light of the fact that the CE Marking process is set out in EU law, which no longer applies in the United Kingdom, the United Kingdom has devised a new route to market culminating in a UKCA Mark to replace the CE Mark. Northern Ireland will, however, continue to be covered by the regulations governing CE Marks. The UK government also plans to introduce new legislation governing medical devices to apply from 1 July 2025. We cannot be sure that the regulations in Northern Ireland will continue to follow that in the EU. Neither can we be sure that future United Kingdom legislation governing medical devices will not diverge substantially from that applicable in the EU, preventing us relying on data and materials developed as part of conformity assessment in the EU to support application for a UKCA in the United Kingdom.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our planned or future products and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. For example, the FDA issued a final rule in February 2024 replacing the QSR with the Quality Management System Regulation ("QMSR"), which incorporates by reference the quality management system requirements of ISO 13485:2016. The FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. FDA regulations and guidance are often revised or reinterpreted by the agency in ways

that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Compliance with the Medical Device Regulation and its associated guidance documents and harmonized standards is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. The changes to the existing regulatory system implemented in the EU by the Regulation include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by this may cause us to incur substantial costs. We may be unable to fulfil these obligations for medical devices we intend to place on the EU market, or our Notified Body, where they are involved, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the Medical Device Regulation. We must obtain the appropriate CE Certificate(s) of Conformity in accordance with the Medical Device Regulation to continue to place our products on the EU market, or other countries that relate their medical device regulations to a CE mark, once we can no longer benefit from the transitional provisions of the Medical Device Regulation. The modifications of the Medical Device Regulation may have an effect on the way we conduct our business in the EEA. Additional regulatory changes may negatively affect our business, financial condition, and results of operations.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned, and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties, and our business operations and financial condition could be adversely affected.

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with principal investigators, healthcare professionals and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements, and relationships with customers, and how we market, sell, and distribute our marketed medical devices. We have a compliance program, code of business conduct and ethics and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal healthcare Anti-Kickback Statute and federal civil False Claims Act, federal data privacy and security laws and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. There are similar laws in other countries. Our relationships and our distributors' relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- The Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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 the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a

false or fraudulent claim for purposes of the federal civil False Claims Act. 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 certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants, or charitable donations. Practices that involve remuneration to those who prescribe, purchase, or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisors, or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute.

- Federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil 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. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil False Claims Act for a variety 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 interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings.

- HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates and their subcontractors that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions, to the 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 (such as physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and foreign laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign beneficiary inducement laws, which are laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018, or BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. Government agencies have continued regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil False Claims Act and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices, and financial arrangements with physicians, other healthcare providers and other customers, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti- Kickback Statute, it may also subject us to violations under other fraud and abuse laws such as the federal civil False Claims Act and civil monetary penalties laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws, we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses, and could divert our management's attention from the operation of our business. Companies settling federal civil False Claims Act, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the OIG in order to avoid exclusion from participation (i.e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may have a material adverse effect on our business, financial condition, and results of operations.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. For example, implementation of the ACA substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the

340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, administrative, executive, and Congressional legislative challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period 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, 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. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Congress is considering additional health reform measures.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical and device product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which products and supplies will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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. Further, the expansion in any government's regulation of the healthcare industry may result in decreased profits to EBR and reduced medical procedure volumes, all of which may adversely affect the Company's business and financial position.

Our global operations expose us to numerous and sometimes conflicting legal and regulatory requirements, and violation of these requirements could harm our business.

We are subject to numerous, and sometimes conflicting, legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anticorruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes emerging markets where legal systems may be less developed or familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time-consuming and requires significant resources. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our customers also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and allegations by our customers or distributors that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. The imposition of new laws or regulations, including potential trade barriers, may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition and results of operations.

Modifications to our products may require new regulatory clearances, CE Marks or other premarket approvals or may require us to recall or cease marketing our products and services until clearances or approvals are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant changes to a device's design, materials, chemical composition, energy source, or manufacturing process, or that would constitute a major change in its intended use, may require a new 510(k) clearance, a de novo classification, or possibly a PMA. Modifications to our products that were implemented without obtaining clearance or approval and for which FDA subsequently concludes that clearance or approval was required, may require us to recall or cease marketing the modified devices until clearance or approval is obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, or clearance. To do that, a manufacturer must determine if a change/modification to labeling of the device is a "major" change to the intended use statement (previously cleared by the FDA) or if a physical change/modification to the device itself "could significantly affect safety or effectiveness." If the labeling change is major and/or the physical change significantly affects safety and effectiveness, the manufacturer must file for an additional 510(k) clearance, de novo classification, or PMA for those changes before the modified device can be lawfully marketed. If the Company concludes in its own self-determination that the changes do not meet either of the thresholds of "major "or "significantly affects," it may simply document those changes by way of an internal letter-to-file as part of the manufacturer's quality system recording keeping. However, the FDA can review a manufacturer's decision and may disagree. The FDA will normally review a decision made by a manufacturer in a letter-to-file during a routine plant inspection, which FDA targets to conduct every two years for high-risk (Class III) device manufacturers and certain low and moderate risk (Class I and II) device manufacturers. In such a review the FDA may determine that a new clearance or approval was required before the device was put into commercial distribution.

If any of our products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under FDA MDR regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations. Comparable foreign regulatory authorities have equivalent rules and powers exist outside the U.S.

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

We are exposed to the risk that our employees, independent contractors, consultants, strategic partners, distributors, and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements

in the healthcare industry, are subject to extensive laws designed 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, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities 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 result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations.

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment, and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs, and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and results of operations.

Any barriers or delays to us obtaining future regulatory approvals would limit the size of the market opportunity for WiSE CRT.

Our business model depends on hospitals and clinics in markets where we obtain the required regulatory approvals adopting our WiSE CRT System for the treatment of heart failure with CRT. We enrolled patients at 43 sites in the U.S. as part of the SOLVE-CRT clinical trial. However, there can be no guarantee that all or any of these sites will adopt WiSE CRT if FDA approval is granted. Even if a site does adopt the WiSE CRT System, the site may not adopt WiSE CRT at the levels required to support our business model and growth strategy. If our technology for CRT procedures is not increasingly adopted or favored by hospitals, clinics, and physicians, our ability to achieve our growth strategy and generate revenue will be significantly impaired.

We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation.

The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. Due to the significant role government entities play in the administration and regulation of many foreign healthcare markets, the Company may be exposed to heightened FCPA, and similar risks arising from its efforts to promote and sell its products and to seek regulatory approval of and reimbursement for its products in such countries. In the future, the Company also may operate in parts of the world that have experienced governmental corruption to some degree. We cannot assure investors that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could significantly disrupt our business and have a material adverse effect on our business, brand, financial condition, and results of operations.

If our facilities become damaged or inoperable, or if we are required to vacate a facility, we may be unable to manufacture our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.

We currently maintain our research and development, manufacturing and administrative operations in a building located in Sunnyvale, California, and we do not have redundant facilities. Should our building be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires (both of which are prevalent in California) or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development, and manufacturing would cease or be delayed, and our products may be unavailable. Because of the time required to authorize manufacturing in a new facility under federal, state, and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would not cover all damages, including losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development, and manufacturing activities if our facilities become inoperable, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to re-establish relationships with such physicians in the future. Consequently, a catastrophic event at our current facility or any future facilities could have a material adverse effect on our business, financial condition, and results of operations.

The current lease for our manufacturing facility expires at the end of December 2026. In January 2025, we entered into a new lease agreement to lease our new corporate headquarters, laboratory and manufacturing facility until December 31, 2036. Relocating our manufacturing facility involves significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

Risks Related to Our Intellectual Property

We are dependent on the protection and enforcement of our intellectual property rights.

The protection of the intellectual property relied upon by EBR is critical to its business and commercial success. Our patent portfolio comprises 63 issued U.S. patents and 55 corresponding granted foreign patents. In addition, as of December 31, 2024, we have 17 pending patent applications worldwide. Though a patent may be issued, there can be no assurance that the patent is valid and enforceable. However, it should be noted in the U.S., a patent granted by the U.S. Patent and Trademark Office is presumed to be valid in court proceedings. In addition, there can be no assurance that any of the Company's pending patent applications will result in the issuance of a patent, or that the scope of protection provided by any patent that is granted will be identical to the scope of the application as originally filed. There is a risk that the Company's competitors may be able to compete with EBR by designing around the claims of EBR's patents, or by otherwise using products and techniques that are outside the scope of EBR's patents.

We may be subject to future third party intellectual property rights disputes.

We do not believe that our activities infringe on any third party's intellectual property rights. However, in the future the Company may be subjected to infringement claims or litigation arising out of patents and pending applications of third parties. Intellectual property authorities may also re-examine the patentability of licensed or owned patents. The defense and prosecution of intellectual property claims can be costly and time consuming to pursue, and their outcome is uncertain. If we are determined to have infringed the rights of third parties, we could be prevented from selling some of our products, which would have a significant negative effect on our business and financial position. We have not budgeted for potential legal costs of intellectual property claims and significant legal costs would have a negative effect on our financial position.

If we are unable to obtain and maintain patent protection or freedom to operate for any products we develop and for our technology, or if the scope of the patent 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 adversely affected.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our products and technology we develop.

We seek to protect our position by filing patent applications in the United States and abroad related to our technologies and products that are important to our business. We also rely on a combination of contractual provisions, confidentiality procedures and copyright, trademark, trade secret and other intellectual property rights to protect the proprietary aspects of our brands, technologies, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on obtaining and maintaining patents, preserving our trade secrets, maintaining the security of our data and know-how and obtaining other intellectual property rights.

We may not be able to obtain and maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. For example, 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, contractors, clients and other vendors who have access to such information and could otherwise become known or be independently discovered by third parties. In addition, the patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable 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 intellectual property at all. Despite our efforts to protect our intellectual property, unauthorized parties may be able to obtain and use information that we regard as proprietary. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. 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, consultants, contractors, collaborators, vendors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag 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 make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. 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 of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors 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. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, or invalidated by third parties. Additionally, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, 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, in which case, our competitors and other third parties 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.

Given that 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, if issued, by showing

the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we will lose our rights to those challenged patents.

In addition, given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Our other intellectual property, including our trademarks, could also be challenged, invalidated, infringed and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks, in which case 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.

We may in the future also be subject to claims by our former employees, consultants or contractors 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, consultants, contractors 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.

Failure to obtain and maintain patents, trademarks, and other 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 patents, trademarks, data, technology, and other intellectual property, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, our owned patents may be subject to a reservation of rights by one or more third parties. For example, this could arise if the research resulting in certain of our owned or in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic

maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications will be due to the USPTO and foreign patent agencies over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. While an unintentional lapse 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 patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent 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 patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which could have a material adverse effect on our business, financial condition, and results of operations.

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

The medical device industry 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 and 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 and/or export our products or to use product names. Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products. 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 in litigation, divert management's attention and resources, damage our reputation, and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom 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, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our customers or business partners in connection with litigation and to obtain licenses or refund subscription fees, which could further exhaust our resources.

Even if we believe a third party's intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability, or priority of patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products or technology we may develop, and any other products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

Further, if patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from developing, manufacturing, or selling our products, or result in obligations to pay license fees, damages, attorney fees and court costs, which could be significant. In addition, if we are found to willfully infringe on 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. We may be unable to obtain necessary licenses on satisfactory terms, if at all. In addition, if any license we obtain is non-exclusive, we may not be able to prevent our competitors and other third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain the necessary licenses, we may not be able to redesign our products to avoid infringement. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or 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, derivation, or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition, and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property, which we may not always be able to detect. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our owned or in-licensed patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body 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.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents 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. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. 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 adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition, and results of operations.

We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.

We may need to obtain or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for our products. It is possible that we may be unable to obtain any additional licenses or acquire such intellectual property rights at a reasonable cost or on reasonable terms, if at all. 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. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In that event, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially and adversely affect our business, financial condition, and results of operations.

If we are unable to protect the confidentiality of our other proprietary information, 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, and other 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 rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, contractors, collaborators, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered 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 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 will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. 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 in the United States and abroad, which could affect our ability to expand in domestic and 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 development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information.

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. 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.

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 breach. Any of the foregoing could materially and adversely affect our business, financial condition, and results of operations.

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

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks, or trade names in foreign countries where we do not have any patents or patent applications and where legal recourse may be limited or unavailable. This may have a significant commercial impact on any potential foreign business operations.

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 may compete with our products, 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 foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do 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 intellectual property rights generally. Proceedings to enforce our intellectual property 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 our patent or trademark applications at risk, 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, many countries, including India, China, and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. 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.

We may be subject to claims that we or our employees, consultants or contractors have wrongfully used, disclosed, or otherwise misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors or claims asserting an ownership interest in intellectual property we regard as our own.

Many of our employees, consultants and contractors were previously employed at or engaged by other medical device, biotechnology, or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants 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 and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, used, disclosed or

otherwise misappropriated intellectual property, including trade secrets or other proprietary information, of their former employers or our competitors or potential competitors. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees, consultants, or contractors have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity.

Litigation may be necessary to defend against such claims, and it may be necessary, or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. For example, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition, and results of operations, and may prevent us from selling our products. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former consultants, contractors or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants 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, 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. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. Any such events could have a material adverse effect on our business, financial condition, and results of operations.

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

Recent 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, or 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-inventor-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, including post-grant review, *inter partes* review and derivation proceedings. Under a first- inventor-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, became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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, 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.

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

We rely on trademarks, service marks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register these trademarks. Our registered or unregistered trademarks, service marks, trade names and brand names may be challenged, infringed, diluted, circumvented, or declared generic or determined to be infringing on other marks. Additionally, we cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and 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. In the event that 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 towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic, and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

Risks Related to Our CDIs and Common Stock

Our common stock may never be listed on a major U.S. stock exchange.

While we may seek the listing of our common stock on a U.S. securities exchange at some time in the future, we cannot ensure when, if ever we will do so, that we will be able to satisfy such listing standards or that our common stock will be accepted for listing on any such exchange. Should we fail to satisfy the initial listing standards of such exchange, or our common stock is otherwise rejected for listing, the trading price of our common stock could suffer, the trading market for our common stock may be less liquid, and our common stock price may be subject to increased volatility.

The issuance of additional securities in connection with financings, acquisitions, investments, our share incentive plans or otherwise may adversely affect the value of and rights associated with our common stock.

Our current stockholders do not have preemptive rights to any Shares that we issue in the future. Under our Amended and Restated Certificate of Incorporation, our board of directors has the authority to issue a total of 610,000,000 shares. Of the total shares authorized, 600,000,000 are classified as shares of common stock and 10,000,000 are classified as shares of preferred stock. The board of directors is authorized to issue the preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our Amended and Restated Certificate of Incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these series of preferred stock may (i) be senior to or on parity with our common stock, which may reduce its value, and (ii) adversely affect the rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, delay, defer, discourage, or prevent a change in control of EBR and may adversely affect the market price of our common stock and the rights of the holders of common stock. Subject to compliance with applicable rules and regulations, the board of directors may also issue common stock or other securities convertible into common stock from time to time in connection with financing, acquisition, investment, our equity incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline, which will negatively impact the value of a stockholder's investment, especially if we sell these securities at prices less than the price paid for shares.

The market price of our CDIs and common stock may be volatile, which could cause the value of our common stock to decline.

The trading price of our CDIs on the Australian Securities Exchange ("ASX") has been volatile and may continue to be subject to fluctuations. In addition, the trading volume in our CDIs and common stock if a market develops may fluctuate and cause significant price variations to occur. Securities markets worldwide experience significant price and volume fluctuations as a result of a variety of factors, many of which are beyond our control but may nonetheless decrease the market price of our CDIs and common stock if a market develops, regardless of our actual operating performance, including:

- public reaction to our press releases, announcements and filings with the SEC and ASX;
- our operating and financial performance;
- changes in market valuations of similar companies;
- departures of key personnel;
- commencement of or involvement in litigation;
- changes in economic and political conditions, financial markets, and/or the technology industry;
- interest rate fluctuations;
- changes in accounting standards, policies, guidance, interpretations, or principles;
- actions by our security holders;
- the failure of securities analysts to cover our common stock and/or changes in their recommendations and estimates of our financial performance;
- Future sales of our common stock or CDIs;
- trading prices and trading volumes of our CDIs on the ASX; and
- the other factors described in these "Risk Factors".

The stock market has in the past experienced extreme price and volume fluctuations, and following periods of such volatility in the overall market and the market price of a company's securities, securities class action litigation has often been instituted against these companies. Such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Additionally, our securities may in the future trade on more than one stock exchange and this may result in price variations between the markets and volatility in our stock price. Our CDIs are currently listed on the ASX, and we may list our common stock on a U.S. securities exchange in the future. Trading in our common stock and CDIs therefore may take place in different currencies (U.S. dollars on the U.S. securities exchange and Australian dollars on the ASX), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Australia). The trading prices of our CDIs and our common stock on two markets may differ as a result of these, or other, factors. Any decrease in the price of our CDIs or common stock on either market could cause a decrease in the trading prices of our CDIs or our common stock on the other market. In addition, investors may seek to profit by exploiting the difference, if any, between the price of our CDIs on the ASX and the price of shares of our common stock on a U.S. securities exchange. Such arbitrage activities could cause our stock price in the market with the higher value to decrease to the price set by the market with the lower value and could also lead to significant volatility in the price of our common stock or CDIs.

The requirements of being an SEC registrant may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As an SEC registrant, we are subject to the reporting and corporate governance requirements of the Exchange Act. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company" as defined in the JOBS Act. Among other things, the Exchange Act requires that we file annual, quarterly and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal control over financial reporting. In order to improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business, financial condition, results of operations and prospects. Although we have already hired additional

personnel to help comply with these requirements, we may need to further expand our legal and finance departments in the future, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure may create uncertainty for SEC registrants, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us, and our business and prospects may be harmed. As a result of disclosure of information in the filings required of an SEC registrant, our business and financial condition will become more visible, which may result in threatened or actual litigation. If such claims are successful, our business, financial condition, results of operations and prospects could be materially harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and materially harm our business, financial condition, results of operations and prospects.

We also expect that being a SEC registrant and these new rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee.

Investors may have difficulty in reselling their shares due to the lack of market or state Blue Sky laws.

Our common stock is not currently traded on any U.S. securities exchange. No market may ever develop for our common stock, or if developed, may not be sustained in the future. The holders of our shares of common stock and persons who desire to purchase them in any trading market that might develop in the future should be aware that there might be significant state law restrictions upon the ability of investors to resell our shares. Accordingly, even if we are successful in having the shares available for trading on the over-the-counter markets, investors should consider any secondary market for our common shares to be a limited one.

The different characteristics of the capital markets in Australia and the United States may negatively affect the trading prices of our CDIs and common stock and may limit our ability to take certain actions typically performed by a U.S. company.

We are subject to ASX listing and associated Australian regulatory requirements and may in the future determine to concurrently list our shares on a U.S. securities exchange as well, which will have its own listing and regulatory requirements. Such exchanges will have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our CDIs and our common stock may not be the same, even allowing for currency differences. Fluctuations in the price of our common stock due to circumstances unusual to the U.S. capital markets could materially and adversely affect the price of the CDIs, or vice versa. Certain events having significant negative impact specifically on the Australian capital markets may result in a decline in the trading price of our CDIs notwithstanding that such event may not impact the trading prices of securities listed in Australia generally or to the same extent, or vice versa.

In addition, the listing and regulatory requirements of the ASX may limit our ability to take certain actions typically performed by a U.S. company. For example, the ASX Listing Rules limit the amount of equity securities that a listed company can issue without the approval of its stockholders over any 12-month period to 15% of the outstanding share capital on issue at the start of the period, unless an exception applies. Failure to obtain this approval may make it more difficult for us to issue equity securities in the future at a time and at a price that we deem appropriate. ASX rules also require stockholder approval for the granting of options and restricted stock units to our directors, even when the underlying equity incentive plan has already been approved. This creates a risk that, if stockholders do not approve the

grants, our directors will not receive their expected amount of equity compensation. This may make it more difficult for us to attract and retain directors, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Further, the ASX Listing Rules prohibit us from buying back CDIs on-market at a price which is more than 5% above the volume weighted average market price of our CDIs, calculated over the last five days on which sales of CDIs were recorded before the day on which the purchase under the buy-back was made, which, as a result, may make it more difficult to repurchase our CDIs on-market. In addition, should we wish to undertake an on-market buy-back, the ASX may impose further requirements on us as if we were subject to share buy-back provisions of the Corporations Act 2001 (Cth) of Australia ("Corporations Act"), which may include the need to obtain stockholder approval to do so.

Finally, the ASX Listing Rules prohibit the issuance of equity securities by a company without stockholder approval during the three-month period after it learns that a person is making, or proposes to make, a takeover for its securities, unless an exception applies. As a result, if a hostile takeover bid is made in respect of our CDIs or common stock, the ASX Listing Rules may limit our ability to issue equity securities, either as a countermeasure to the takeover bid or to fund operations.

If securities and industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our CDIs on the ASX may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts currently covering our securities ceases coverage, the trading price for our CDIs on the ASX could be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our CDI performance, or if our results of operations fail to meet the expectations of analysts, the price of our CDIs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our CDI price or trading volume to decline.

Our principal stockholders could collectively exert control over us and may not make decisions that are in the best interests of all stockholders.

As of December 31, 2024, our principal stockholders beneficially owned a significant percentage of our voting stock. If these significant stockholders were to act together, they would be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Accordingly, there is a risk that these stockholders, although unrelated to each other, may make collective decisions that do not accord with, or are not in the best interests of, other stockholders and CDI holders. For example, the principal stockholders could, through their concentration of ownership, delay or prevent a change of control, even if a change of control is in the best interests of our other stockholders and CDI holders.

Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware law could make an acquisition of us more difficult and may prevent attempts by stockholders to replace or remove current members of the Board.

Certain provisions of Delaware law, our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws could discourage, delay or prevent a change of control or deter tender offers for our common stock that stockholders and CDI holders may consider favorable, including transactions in which CDI holders might otherwise receive a premium for their CDIs.

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions, including effecting changes in our management. These provisions include:

- providing for a classified board of directors with staggered, three-year terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- not providing for cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- authorizing our board of directors to issue, without stockholder approval, preferred stock rights senior to those of common stock, which could be used to significantly dilute the ownership of a hostile acquiror;
- prohibiting stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- requiring the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, to amend provisions of our certificate of incorporation relating to the management of our business, our board of directors, stockholder action by written consent, advance notification of stockholder nominations and proposals, forum selection and the liability of our directors, or to amend our bylaws, which may inhibit the ability of stockholders or an acquiror to effect such amendments to facilitate changes in management or an unsolicited takeover attempt;
- requiring special meetings of stockholders may only be called by our chairperson of the board, if any, our chief executive officer, our president or a majority of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- requiring advance notification of stockholder nominations and proposals, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

The anti-takeover provisions of Delaware law and provisions in our organizational documents may prevent our stockholders from receiving the benefit from any premium to the market price of our common stock offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common stock if they are viewed as discouraging takeover attempts in the future.

The costs and management time involved in complying with Delaware laws, Australian laws and U.S. reporting requirements are likely to be significant.

As a Delaware company with an ASX listing and a registration as a foreign company in Australia, we need to ensure continuous compliance with Delaware law and relevant Australian laws and regulations, including the ASX Listing Rules and certain provisions of the Corporations Act. To the extent of any inconsistency between Delaware law and Australian law and regulations, we may need to make changes to our business operations, structure or policies to resolve such inconsistency. If we are required to make such changes, this is likely to result in interruptions to our operations, additional demands on key employees and extra costs.

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums 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.

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware and any appellate court therefrom are the exclusive forums for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action asserting a claim against us or any of our current or former directors, officers, or other employees, arising under the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation, or our Amended and Restated Bylaws
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws;
- any claim or cause of action as to which Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers, or other employees, that is governed by the internal-affairs doctrine or otherwise related to the Company's internal affairs.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent

having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Amended and Restated Certificate of Incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such an instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of Amended and Restated Certificate of Incorporation. This may require significant additional costs associated with resolving such actions in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have developed, implemented, and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communication systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic, or competitive in nature ("Information Systems and Data").

Our third-party service providers help identify, assess, and manage the Company's cybersecurity threats and risks. Our cybersecurity function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods, including, for example: manual tools, automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and threat actors, conducting scans of the threat environment, evaluating threats reported to us, and use of external intelligence feeds.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, for example by sharing common methodologies, reporting channels, and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards, and policies designed to manage and mitigate material cybersecurity risks, including, for example:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- monitoring of our systems in real-time to identify, contain, and report exposures as appropriate;
- cybersecurity awareness training for our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents;
- incident detection and response measures;
- a vulnerability management policy;
- business continuity plans;

- implementation of security standards/certifications;
- encryption of data;
- network security controls;
- data segregation;
- access controls;
- physical security;
- asset management, tracking and disposal;
- a vendor risk management program;
- penetration testing; and
- cybersecurity insurance.

We use third-party service providers from time to time to assess, test, or otherwise assist with aspects of our management of material risks from cybersecurity threats, including, for example: threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, and managed cybersecurity service providers.

We also use third-party service providers to perform a variety of functions throughout our business, such as hosting companies. We have a third-party risk management process for service providers, suppliers, and vendors, which includes conducting audits. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customers' patients or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation*."

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the audit and risk committee oversight of cybersecurity and other information technology risks. The audit and risk committee oversees management's implementation of our cybersecurity risk management program. Pursuant to its charter, the audit committee's oversight of the integrity of our information technology systems and cybersecurity risks includes the review and assessment, with management, of the adequacy of controls and security for our Information Systems and Data, as well as our contingency plans in the event of a breakdown or security breach affecting our information technology systems.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management and third-party service providers. These individuals are responsible for helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy and communicating key priorities to relevant personnel. Additionally, they are responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Chief Executive Officer and Chief Financial Officer. These individuals work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. The Company's incident response plan includes reporting to the audit and risk committee on certain cybersecurity risks, including any material cybersecurity incidents, as well as certain incidents with lesser impact potential.

The audit and risk committee reports to the full Board regarding its activities, including those related to cybersecurity. In addition, management may from time to time directly provide the full Board with briefings on our cyber risk management.

Item 2. Properties

We lease a single office and laboratory facilities for our business and operations located at 480 Oakmead Parkway in Sunnyvale, California, where we occupy approximately 15,237 square feet of office space under a lease until December 31, 2026, at a rate of $50,000 per month. In January 2025, we entered into a new lease agreement to lease our new corporate headquarters, laboratory and manufacturing facility at 4600 Patrick Henry Drive in Santa Clara, California, where we will occupy approximately 51,136 square feet under a lease until December 31, 2036. We believe that our current facilities are adequate to meet our current needs and that, should it be needed, suitable additional or alternative space will be available to accommodate our operations.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

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

Market Information for Common Stock

Our securities began trading on the Australian Securities Exchange on November 24, 2021, under the symbol "EBR". Prior to such time there was no public market for our securities. There is no principal market in the U.S. for our CDIs or shares of our common stock.

Holders of our Common Stock

As of March 15, 2025, we had 372,851,324 shares of common stock outstanding, held of record by 25 stockholders. The holders included CHESS Depositary Nominees Pty Limited ("CDN"), which held 372,261,472 shares of our common stock. CDN, a subsidiary of ASX Limited, acts as our Australian depositary nominee and issues depository interests, in the form of CDIs, to the CDI holders; of which there were approximately 3,999 registered owners of our CDIs on March 15, 2025, a substantial majority of whom are non-U.S. holders. There were no shares of preferred stock outstanding.

Dividend Policy

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends as may be declared from time to time by our Board of Directors out of legally available funds. However, we have never paid cash dividends on any of our capital stock, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

Equity Compensation Plan Information

The following table provides information about the common stock that may be issued upon the exercise of options, warrants and rights under all our existing equity compensation plans as of December 31, 2024:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights [1] (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	41,918,671[2]	$ 0.38	15,394,349[3]
Equity compensation plans not approved by security holders	—	—	—
Total	41,918,671	$ 0.38	15,394,349

(1) The weighted-average exercise price is calculated based solely on the exercise prices of the outstanding stock options and warrants.
(2) Includes 19,055,904 stock options issued under the 2013 Stock Plan, 22,153,134 issued under the 2021 Stock Plan, and 709,633 issued outside the 2021 Stock Plan.
(3) Represents shares available for issuance under the 2021 Stock Plan.

Recent Sales of Unregistered Securities

During the year ended December 31, 2024, we have issued the following securities that were not registered under the Securities Act:

1. On September 25, 2024, we issued 55,856,325 shares of common stock, in connection with an institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement offer ("Entitlement Offer") on the ASX, at a purchase price of $0.56 per share. We raised approximately $29.4 million, net of issuance costs of approximately $1.9 million. Bell Potter Securities Limited, Morgans Corporate Limited, and E&P Capital Pty Limited were the joint lead managers and book runners for the Entitlement Offer. Wilsons Corporate finance Limited was also acting as a joint lead manager. The Entitlement Offer was fully underwritten by Bell Potter Securities Limited.
2. On October 16, 2024, we issued 5,075,733 shares of common stock, in connection with the retail component of a 1-for-20 pro-rata non-renounceable entitlement offer on the ASX, at a purchase price of $0.54 per share. We raised approximately $2.6 million, net of issuance costs of approximately $0.2 million. Bell Potter Securities Limited, Morgans Corporate Limited, and E&P Capital Pty Limited were the joint lead managers and book runners for the Entitlement Offer. Wilsons Corporate finance Limited was also acting as a joint lead manager. The Entitlement Offer was fully underwritten by Bell Potter Securities Limited

The offers, sales, and issuances of the securities described in paragraphs 1 and 2 above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering or Regulation S as an offering made outside the United States. The recipients of securities in each of these transactions deemed to be exempt in reliance on Section 4(a)(2) of the Securities Act or Regulation D acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us. Appropriate legends or notices were affixed to the securities issued in reliance on Regulation S to ensure compliance with Regulation S restrictions.

Purchases of Equity Securities by the Issuer and Affiliate Purchases

None.

Item 6. [Reserved]

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

The following discussion and analysis of financial condition and results of operations (MD&A) should be read in conjunction with our consolidated financial statements, related notes and other financial information appearing elsewhere in this Annual Report on Form 10-K. In addition to historical consolidated financial information, the following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a variety of factors, including but not limited to those discussed in "Risk Factors" and "Forward-Looking Statements" in this Annual Report on Form 10-K.

Executive Overview

EBR is a U.S. based medical device company that is developing the WiSE CRT System, an implantable cardiac pacing system able to provide stimulation to endocardial heart tissue for the correction of heart rhythm conditions without requiring the use of leads. That implantable investigational device is part of a cardiac CRT, potentially offering endocardial heart tissue stimulation without the complications associated with traditional lead-based systems. CRM systems use leads to conduct electricity from an IPG to electrodes that deliver therapeutic electric pulses to heart tissue. While leads are a critical part of most CRM systems, they have long been recognized as a primary shortcoming of these systems and are a leading cause of device failure.

Financial Overview

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. Since our inception, our operations have been financed primarily by net proceeds from the sale of our CDIs, common stock, convertible preferred stock, and indebtedness. As of December 31, 2024, we had $66.0 million in cash, cash equivalents, and marketable securities and an accumulated deficit of $353.5 million.

On September 25, 2024, we issued 55,856,325 shares of common stock, in connection with an institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement offer on the ASX, at a purchase price of $0.56 per share. We raised approximately $29.4 million, net of issuance costs of approximately $1.9 million. On October 16, 2024, we issued 5,075,733 shares of common stock, in connection with the retail component of a 1-for-20 pro-rata non-renounceable entitlement offer on the ASX, at a purchase price of $0.54 per share. We raised approximately $2.6 million, net of issuance costs of approximately $0.2 million.

Factors Affecting Our Business

There are a number of factors that have impacted, and we believe will continue to impact, our results of operations and growth. These factors include:

- Regulatory approvals/clearances. Our business strategy depends on the successful FDA submission and obtaining approval by the FDA of our WiSE CRT System on a timely basis.
- Market acceptance. If our WiSE System is approved, the growth of our business depends on our ability to gain wide acceptance of our WiSE CRT System by continuing to make physicians and other hospital staff aware of the benefits of WiSE CRT to generate increased demand and frequency of use and thus increase sales to our hospital customers. Our ability to grow our business will also depend on our ability to expand our customer base in existing or new target markets.
- Sales force size and effectiveness. If our WiSE CRT System is approved, the rate at which we grow our sales force and the speed at which newly hired salespeople become effective can impact our revenue growth or our costs incurred in anticipation of such growth. We intend to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts as well as broaden awareness of our products to new hospital accounts.
- Reimbursement. The level of reimbursement from third-party payors for procedures performed using our products could have a substantial impact on the prices we are able to charge for our products and how widely our products are accepted. The level at which reimbursement is set for procedures using our products, and any increase in reimbursement for procedures using our products, will depend substantially on our ability to generate clinical evidence, to gain advocacy in the respective physician societies and to work with the Centers for Medicare & Medicaid Services and payors.

- Clinical results. Publications of clinical results by us, our competitors and other third parties can have a significant influence on whether, and the degree to which, our products are used by physicians and the procedures and treatments those physicians choose to administer for a given condition.

While these factors may present significant opportunities for us, they also pose significant risks and challenges that we must address.

Components of our Consolidated Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses primarily consist of personnel-related expenses, including salaries, bonuses, fringe benefits and other compensation-related costs, including stock-based compensation expense, for employees engaged in research and development functions. Research and development expenses also include costs of conducting our ongoing clinical studies, such as expenses associated with our clinical research organization, or CRO, who provides project management and other services related to our SOLVE-CRT study, outside service fees paid to third party consultants and contractors related to our product candidate engineering, quality assurance and regulatory approval, as well as contract manufacturing of our product candidate and allocated facility costs.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and other long-term assets, which are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

The successful development of product candidates is subject to numerous risks and uncertainties. For a discussion of certain risks related to the development of product candidates and costs of clinical trials, see "*Item 1A. Risk Factors*" herein.

We anticipate that our research and development expenses will increase significantly in the future as we:

- hire and retain additional personnel, including research, clinical, development, manufacturing, quality control, quality assurance and regulatory personnel;
- conduct additional clinical studies beyond our current SOLVE-CRT study;
- continue to advance the research and development of our WiSE CRT system;
- develop, establish, and validate our commercial-scale current good manufacturing practice ("cGMP").

General and Administrative Expenses

General and administrative expenses primarily consist of personnel-related costs, including salaries, bonuses, fringe benefits and other compensation-related costs, including stock-based compensation expense, for our personnel and external contractors involved in our executive, finance, legal and other administrative functions as well as our commercial function, who is involved in market access related activities. General and administrative expenses also include costs incurred for outside services associated with such functions, including costs associated with obtaining and maintaining our patent portfolio and professional fees for accounting, auditing, tax, legal services, and other consulting expenses.

We anticipate that our general and administrative expenses will increase significantly in the future as we:

- hire and retain additional general and administrative personnel to support the expected growth in our research and development activities and the preclinical and clinical development of our product candidates;
- continue to expand our commercial and administrative function to support the growth of our WiSE CRT commercialization;
- incur additional commercialization expenses prior to any regulatory approval of our product candidates;
- pursue payor coverage and reimbursement for our current and future product candidates;
- maintain, expand, and protect our intellectual property portfolio; and

- incur increased expenses associated with operating as a U.S. publicly reporting company, including increased costs of accounting, audit, legal, regulatory, and tax-related services, and director and officer insurance premiums.

Other Income (Expenses), net

Interest expense

Interest expense primarily consists of cash and non-cash interest related to our notes payable. See "Loan and Security Agreements" section below for more details about our debt agreements.

Interest income

Interest income consists of interest income, including accretion of discounts, generated from our cash, cash equivalent, and marketable securities.

Other income

Other income includes reimbursements of clinical trial expenses as well as refundable tax incentives from the Australian Taxation Office.

Gain/ (loss) on foreign currency

Gains and losses arising from the settlement and remeasurement of monetary assets and liabilities denominated in currencies other than a subsidiary's functional currency.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our audited consolidated financial condition and results of operations.

Pre-launch inventory

We capitalized pre-launch inventory costs associated with its products prior to regulatory approval when, based on management judgement, future commercialization was considered probable and future economic benefit was expected to be realized. We assess the regulatory approval process and where the product stands in relation to that approval process including any known constraints or impediments to approval. Pre-launch inventory costs associated with products that have not yet received regulatory approval are capitalized if there is probable future commercial use and future economic benefit. If future commercial use and future economic benefit are not considered probable, then costs associated with pre-launch inventory that has not yet received regulatory approval are expensed as research and development expense during

the period the costs are incurred. The determination to capitalize pre-launch inventory is based on the specific facts and circumstances relating to the product.

Capitalization of pre-launch inventory began during the year ended December 31, 2024 when we determined that: (i) positive clinical trial results had been obtained, as evidenced by meeting both the primary efficacy and safety endpoints at the interim analysis, which supported our belief that regulatory approval is probable; (ii) uncertainties regarding regulatory approval had been significantly reduced, as evidenced by our submission of all modules of the pre-market approval application and ongoing communication with the regulatory bodies; and (iii) it is probable that these capitalized costs will provide future economic benefit, in excess of capitalized costs, as evidenced by the lack of alternative therapies for our target market and the anticipated average selling price of the WiSE CRT System.

Once we capitalize pre-launch inventory for a product candidate that is not yet approved, we monitor, on a quarterly basis, the status of this candidate within the regulatory approval process. We could be required to expense previously capitalized costs related to pre-launch inventory upon a change in management's judgment of future commercial use and net realizable value, due to a denial or delay of approval by regulatory bodies, a delay in the timeline for commercialization or other potential factors. On a quarterly basis, the Company evaluates all inventory, including capitalized pre-launch inventory for which regulatory approval has not yet been obtained, to determine if any lower of cost or net realizable value adjustment is required. As it relates to pre-launch inventory, we consider several factors including expected timing of FDA approval, projected sales volume and estimated selling price.

Clinical trial accrual

The clinical trial accrual involves identifying services that third parties, contracted by us, have performed and estimating the associated cost incurred for these services which remain uninvoiced as of the balance sheet date. In addition, the clinical trial accrual involves the measurement of milestone achievements achieved by the patients participating in the clinical trial and the associated costs which have not been invoiced as of the balance sheet date. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. Our clinical trial accrual is dependent, in part, upon the receipt of timely and accurate reporting from the third parties. We estimate our liability using our judgment based upon the facts and circumstances known at the time. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates.

Stock-Based compensation

We measure all stock options and other stock-based awards based on their fair value on the date of the grant. Those awards typically have a graded vesting schedule and compensation expense for awards with only service conditions are recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur.

We use the Black-Scholes option pricing model, which incorporates assumptions and estimates, to measure the fair value of its option awards on the date of grant of each stock option award.

We determined the assumptions for the Black-Scholes option-pricing model as discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

- *Fair Value of Our Common Stock.* Our stock is publicly traded on the ASX, and therefore we use the closing market price on the day before the option grant.
- *Expected Term*. The expected term represents the period that the stock-based awards are expected to be outstanding. As we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term, the expected term of stock options granted has been determined using the simplified method, which is the average of the midpoints between the vesting date and the contractual term for all vesting tranches.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the rate of the U.S. 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 Volatility.* The expected volatility was derived from the combination of the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business, and our stock price, as quoted on the ASX.
- *Dividend Rate.* The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously.

Income Taxes

We are subject to income taxes in the United States and multiple foreign jurisdictions. Our effective tax rates differ from the United States federal statutory rate, primarily due to changes in our valuation allowance, stock-based compensation expense, state and foreign tax benefit, federal research and development tax credits and other adjustments. Our effective tax rate was 0.01% for each of the years ended December 31, 2024 and 2023. The calculation of our provision for income taxes involves the use of estimates, assumptions and judgments while taking into account current tax laws, our interpretation of current tax laws and possible outcomes of future tax audits. We review our tax positions quarterly and adjust the balances as new information becomes available.

Significant management judgement is required in assessing our ability to realize any future benefit from our net deferred tax assets. Due to our history of net losses, the difficulty in predicting future results, the length of statutory carryforward periods, and tax planning alternatives, we believe that we cannot rely on projections of future taxable income to realize most of our deferred tax assets. Accordingly, we have established a full valuation allowance against our United States federal and states net deferred tax assets. We intend to maintain this valuation allowance until sufficient positive evidence exists to support its reversal. Our income tax expense recorded in the future will be reduced to the extent that sufficient positive evidence materializes to support a reversal, or decrease in, our valuation allowance.

We recognize tax benefits from uncertain tax positions only if it is more likely than not (more than 50%) that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. We file annual income tax returns in multiple taxing jurisdictions around the world and a number of years may elapse before an uncertain tax position is audited by the relevant tax authorities and finally resolved. We have established reserves to address potential exposures related to tax positions that could be challenged by tax authorities. While it is often difficult to predict the final outcome or the timing of resolution of any particular uncertain tax position and we can provide no assurance that the final tax outcome of these matters will not be materially different, we believe that we have adequately reserved for our uncertain tax positions.

Our future effective tax rates could be adversely affected if actual earnings are different than our estimates, by changes in the valuation of our deferred tax assets or liabilities, outcomes resulting from income tax examinations, or by changes or interpretations in tax laws, regulations or accounting principles.

Recent Accounting Pronouncements

See the section titled “Summary of Significant Accounting Policies—Recently issued accounting pronouncements” in Note 2 to our financial statements included in this Annual Report on Form 10-K for information on recent accounting pronouncements and the expected impact on our financial statements.

Non- GAAP Financial Measures

Adjusted earnings before interest, income taxes, depreciation and amortization (“EBITDA”), a non-GAAP measure used by management to assess operating performance, is defined as net loss, excluding interest expense, net, depreciation and amortization, stock-based compensation, and expenses associated with our Form 10 filling. Adjusted EBITDA is intended as a supplemental measure of our performance and provides useful information to management and investors regarding our operating results. Adjusted net loss per common share is defined as Adjusted EBITDA divided by the weighted-average number of shares outstanding.

We present Adjusted EBITDA in this filing because we believe it assists investors and analysts in comparing our operating performance across reporting periods on a consistent basis by excluding items that we do not believe are

indicative of our ongoing operating performance. Period-to-period comparison of Adjusted EBITDA helps our management identify additional trends in our company's financial results that may not be shown solely by period-to-period comparison of net loss. In addition, we believe that providing Adjusted EBITDA, together with a reconciliation of Adjusted EBITDA to net loss, helps investors make comparisons between our company and other companies that may have different capital structures, different capitalized asset values, different forms of employee compensation and different strategic nonrecurring projects. Adjusted EBITDA has its limitations as an analytical tool because of the excluded items, and you should not consider it in isolation or as a substitute for analysis of our results as reported under U.S. GAAP. Some of these limitations include:

- Adjusted EBITDA does not reflect interest expense and interest income because these items are not directly attributable to the performance of our business operations and may vary over time due to a variety of financing transactions that we have entered into or may enter into in the future.
- Adjusted EBITDA does not reflect certain non-cash items, including depreciation and amortization, and stock-based compensation expense. We believe that excluding the effect of these expenses from Adjusted EBITDA assists management and investors in making period-to-period comparisons in our company's operating performance because the amount of such expenses in any specific period may not directly correlate to the underlying performance of our business operations.
- Adjusted EBITDA does not reflect the impact of certain cash charges resulting from matters we do not find indicative of our ongoing operations, such as costs associated with our filing of Form 10-12G.

A reconciliation between net loss and adjusted EBITDA, and net loss per common share and adjusted net loss per common share are presented below:

	Year Ended December 31,	
(in thousands, except per share amounts)	2024	2023
Reconciliation of net loss to Non-GAAP Adjusted EBITDA:		
Net loss	$ (40,798)	$ (35,037)
Interest expense, net	2,849	1,202
Depreciation and amortization	587	752
Stock-based compensation [(a)]	1,742	1,306
Expenses associated with Form 10 filling [(b)]	1,398	-
Adjusted EBITDA	$ (34,222)	$ (31,777)
Weighted-average number of shares outstanding:		
Basic and diluted	324,995	288,875
Net loss per common share:	$ (0.13)	$ (0.12)
Adjusted net loss per common share:	$ (0.11)	$ (0.11)

(a) Represents non-cash expense associated with our share-based payments.
(b) Represents nonrecurring expenses associated with our Form 10 filing in 2024.

Results of Operations

The following discussion analyzes our operating results for the year ended December 31, 2024, and compares those results to results for the year ended December 31, 2023.

Comparison of the Years Ended December 31, 2024 and 2023

We recorded a net loss of $40.8 million in 2024, an increase of $5.8 million, or 16.4%, from 2023. The increased loss in 2024 was primarily due to an increase in general and administrative expenses and interest expense in 2024, as discussed below. We expect to continue reporting losses until such time as we obtain FDA approval, commercialize our WiSE CRT System, and are able to generate revenue and gross margin sufficient to offset our operating expenses.

The following table summarizes our operating results for 2024 and 2023:

(in thousands)	Year Ended December 31, 2024	2023	Change Amount	%
Operating expenses:				
Research and development	$ 27,065	$ 27,146	$ (81)	(0.3%)
General and administrative	11,254	7,403	3,851	52.0%
Total operating expenses	38,319	34,549	3,770	10.9%
Total other (expense), net	(2,478)	(486)	(1,992)	409.9%
Loss before income tax	(40,797)	(35,035)	(5,762)	16.4%
Income tax expense	(2)	(2)	-	-
Net loss	$ (40,799)	$ (35,037)	$ (5,762)	16.4%

Operating Expenses

Research and Development

The following table presents our total research and development expenses by category:

(in thousands)	Year Ended December 31, 2024	2023	Change Amount	%
Research and development expenses:				
R&D personnel expense	$ 17,770	$ 14,278	$ 3,492	24.5%
Clinical expenses	2,023	3,384	(1,361)	(40.2%)
Quality assurance	272	127	145	114.2%
Contract manufacturing, materials & components	5,340	7,853	(2,513)	(32.0%)
Facility allocation & depreciation	1,660	1,504	156	10.4%
Total research and development expense	$ 27,065	$ 27,146	$ (81)	(0.3%)

Research and development expenses decreased by $0.1 million, or 0.3%, during the year ended December 31, 2024, as compared to the year ended December 31, 2023. The decrease was primarily due to a $2.5 million decrease in contract manufacturing, materials and components, resulting from a decrease in professional services related to the development testing of the WiSE CRT System, as well as capitalization of certain inventory purchases. Clinical trial related expenses decreased by $1.4 million, primarily due to completing enrollment in the SOLVE-CRT Study in July 2022. This decrease was offset by a $3.5 million increase in personnel-related expenses, including salaries, bonuses, and certain fringe benefits as a result of the expansion of our workforce to support the ongoing development of the WiSE CRT System.

General and Administrative Expenses

General and administrative expenses increased by $3.9 million, or 52.0%, during the year ended December 31, 2024, as compared to the year ended December 31, 2023. Professional fees increased by $2.4 million, primarily resulting from higher audit, legal, regulatory, and tax-related services in connection with preparation for our filing of a registration statement on Form 10. Personnel-related expenses, including salaries, bonuses and certain fringe benefits increased by $1.1 million as a result of the expansion of our workforce to support our business needs. Corporate expenses increased by $0.4 million, which resulted from an increase in expenses related to investor relations, insurance premiums, and computer supplies and software as a result of the expansion of our workforce.

Other Expense, net

Other expense, net increased by $2.0 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023. The change was caused by increased interest expense, decreased interest income, and decreased refundable tax incentives in 2024 as compared to 2023. Interest expense increased by $1.5 million, which resulted from an additional $20.0 million in borrowings on June 30, 2023. Refundable tax incentives decreased by $0.4 million in 2024, compared to 2023, which included two years of refundable tax incentives due to the timing of tax filings. During the year ended December 31, 2024, we earned interest income, including the accretion of discounts, from investment in marketable securities of $3.2 million, a decrease of $0.1 million as compared to the year ended December 31, 2023.

Liquidity and Capital Resources

We believe that we maintain a level of liquidity sufficient to allow us to meet our financial obligations as they become due for the next twelve months. We manage our cash and capital structure to maximize shareholder return, maintain our financial condition and maintain flexibility for future strategic initiatives. We continuously assess our working capital needs, debt and leverage levels, debt maturity schedule, capital expenditure requirements and future investments. As of December 31, 2024 and 2023, we had approximately $66.0 million and $73.4 million, respectively, in cash, cash equivalents, and marketable securities. In the long-term, our ability to support our working capital and capital expenditure requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost of our research and development activities for new and modified products;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of other collaborative, licensing and other arrangements that may establish including any contract manufacturing arrangements;
- the timing, receipt and amount of sales from our current and potential products;
- the degree of success we experience in commercializing our products;
- the emergence of competing or complementary technologies;
- the impact of global business, political and macroeconomic conditions, including inflation, rising interest rates, uncertainty with respect to the federal budget, instability in the global banking system, volatile market conditions, supply chain disruptions, cybersecurity events, and global events, including regional conflicts around the world;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

To the extent that current and anticipated future sources of liquidity are insufficient to fund our future business activities and cash and other requirements, we may be required to seek additional equity or debt financing. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of additional debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. In the event that additional financing is required from outside sources, there is a possibility we may not be able to raise it on terms acceptable to us or at all. Further, the current macroeconomic environment may make it difficult for us to raise capital on terms favorable to us or at all. If we are unable to raise additional capital when desired, our business, operating results, and financial condition could be adversely affected.

Loan and Security Agreements

On June 30, 2022, we entered into a loan and security agreement with Runway Growth Finance Corp. The debt is secured against substantially all of our assets, except for intellectual property, but includes all proceeds from the sale of intellectual property. The loan agreement provides three term loan tranches. We received the initial draw of $20,000,000 in June 2022. We received positive interim analysis data, sufficient to proceed with the clinical trial and premarket approval submission to the U.S. Food and Drug Administration, which allowed us to draw the second tranche of $20,000,000 in June 2023. The final tranche provided $10,000,000 from the date of approval from the FDA for the WiSE CRT System and ended on June 30, 2024. We did not receive FDA approval by June 30, 2024, and therefore did not meet the draw requirements of the third and final tranche.

Interest on the term loan accrues on the principal amount outstanding at a floating per annum rate equal to the greater of the rate of interest noted in The Wall Street Journal Money Rates section, as the “Prime Rate” or 4.00% plus a margin of 4.9% and is payable monthly in arrears and shall be computed on the basis of a 360-day year for the actual number of days elapsed. We are required to make interest only payments from July 2022 to May 2027. The note payable has a maturity date of June 15, 2027, at which time any unpaid interest, outstanding principal balance, and a final payment of 4.5% of the original principal amount borrowed shall be due in full. If we repay the loan prior to maturity, we will be required to pay a prepayment fee of 0.5% - 1% of the outstanding principal balance. We are also required to pay a 3% success fee of the funded principal amount of the term loan at the time of a liquidity event, as defined in the loan and security agreement. The success fee is enforceable within 10 years from the execution date of the agreement.

As of December 31, 2024 and 2023, the outstanding principal balance was $41,800,000, which included the principal borrowings under tranche one and tranche two, as well as the final payment of 4.5% of the principal borrowings to date.

We are subject to customary financial and reporting covenants under the loan and security agreement. As of December 31, 2024 and 2023, we were in compliance with all debt covenants.

Recent Financings

On June 28, 2023, we issued 27,472,527 CDIs in connection with the first tranche of an institutional placement on the ASX, and on July 10, 2023, we issued 5,494,506 CDIs in connection with the second and final tranche of the institutional placement. On July 25, 2023, we issued 2,921,307 shares of common stock in connection with a Security Purchase Plan ("SPP"). We raised a total of approximately $20.6 million, net of issuance costs of approximately $1.0 million. Of this amount, $18.9 million were net cash proceeds from the institutional placement, and $1.7 million were cash proceeds from the SPP.

On September 25, 2024, we issued 55,856,325 CDIs in connection with an institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement offer on the ASX. We raised approximately $29.4 million, net of issuance costs of approximately $1.9 million. On October 16, 2024, we issued 5,075,733 CDIs in connection with the retail component of a fully underwritten 1-for-20 pro-rata non-renounceable entitlement offer. We raised approximately $2.6 million, net of issuance costs of approximately $0.2 million.

Contractual Obligations and Commitments

As of December 31, 2024, we had $1.1 million in operating lease liabilities for our corporate headquarters and laboratory space, located in Sunnyvale, California. In January 2025, we entered into a new lease agreement to lease our new corporate headquarters. See Note 6, "Leases", in the notes to consolidated financial statements for additional information regarding leased properties.

As of December 31, 2024, the outstanding principal balance under our loan and security agreement described above was $41,800,000, which included the principal borrowings under tranche one and tranche two, as well as the final payment of 4.5% of the principal borrowings to date.

In addition, we have entered into an equipment purchase agreement for the purchase of certain software. As of December 31, 2024, the outstanding principal balance was $37,286. Additionally, we enter into contracts in the normal course of business with third-party contract organizations for clinical trials, manufacturing and other services and products for operating purposes. In certain instances, our purchase agreements allow us to cancel, reschedule, or adjust our purchase requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our purchase commitments are firm and noncancelable. As of December 31, 2024, our obligation under such arrangements was approximately $14.4 million.

Working Capital

December 31, 2024, Compared to December 31, 2023

As of December 31, 2024, we had working capital of $56.1 million, comprised of current assets of $64.5 million and current liabilities of $8.3 million. Current assets, consisting of cash and cash equivalents, marketable securities, pre-launch inventory, prepaid expenses, non-trade receivables and other current assets, decreased by $9.9 million as of December 31, 2024, compared to December 31, 2023. Current liabilities, consisting primarily of accounts payable, accrued liabilities, operating lease liability, the current portion of notes payable and interest payable, increased by approximately $1.9 million as of December 31, 2024, compared to December 31, 2023. The proceeds from borrowings under tranche 2 of the loan and security agreement, as well as the sale of common stock in 2023, contributed to the increase in cash, cash equivalents, and marketable securities during 2023, resulting in an increase in working capital as of December 31, 2023.

Cash Flows

December 31, 2024, Compared to December 31, 2023

The following table summarizes our cash flows for the years ended December 31, 2024 and 2023:

(in thousands)	Year Ended December 31, 2024	2023
Net cash used in operating activities	$ (41,230)	$ (32,698)
Net cash provided by (used in) investing activities	1,113	(8,641)
Net cash provided by financing activities	32,484	40,466
Effect of exchange rate change on cash	(28)	(5)
Net change in cash and cash equivalents	$ (7,661)	$ (878)

Operating Activities

Net cash used in operating activities during the year ended December 31, 2024, was $41.2 million, compared to $32.7 million during the year ended December 31, 2023, representing an increase in use of $8.5 million. This increase was primarily attributed to an increase in net loss of $5.8 million, a decrease in cash from changes in working capital of $2.8 million, offset by a $0.1 increase in non-cash adjustments.

- The increase in net loss of $5.8 million primarily resulted from increases in personnel costs due to the expansion of our workforce, increases in professional fees due to the preparation for the Form 10 filing, and increase other expense mainly driven by interest expense, as further described under "Results of Operations" above.
- The decrease in changes from working capital activities primarily consisted of $2.8 million use of cash for pre-launch inventory purchases during the year ended December 31, 2024, a $0.8 million decrease in prepaids expenses due to decreased vendor prepayment requirements for research and development materials and professional services, a $0.3 million decrease in non-trade receivables due to the timing of collections, a $0.2 million decrease in other assets due to additional receipt of refundable tax incentives from the Australian Taxation Office in 2023, and a $0.1 million decrease in interest payable. These decreases were partially offset by a $1.4 million increase in accounts payable due to the timing of invoice payments.
- Non-cash items primarily consisted of increases in share-based compensation of $0.4 million due to new options issuance to new hires and existing employees, offset by a decrease in accretion of discount on marketable securities of $0.3 million driven by fluctuating interest rates and maturity term.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2024, was $1.1 million, compared to $8.6 million used in investing activities during the year ended December 31, 2023, representing a decrease in cash used of $9.7 million. The decrease was attributable to a $11.9 million decrease in the purchase of marketable securities and a $0.1 million decrease in the purchase of property and equipment. These decreases were offset by a $2.3 million increase in the maturities and sales of marketable securities during the year ended December 31, 2024, as compared to the year ended December 31, 2023.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2024, was $32.5 million, compared to $40.5 million during the year ended December 31, 2023, representing a decrease of $8.0 million. This decrease is primarily attributed to the $19.7 million borrowing, net of issuance cost, under tranche 2 of the loan and security that took place during the year ended December 31, 2023. This decrease was partially offset by a $11.3 million increase in proceeds from a capital raise, net of issuance cost, during the year ended December 31, 2024, as well as by a $0.4 million increase in proceeds from exercise of stock options.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information specified under this item.

Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

To the stockholders and the Board of Directors of EBR Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of EBR Systems, Inc. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Tempe, Arizona

March 24, 2025

We have served as the Company's auditor since 2022.

EBR SYSTEMS, INC.
Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 6,917,546	$ 14,578,752
Marketable securities	53,746,411	57,736,274
Non-trade receivables and unbilled reimbursements, net	441,439	230,734
Pre-launch inventory	1,391,008	-
Prepaid expenses	1,693,560	1,446,634
Other current assets	276,419	382,522
Total current assets	64,466,383	74,374,916
Property and equipment, net	794,959	1,088,771
Right of use operating lease asset	929,243	1,719,590
Marketable securities	5,303,950	1,125,554
Pre-launch inventory, noncurrent	1,451,532	-
Other assets	613,427	589,646
TOTAL ASSETS	**$ 73,559,494**	**$ 78,898,477**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,247,453	$ 1,856,134
Accrued expenses and other liabilities	4,295,841	4,095,347
Interest payable	224,889	224,309
Operating lease liability	522,525	250,876
Current portion of notes payable	37,286	21,496
Total current liabilities	8,327,994	6,448,162
Other liabilities	37,617	76,946
Operating lease liability	574,777	1,670,230
Notes payable, net	40,263,605	39,646,687
Total liabilities	49,203,993	47,842,025
Commitments and contingencies (Note 15)		
STOCKHOLDERS' EQUITY		
Common stock, $0.0001 par value; 600,000,000 shares authorized, 371,076,200 and 307,020,758 shares issued and outstanding at December 31, 2024 and 2023, respectively	37,108	30,703
Additional paid-in capital	376,902,576	342,721,880
Accumulated deficit	(353,457,680)	(312,659,408)
Accumulated other comprehensive income	873,497	963,277
Total stockholders' equity	24,355,501	31,056,452
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 73,559,494**	**$ 78,898,477**

These financial statements should be read in connection with the notes to consolidated financial statements.

EBR SYSTEMS, INC.
Consolidated Statements of Operations

	Year Ended December 31,	
	2024	**2023**
Operating expenses		
Research and development	$ 27,065,427	$ 27,146,026
General and administrative	11,253,601	7,402,921
Total operating expenses	38,319,028	34,548,947
Loss from operations	(38,319,028)	(34,548,947)
Other (expense) income		
Interest expense	(6,029,668)	(4,483,731)
Interest income	3,180,984	3,281,440
Other income	360,996	718,959
Gain (loss) on foreign currency	9,979	(2,984)
Total other (expense), net	(2,477,709)	(486,316)
Loss before income tax	(40,796,737)	(35,035,263)
Income tax benefit (expense)	(1,535)	(1,625)
Net loss	$ (40,798,272)	$ (35,036,888)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.13)	$ (0.12)
Weighted-average number of common shares outstanding:		
Basic and diluted	324,995,419	288,875,373

These financial statements should be read in connection with the notes to consolidated financial statements.

EBR SYSTEMS, INC.
Consolidated Statements of Comprehensive Loss

	Year Ended December 31,	
	2024	**2023**
Net loss	$ (40,798,272)	$ (35,036,888)
Other comprehensive (loss) income		
Change in unrealized (loss) income on marketable securities	(45,310)	171,135
Foreign currency translation adjustments	(44,470)	(2,698)
Total other comprehensive (loss) income	(89,780)	168,437
Comprehensive loss	$ (40,888,052)	$ (34,868,451)

These financial statements should be read in connection with the notes to consolidated financial statements.

EBR SYSTEMS, INC.
Consolidated Statement of Changes in Stockholders' Equity

	Common Stock		Additional	Accumulated	Total Other	Total
	Shares	Par Value	Paid-in Capital	Deficit	Comprehensive Income	Stockholders' Equity
Balance at December 31, 2022	270,752,201	$ 27,077	$ 320,749,696	$ (277,622,520)	$ 794,840	$ 43,949,093
Exercise of stock options	380,217	38	54,834	-	-	54,872
Stock-based compensation	-	-	1,305,811	-	-	1,305,811
Issuance of common stock, net of issuance costs	35,888,340	3,588	20,611,539	-	-	20,615,127
Net loss	-	-	-	(35,036,888)	-	(35,036,888)
Other comprehensive income	-	-	-	-	168,437	168,437
Balance at December 31, 2023	307,020,758	30,703	342,721,880	(312,659,408)	963,277	31,056,452
Exercise of stock options	3,123,384	312	485,721	-	-	486,033
Stock-based compensation	-	-	1,742,279	-	-	1,742,279
Issuance of common stock, net of issuance costs	60,932,058	6,093	31,952,696	-	-	31,958,789
Net loss	-	-	-	(40,798,272)	-	(40,798,272)
Other comprehensive loss	-	-	-	-	(89,780)	(89,780)
Balance at December 31, 2024	371,076,200	$ 37,108	$ 376,902,576	$ (353,457,680)	$ 873,497	$ 24,355,501

These financial statements should be read in connection with the notes to consolidated financial statements.

EBR SYSTEMS, INC.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (40,798,272)	$ (35,036,888)
Adjustment to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	587,485	752,257
Amortization of deferred loan costs and discount on notes payable	616,918	476,037
Lease amortization	379,550	413,517
Stock-based compensation	1,742,279	1,305,811
Allowance for credit losses	4,520	40,485
Accretion of discount on marketable securities	(1,620,509)	(1,344,781)
Changes in operating assets and liabilities:		
Non-trade receivables and unbilled reimbursements	(214,842)	86,837
Pre-launch inventory	(2,842,540)	-
Prepaid expenses	(247,712)	556,143
Other assets	57,253	206,424
Accounts payable	1,347,741	(86,347)
Accrued expenses and other liabilities	170,736	215,483
Interest payable	580	126,294
Operating lease liability	(413,007)	(408,786)
Net cash used in operating activities	(41,229,820)	(32,697,514)
Cash flows from investing activities:		
Purchase of property and equipment	(273,437)	(354,054)
Purchase of marketable securities	(65,515,010)	(77,461,260)
Maturities of marketable securities	65,776,000	67,400,000
Sales of marketable securities	1,125,676	1,774,324
Net cash provided by (used in) investing activities	1,113,229	(8,640,990)
Cash flows from financing activities:		
Repayment of notes payable	(44,743)	-
Proceeds from notes payable	82,029	20,000,000
Payments of deferred loan costs	-	(204,075)
Proceeds from common stock offering	34,021,550	21,615,076
Payment of common stock offering costs	(2,060,823)	(999,949)
Proceeds from exercise of stock options	486,033	54,872
Net cash provided by financing activities	32,484,046	40,465,924
Effect of exchange rate change on cash	(28,661)	(5,006)
Net change in cash and cash equivalents	(7,661,206)	(877,586)
Cash and cash equivalents, beginning of the period	14,578,752	15,456,338
Cash and cash equivalents, end of the period	$ 6,917,546	$ 14,578,752
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 5,412,170	$ 3,881,400
Cash paid for income taxes	$ 1,625	$ 775
Supplemental disclosure of non-cash investing and financing activities:		
Remeasurement of lease liabilities	$ 410,797	$ -
Purchases of property and equipment not yet paid	$ 47,868	$ -
Accrued common stock offering costs	$ 1,938	$ -
Purchases of property and equipment with note payable	$ 82,029	$ -

These financial statements should be read in connection with the notes to consolidated financial statements.

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

Note 1 - Business and organization

Business overview

EBR Systems, Inc. and subsidiaries (collectively, "EBR", "we", "our" or the "Company") is a United States based medical device company that is developing the WiSE CRT System, an implantable cardiac pacing system able to provide stimulation to endocardial heart tissue for the correction of heart rhythm conditions without requiring the use of leads. This implantable, investigational device delivers left-ventricle endocardial pacing for cardiac resynchronization therapy ("CRT"), without the use of wires or leads going into the heart. WiSE CRT System is currently undergoing the premarket review by the FDA which is intended to assess the safety and efficacy of the system.

The Company completed its initial public offering of CDIs ("CHESS Depositary Interests") and began trading on the Australian Securities Exchange ("ASX") on November 24, 2021, under the symbol "EBR".

The Company operates wholly owned foreign subsidiary entities in Australia, EBR Systems (AUST) Pty Ltd ("EBR-AU"), and the United Kingdom, EBR Systems (UK) Limited ("EBR-UK"), which establish clinical trials in Australia and the United Kingdom, respectively, and work on intellectual property development. EBR-AU was incorporated on February 23, 2017, and EBR-UK was incorporated on July 31, 2015.

Note 2 - Summary of significant accounting policies

Basis of presentation

These consolidated financial statements include the accounts of EBR Systems, Inc. and its subsidiaries, and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company has eliminated all intercompany transactions and balances during consolidation.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, judgments, and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Significant estimates and assumptions made by management include the fair value of stock-based awards issued, capitalized pre-launch inventory, clinical trial accrual, and the valuation allowance on deferred taxes.

Fair Value Measurements

The Company measures certain assets and liabilities at fair value, which is defined as the price that would be received from the sale of an asset or paid to transfer a liability on the measurement date in an orderly transaction between market participants in the principal or most advantageous market for the asset or liability. The fair value measurement guidance establishes a fair value hierarchy which requires the Company to maximize the use of observable inputs when measuring fair value. The following levels of inputs may be used to measure fair value:

- Level 1: Valuation techniques in which all significant inputs are unadjusted quoted prices from active markets for assets or liabilities that are identical to the assets or liabilities being measured.
- Level 2: Valuation techniques in which significant inputs include quoted prices from active markets for assets or liabilities that are similar to the assets or liabilities being measured and/or quoted prices for assets or liabilities that are identical or similar to the assets or liabilities being measured from markets that are not active. Also, model-derived valuations in which all significant inputs are observable in active markets are Level 2 valuation techniques.
- Level 3: Valuation techniques in which one or more significant inputs are unobservable. Such inputs reflect our estimate of assumptions that market participants would use to price an asset or liability.

Foreign currency translation

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

The functional currencies of our foreign subsidiaries are their local currencies. Accordingly, the Company translates the foreign currency financial statements into US Dollars using the reporting period-end or average exchange rates. Assets and liabilities of these subsidiaries were translated at exchange rates as of the balance sheet dates. Expenses are translated at average rates in effect for the periods presented. The cumulative translation adjustment is included in the accumulated other comprehensive income within stockholders' equity. Gains and losses arising from the settlement and remeasurement of monetary assets and liabilities denominated in currencies other than a subsidiary's functional currency are included in "gain (loss) on foreign currency" in the period in which they occur.

Employee benefits

The Company maintains an employee retirement/savings plan (the "Retirement Plan") that permits participants to make tax-deferred contributions by salary reductions pursuant to Section 401(k) of the Internal Revenue Code. The Company may make discretionary contributions. For the years ended December 31, 2024 and 2023, the Company did not make any contributions.

Cash and cash equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash. Cash equivalents are reported at fair value.

Marketable securities

Marketable securities, all of which are available-for-sale, consist of U.S. treasury bonds, U.S. government notes, and corporate debt securities. Marketable securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income, except for losses from impairments which are determined to be other than temporary. For the years ended December 31, 2024 and 2023, there were no losses from impairments. Realized gains and losses and declines in value judged to be other-than-temporary are included in the determination of net loss and are included in other income and expense. Interest and dividends on available-for-sale securities are included in other income and expense. See Note 3, "Cash, cash equivalents, and marketable securities" for additional disclosure on marketable securities.

Liquidity

The accompanying financial statements are prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. For the years ended December 31, 2024 and 2023, the Company incurred a net loss of $40,798,272 and $35,036,888, respectively. During the years ended December 31, 2024 and 2023, the Company had negative cash flows from operations of $41,229,820 and $32,697,514, respectively. The Company has incurred operating losses and negative cash flows from operations since inception and anticipates such conditions to continue in the foreseeable future. As of December 31, 2024, the Company had working capital of $56,138,389 and accumulated deficit of $353,457,680. The Company continues to face risks similar to those of other companies of similar size in its industry, including, but not limited the need for successful commercialization of products, the need for additional capital, or financing, to fund operating losses, protection of proprietary technology, and dependence on key individuals. The Company has funded its operations through the issuance of common stock and debt instruments, as further discussed in Note 7, "Notes payable" and Note 9, "Common stock" below.

Concentration of credit risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents are primarily held at U.S. financial institutions that management believes are of high credit quality. Such deposits exceed federally insured limits.

Non-trade receivables and unbilled reimbursements

Non-trade receivables are recorded for amounts due to the Company related to reimbursements of clinical trials expenses based upon contracted terms, and the sale of materials to contract manufacturers. Unbilled reimbursements represent amounts for services that have been rendered but for which reimbursements have not been billed. See Note 5, "Consolidated balance sheet components" for additional information on non-trade receivables and unbilled reimbursements.

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

Pre-launch inventory

Inventory costs associated with products that have not yet received regulatory approval are capitalized if there is probable future commercial use and future economic benefit. If future commercial use and future economic benefit are not considered probable, then costs associated with pre-launch inventory that has not yet received regulatory approval are expensed as research and development expense during the period the costs are incurred. The determination to capitalize is based on the particular facts and circumstances relating to the product. Capitalization of such pre-launch inventory begins when the Company determines that (i) positive clinical trial results have been obtained in order to support regulatory approval is probable; (ii) uncertainties regarding regulatory approval have been significantly reduced; and (iii) it is probable that these capitalized costs will provide future economic benefit, in excess of capitalized costs.

As of December 31, 2024 and 2023, the Company capitalized $2,842,540 and $0 of pre-launch inventory costs, respectively. At December 31, 2024, the Company had $1,391,008 and $1,451,532 of capitalized pre-launch inventory recorded in current and noncurrent assets, respectively, based on the Company's forecasted utilization within the next year from the balance sheet date. Pre-launch inventory, consisting of raw materials, is recorded at the lower of cost (determined using the first-in, first-out method) and net realizable value. The Company could be required to write down previously capitalized costs related to pre-launch inventories upon a change in facts and circumstances, including among other potential factors, a denial or significant delay of approval by regulatory bodies, a delay in commercialization, or other adverse factors.

Property and equipment

Property and equipment is carried at acquisition cost less accumulated depreciation. The cost of normal, recurring, or periodic repairs and maintenance activities related to property and equipment are expensed as incurred.

Depreciation is computed using the straight-line method based on the estimated useful lives of the related assets. The estimated useful lives by asset classification are generally as follows:

Equipment	3 - 8 years
Computer software	3 years
Leasehold improvements	Lesser of 15 years or the remainder of the lease

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for potential impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that carrying value exceeds fair value. Fair value is determined using various valuation techniques, including discounted cash flow models, quoted market values, and third-party independent appraisals, depending on the nature of the asset. For the years ended December 31, 2024 and 2023, the Company did not recognize any impairment charges associated with long-lived assets.

Leases

At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. Leases with a term greater than twelve months are recognized on the balance sheet date as right of use ("ROU") operating lease assets and current and non-current lease liabilities, as applicable. The Company has elected not to recognize leases on the balance sheet, with terms of twelve months or less. The Company includes lease option extensions in the assessment of the lease arrangement when it is reasonably certain the option will be exercised.

Lease liabilities and the corresponding right of use operating lease assets are recorded based on the present value of lease payments to be made over the lease term. The discount rate used to calculate the present value is the rate implicit in the lease, or if not readily determinable, the Company's incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right of use operating lease asset may be required for items such as initial direct costs or incentives received. Lease payments on operating leases are recognized on a straight-line basis over the expected term of the lease. Lease payments on financing leases are recognized using the effective interest method. See Note 6, "Leases" for additional disclosure on leases.

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

For all asset classes of its leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets.

Revenue Recognition

To date the Company's sole product is in the late stages of development and has not been approved for sale by the FDA, as such no revenue has been recorded from the sale of products. Once the Company receives FDA approval, revenue from product sales will be recognized upon the transfer of control, which is generally upon shipment or delivery, depending on the delivery terms set forth in the customer contract. Provisions for discounts, rebates, and sales incentives to customers, and returns and other adjustments will be provided for in the period the related sale is recorded.

Research and development

Research and development costs are expensed when incurred. Research and development costs include operating expenses for the Company's engineering and product management functions supporting research, new development, and related product enhancement. Additionally, costs incurred in connection with preclinical development, clinical testing, as well as costs associated with the regulatory and FDA approval process are also included as a component of research and development expense.

General and administrative

General and administrative includes operating expenses incurred in our executive, finance, legal, marketing and other administrative functions.

Stock-based compensation

The Company recognizes stock-based compensation expense related to employees over the requisite service period based on the grant-date fair value of the awards. The fair value of options granted is estimated using the Black-Scholes option valuation model. The Company recognizes the grant-date fair value of an award as compensation expense on a straight-line basis over the requisite service period, which typically corresponds to the vesting period for the award. The Company elects to account for forfeitures as they occur and, upon forfeiture of an award prior to vesting, the Company reverses any previously recognized compensation expense related to that award. See Note 11, "Stock-based compensation" for additional details.

Interest Income

The Company earned interest income, including accretion of discount, from investments in marketable securities of $3,180,984 and $3,281,440 for the years ended December 31, 2024 and 2023, respectively.

Other Income

The Company periodically receives reimbursements of clinical trial expenses, which are recorded as other income in the accompanying consolidated statements of operations. Additionally, other income includes refundable tax incentives from the Australian Taxation Office. Components of Other Income were as follows for the years ended December 31, 2024 and 2023:

	2024	2023
Clinical trial reimbursements	$ 10,462	$ 57
Research and development tax incentive	350,534	718,902
Total other income	$ 360,996	$ 718,959

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

Income taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities reflect the tax effects of net operating losses, tax credits, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These are determined using enacted tax rates in effect for the year in which such temporary differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date.

The Company records deferred tax assets to the extent the Company believes these assets will more likely than not be realized. In making such a determination, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial operations. When we establish or reduce the valuation allowance against our deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period that determination to change the valuation allowance is made.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements on a particular tax position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. The amount of unrecognized tax benefits is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to unrecognized tax benefits in the provision for income taxes.

Earnings per share

Basic income or loss per share is determined by dividing net income or loss by the weighted average common shares outstanding during the period. Diluted income or loss per share is determined by dividing net income by diluted weighted average shares outstanding during the period. Diluted weighted average shares reflect the dilutive effect, if any, of potential common shares. To the extent their effect is dilutive, employee equity awards and other commitments to be settled in common stock are included in the calculation of diluted income or loss per share based on the treasury stock method. Potential common shares are excluded from the calculation of dilutive weighted average shares outstanding if their effect would be anti-dilutive at the balance sheet date based on a treasury stock method or due to a net loss.

Recently issued accounting pronouncements

In December 2023, the FASB issued ASU 2023-09, "*Improvements to Income Tax Disclosures*". The ASU focuses on income tax disclosures around effective tax rates and cash income taxes paid. ASU 2023-09 is effective for public filers for fiscal years beginning after December 15, 2024. The Company believes the adoption of ASU 2023-09 will not have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures.* This ASU improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, the ASU enhances interim disclosure requirements, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, provides new segment disclosure requirements for entities with a single reportable segment, and other disclosure requirements. The Company adopted ASU 2023-07 in the year ended December 31, 2024. Refer to Note 14 for enhanced disclosures associated with the adoption of this ASU.

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. In January 2025, the FASB issued an update 2025-01 "*Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date",* which revises the effective date of ASU 2024-03 to clarify that all public business entities are required to adopt the guidance in annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact of this standard on its disclosures.

Note 3 – Cash, cash equivalents, and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following at December 31, 2024 and 2023:

	2024	2023
Cash and cash equivalents:		
Cash	$ 3,210,556	$ 975,310
Money market funds	3,706,990	11,615,762
US Treasury securities	-	1,987,680
Total cash and cash equivalents	$ 6,917,546	$ 14,578,752
Marketable securities, short-term:		
Asset backed securities	$ 2,002,957	$ -
Commercial paper	1,156,709	21,113,569
Corporate bonds	23,951,700	14,836,424
US Government Agency bonds	-	2,794,510
US Treasury securities	26,635,045	18,991,771
Total marketable securities, short-term	$ 53,746,411	$ 57,736,274
Marketable securities, long-term:		
Asset backed securities	$ 2,305,317	$ 1,125,554
Corporate bonds	2,386,774	-
US Treasury securities	611,859	-
Total marketable securities, long-term	$ 5,303,950	$ 1,125,554
Total cash, cash equivalents, and marketable securities	$ 65,967,907	$ 73,440,580

During the year ended December 31, 2024, marketable securities were sold or matured for proceeds of $66,901,676 with no gain or loss realized. During the year ended December 31, 2023, marketable securities were sold or matured for proceeds of $69,174,324 with a realized gain of $276. See Note 4, "Fair value measurements" for additional information regarding the fair value of cash equivalents and marketable securities.

The following tables summarizes the unrealized gains and losses related to the Company's available-for-sale marketable securities, by major security type, as of December 31, 2024 and 2023:

	As of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
Asset backed securities	$ 4,304,662	$ 3,612	$ -	$ 4,308,274
Commercial paper	1,161,157	-	(4,448)	1,156,709
Corporate bonds	26,341,019	19,868	(22,413)	26,338,474
US Treasury securities	27,235,916	26,291	(15,303)	27,246,904
Total marketable securities	$ 59,042,754	$ 49,771	$ (42,164)	$ 59,050,361

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

	As of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
Asset backed securities	$ 1,126,999	$ -	$ (1,445)	$ 1,125,554
Commercial paper	21,101,403	17,445	(5,279)	21,113,569
Corporate bonds	14,811,749	25,601	(926)	14,836,424
US Government Agency bonds	2,796,078	1,297	(2,865)	2,794,510
US Treasury securities	18,972,928	18,843	-	18,991,771
Total marketable securities	$ 58,809,157	$ 63,186	$ (10,515)	$ 58,861,828

The following table shows the unrealized losses and fair values for those marketable securities that were in an unrealized loss position as of December 31, 2024 and 2023, aggregated by major security type and the length of time the marketable securities have been in a continuous loss position:

	As of December 31, 2024					
	In Loss Position for Less Than 12 Months		In Loss Position for 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 1,156,709	$ (4,448)	$ -	$ -	$ 1,156,709	$ (4,448)
Corporate Bonds	13,839,116	(22,413)	-	-	13,839,116	(22,413)
US Treasury Securities	14,094,715	(15,303)	-	-	14,094,715	(15,303)
Total	$ 29,090,540	$ (42,164)	$ -	$ -	$ 29,090,540	$ (42,164)

	As of December 31, 2023					
	In Loss Position for Less Than 12 Months		In Loss Position for 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Asset backed securities	$ -	$ -	$ 1,125,554	$ (1,445)	$ 1,125,554	$ (1,445)
Commercial paper	9,439,882	(5,279)	-	-	9,439,882	(5,279)
Corporate bonds	2,285,253	(926)	-	-	2,285,253	(926)
US Government Agency bonds	1,506,668	(2,865)	-	-	1,506,668	(2,865)
Total	$ 13,231,803	$ (9,070)	$ 1,125,554	$ (1,445)	$ 14,357,357	$ (10,515)

The contractual maturities of the Company's marketable securities as of December 31, 2024, were as follows:

	Fair Value
One year or less	$ 53,746,411
One year to two years	2,998,632
Two years to three years	2,305,318
Total	$ 59,050,361

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Note 4 – Fair value measurement

Management's assessment of the significance of a particular input to the fair value measurement requires judgement and may affect the valuation of financial assets and liabilities and their placement within the fair value hierarchy, as discussed in Note 2, "Summary of significant accounting policies". At December 31, 2024 and 2023, the fair value measurement of the Company's financial assets measured on a recurring basis were as follows:

	Fair Values as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 3,706,990	$ -	$ -	$ 3,706,990
Marketable securities				
Asset backed securities	-	4,308,274	-	4,308,274
Commercial paper	-	1,156,709	-	1,156,709
Corporate bonds	-	26,338,474	-	26,338,474
US Treasury securities	-	27,246,904	-	27,246,904
Total	$ 3,706,990	$ 59,050,361	$ -	$ 62,757,351

	Fair Values as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 11,615,762	$ -	$ -	$ 11,615,762
US Treasury securities	1,987,680	-	-	1,987,680
Marketable securities				
Asset backed securities	-	1,125,554	-	1,125,554
Commercial paper	-	21,113,569	-	21,113,569
Corporate bonds	-	14,836,424	-	14,836,424
US Government Agency bonds	-	2,794,510	-	2,794,510
US Treasury securities	-	18,991,771	-	18,991,771
Total	$ 13,603,442	$ 58,861,828	$ -	$ 72,465,270

In the Company's consolidated balance sheets, the carrying values of non-trade receivables, other assets, accounts payable and accrued expenses approximated their fair values due to the nature and relatively short maturities. The fair value of debt approximates its carrying value as it is variable rate debt or has relatively short maturities.

Note 5 –Consolidated balance sheet components

Non-trade receivables and unbilled reimbursements, net

Non-trade receivables and unbilled reimbursements include reimbursement of clinical trial expenses incurred, and the sale of materials to contract manufacturers. Non-trade receivables and unbilled reimbursements consisted of the following as of December 31, 2024 and 2023:

	2024	2023
Non-trade receivables	$ 433,051	$ 237,128
Unbilled reimbursements	8,388	135,772
Non-trade receivables and unbilled services	441,439	372,900
Less: allowance for credit losses	-	(142,166)
Non-trade receivables and unbilled services, net	$ 441,439	$ 230,734

During the year ended December 31, 2024 and 2023, the allowance for credit losses totaled $4,520 and $40,485, respectively.

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Property and equipment, net

Property and equipment consisted of the following as of December 31, 2024 and 2023:

	2024	2023
Equipment	$ 3,433,881	$ 3,159,822
Computer software	574,780	574,780
Leasehold improvements	513,727	499,148
Total property and equipment	4,522,388	4,233,750
Less accumulated depreciation and amortization	(3,727,429)	(3,144,979)
Total property and equipment, net	$ 794,959	$ 1,088,771

Depreciation and amortization expense on property and equipment was $587,485 and $752,257 for the years ended December 31, 2024 and 2023, respectively. There were no impairments recorded during the year ended December 31, 2024 and 2023.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following at December 31, 2024 and 2023:

	2024	2023
Accrued compensation and related liabilities	$ 3,116,301	$ 2,324,040
Accrued development expenses	482,417	875,501
Accrued warranty reserve	692,404	826,924
Accrued other expenses	4,719	68,882
Accrued expenses and other liabilities	$ 4,295,841	$ 4,095,347

See Note 15, “Commitments and contingencies” for additional disclosure on accrued warranty reserves.

Note 6 – Leases

The Company has an operating lease for its corporate headquarters and laboratory space, located in Sunnyvale, California. The initial lease expired June 30, 2024, with an option to extend the lease an additional sixty-months, which was used in the calculation of the right of use operating lease asset and operating lease liability. The Company held no other lease agreements at December 31, 2024. In January 2024, the Company signed an addendum to the operating lease, extending the expiration of the lease through June 30, 2025, and adjusting the monthly rent from $35,606 per month to $50,000 per month. The January 2024 lease remeasurement resulted in a $1,169,822 reduction in the right of use operating lease asset and corresponding reduction to operating lease liability. In March 2024, the Company signed an additional addendum to the operating lease, extending the expiration of the lease through December 31, 2025. The March 2024 lease remeasurement resulted in a $261,012 increase in the right of use operating lease asset and corresponding increase in operating lease liability. In July 2024, the Company signed an additional addendum to the operating lease, extending the expiration of the lease through December 31, 2026. The July 2024 lease remeasurement resulted in a $498,013 increase in the right of use operating lease asset and corresponding increase in operating lease liability.

In January 2025, the Company executed a lease that had not yet commenced for its new corporate headquarters, laboratory and manufacturing facility in Santa Clara, California. The lease payments begin on the later of: (i) June 1, 2025; or (ii) the date the tenant improvements are deemed complete, which is expected to be January 2026. The monthly base rent payment is $52,000 in year one; $80,340 in year two; $110,334 in year three; $145,282 in year four; and increasing 3% annually thereafter. The lease provides for a term of 132 months and includes an option to extend the lease for an additional five years.

Amounts reported in the consolidated balance sheets for operating leases in which the Company is the lessee as of December 31, 2024 and 2023, were as follows:

	2024	2023
Right of use operating lease asset	$ 929,243	$ 1,719,590
Lease liability, current	522,525	250,876
Lease liability, noncurrent	574,777	1,670,230
Remaining lease term	2.00 years	5.50 years
Discount rate	10.00%	10.00%

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The following table presents the components of lease costs in our statements of operations for the years ended December 31, 2024 and 2023:

	2024	2023
Operating lease costs	$ 473,956	$ 413,517
Variable lease costs	123,528	122,664
Short-term lease costs	15,861	-
Total lease expense	$ 613,345	$ 536,181

Future lease payments for non-cancellable operating leases as of December 31, 2024, were as follows:

Years Ended December 31,	
2025	600,000
2026	600,000
Total undiscounted lease payments	1,200,000
Less: effects of discounting	(102,698)
Total operating lease liabilities	$ 1,097,302

Note 7 - Notes payable

At December 31, 2024 and 2023, notes payable consisted of the following:

	2024	2023
Notes payable, current		
Current portion of notes payable	$ 37,286	$ 21,496
Notes payable, non-current		
Long-term portion of notes payable	41,800,000	41,800,000
Less: unamortized deferred loan costs	(523,291)	(734,579)
Less: unamortized discount	(1,013,104)	(1,418,734)
Notes payable, non-current, net	$ 40,263,605	$ 39,646,687
Total notes payable, net	$ 40,300,891	$ 39,668,183

The following table presents information regarding the Company's notes payable principal repayment obligations as of December 31, 2024:

Years Ended December 31,	
2025	$ 37,286
2026	-
2027	41,800,000
Total minimum payments	$ 41,837,286

Runway Growth Finance Corp

On June 30, 2022, the Company entered into a loan and security agreement with Runway Growth Finance Corp. The debt is secured against substantially all assets of the Company, except for the Company's intellectual property but includes all proceeds from the sale of intellectual property. The loan agreement provides three term loan tranches. The Company received the initial draw of $20,000,000 in June 2022. The Company received positive interim analysis data, sufficient to proceed with the clinical trial and premarket approval submission to the U.S. Food and Drug Administration, which allowed the Company to draw the second tranche of $20,000,000 in June 2023. As of December 31, 2024 and 2023, the outstanding principal balance was $41,800,000 and $41,800,000, respectively. The final tranche provides $10,000,000 and the draw period commences on the date the Company has received approval from the FDA for the WiSE CRT System and ended on June 30, 2024. The Company did not receive FDA approval by June 30, 2024, and therefore did not meet the draw requirements of the third and final tranche.

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Interest on the term loan accrues on the principal amount outstanding at a floating per annum rate equal to the greater of the rate of interest noted in The Wall Street Journal Money Rates section, as the "Prime Rate" or 4.00% plus a margin of 4.9% and is payable monthly in arrears and shall be computed on the basis of a 360-day year for the actual number of days elapsed. The Company is required to make interest only payments from July 2022 to May 2027. The note payable has a maturity date of June 15, 2027, at which time any unpaid interest, outstanding principal balance, and a final payment of 4.5% of the original principal amount borrowed shall be due in full. If the Company repays the loan prior to maturity, the Company will be required to pay a prepayment fee of 0.5% - 1% of the outstanding principal balance. The Company is also required to pay a 3% success fee of the funded principal amount of the term loan at the time of a liquidity event, as defined in the loan and security agreement. The success fee is enforceable within 10 years from the execution date of the agreement.

The Company has accounted for the final payment of $1,800,000 as a discount of the note that will be amortized over the life of the loan using the effective interest method. Amortization of the discount was $405,630 and $291,573 during the year ended December 31, 2024 and 2023, respectively. This amount was recorded as additional interest expense in the accompanying consolidated statements of operations. As of December 31, 2024 and 2023, the note has been shown net of unamortized discounts of $1,013,104 and $1,418,734, respectively.

The Company incurred loan costs of $998,393, which are being amortized over the life of the loan using the effective interest method. Amortization of loan costs was $211,288 and $184,464 for the years ended December 31, 2024 and 2023. As of December 31, 2024 and 2023, the note has been shown net of unamortized loan costs of $523,291 and $734,579, respectively.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of December 31, 2024 and 2023, the Company was in compliance with all debt covenants.

Bank of America Leasing & Capital, LLC

In May 2021, the Company entered into an equipment purchase agreement for the purchase of certain software totaling $128,974. The purchase agreement requires 30 equal payments of $4,299 beginning December 1, 2021, through May 1, 2024. At December 31, 2024 and 2023, the outstanding principal balance was $0 and $21,496, respectively, and was included in the current portion of notes payable in the consolidated balance sheets.

In March 2024, the Company entered into an equipment purchase agreement for the purchase of software totaling $82,029. The purchase agreement requires 11 equal payments of $7,457 beginning July 1, 2024, through May 1, 2025. As of December 31, 2024, the outstanding principal balance was $37,286 and was included in the current portion of notes payable in the consolidated balance sheets.

Note 8 – Convertible preferred stock

As of December 31, 2024 and 2023, 10,000,000 shares of convertible preferred stock were authorized, of which no shares were issued or outstanding.

Note 9 – Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors. As of December 31, 2024 and 2023, no dividends have been declared.

As of December 31, 2024 and 2023, 600,000,000 shares were authorized, of which 371,076,200 shares and 307,020,758 shares, respectively, were outstanding.

The Company completed its initial public offering and began trading on the Australian Securities Exchange ("ASX") on November 24, 2021, under the symbol "EBR". The ASX uses an electronic system called CHESS for the clearance and settlement of trades on the ASX. The State of Delaware does not recognize the CHESS system of holding securities or electronic transfers of legal title to shares. To enable companies to have their securities cleared and settled electronically through CHESS, CHESS depository instruments called CDIs are issued. CDIs are units of beneficial ownership in shares and are traded in a manner similar to shares of Australian companies listed on the ASX. The legal title to the shares are held by a depository, CDN, which is a wholly owned subsidiary of the ASX, and is an approved general participant of ASX Settlement.

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In June 2023, the Company completed an offering of 27,472,527 CDIs representing the same number of common stock at $0.91 Australian dollars per share, for proceeds of $15,604,896, net of $895,314 of related offering costs. In July 2023, the Company issued an additional 8,415,813 CDIs representing the same number of common stock at $0.91 Australian dollars per share, for proceeds of $5,010,231, net of $104,634 of related offering costs.

In September 2024, the Company completed a fully underwritten institutional placement, and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement issuance of 55,856,325 CDIs representing the same number of common stock at $0.82 Australian dollars per share, for proceeds of $29,407,263, net of $1,852,729 of related issuance costs.

In September 2024, the Company announced the retail component of the fully underwritten 1-for-20 pro-rata non-renounceable entitlement offer of 5,075,733 CDIs representing the same number of common stock at $0.82 Australian dollars per share. On October 16, 2024, the Company issued 5,075,733 CDIs and received proceeds of $2,551,526, net of $210,032 of related issuance costs.

Additionally, the Company has reserved the following shares of common stock for issuance as of December 31, 2024:

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	19,055,904
2021 Equity Incentive Plan	37,547,483
Outside of 2021 Equity Incentive Plan	709,633
Total shares of Common stock reserved for issuance	77,102,399

Note 10 – Warrants

Equity classified common stock warrants

The Company has issued the following warrants to purchase shares of its common stock, which are outstanding as of December 31, 2024 and 2023. These warrants are exercisable at any time at the option of the holder until their expiration date.

	Number of Shares	Weighted average exercise price	Weighted average remaining contractual term
Balance at January 1, 2023	19,789,379	$ 0.57	7.28
Issued	-	-	-
Expired	-	-	-
Balance at December 31, 2023	19,789,379	0.57	6.28
Issued	-	-	-
Expired/forfeited	-	-	-
Balance at December 31, 2024	19,789,379	$ 0.57	5.28

Note 11 – Stock-based compensation

The Company and its stockholders adopted an equity incentive plan (the "2013 Plan") in 2013, which reserved shares of the Company's common stock for the granting of incentive and nonqualified stock options to employees, directors, and consultants. On October 14, 2021, the Company replaced the 2013 Plan with the 2021 Plan, as the 2013 Plan was expiring. Under the 2021 Plan, 37,547,483 shares of common stock are reserved. The Company may grant options to purchase common stock, stock appreciation rights, restricted stock awards and other forms of stock-based compensation. Stock options generally vest over four years and expire no later than 10 years from the date of grant. The Board of Directors has the authority to select the employees to whom options are granted and determine the terms of each option, including: i) the number of shares of common stock subject to the option; ii) when the option becomes exercisable; iii) the option exercise price, which must be at least 100% of the fair market value of the common stock as of the date of grant; and iv) the duration of the option, which may not exceed 10 years.

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As of December 31, 2024, options to purchase a total of 22,153,134 shares of common stock remained outstanding and 15,394,349 shares remain available for grant under the 2021 Plan, and 709,633 remained outstanding outside of the 2021 Plan. As of December 31, 2024, options to purchase a total of 19,055,904 shares of common stock remained outstanding under the 2013 Plan. As of December 31, 2024, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the year ended December 31, 2024, was as follows:

	Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding at January 1, 2024	38,214,582	$ 0.31	7.09
Granted	10,004,948	0.63	
Cancelled	(3,177,475)	0.50	
Exercised	(3,123,384)	0.16	
Outstanding at December 31, 2024	41,918,671	$ 0.38	6.88
Vested and expected to vest at December 31, 2024	41,918,671	$ 0.38	6.88
Exercisable at December 31, 2024	26,879,873	$ 0.27	5.74

The fair value of the options granted to employees is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the volatility of the Company's common stock, an assumed risk-free interest rate and expected dividends. The Company uses the simplified calculation of expected life and volatility is based on an average of the historical volatilities of the common stock of several publicly traded entities with characteristics similar to those of the Company. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The Company uses the straight-line method for expense attribution. The weighted-average grant-date fair values of stock options granted during the year ended December 31, 2024 and 2023, was $0.42 per share and $0.37 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the year ended December 31, 2024 and 2023:

	2024	2023
Expected term (in years)	7.00	7.00
Expected volatility	63.98% - 67.34%	68.03% - 72.08%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	3.67% - 4.71%	3.38% - 4.44%

The following table presents classification of stock-based compensation expense within the accompanying consolidated statements of operations for the years ended December 31, 2024 and 2023:

	2024	2023
Research and development	$ 849,740	$ 674,088
General and administrative	892,539	631,723
Total	$ 1,742,279	$ 1,305,811

At December 31, 2024, there was $5,714,799 of unamortized stock-based compensation cost, respectively, related to unvested stock options which is expected to be recognized over a weighted average period of 3.11 years.

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Note 12 – Income taxes

The Company recorded income tax expense of $1,535 and $1,625 for the years ended December 31, 2024 and 2023. The Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets.

The components of income (loss) before income taxes are as follows:

	2024	2023
Domestic	$ (40,257,704)	$ (34,789,313)
Foreign	(539,033)	(245,950)
Total	$ (40,796,737)	$ (35,035,263)

The components of the provision (benefit) for income taxes are as follows:

	2024	2023
Current income tax expense:		
Federal	$ -	$ -
State	1,535	1,625
Foreign	-	-
Total current income tax expense	$ 1,535	$ 1,625
Deferred income tax expense:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total deferred tax expense	$ -	$ -
Net deferred tax assets	$ 1,535	$ 1,625

The Company's effective tax rate of 0.01% for each of the years ended December 31, 2024 and 2023 differs from the statutory U.S. federal rate as follows:

	2024	2023
Statutory tax rate	$ (8,567,315)	$ (7,321,441)
R&D credit generation	(298,158)	(344,374)
State and foreign tax benefit	(3,594,350)	(3,773,101)
Other non-deductible expenses	290,513	651,633
Change in valuation allowance	12,170,845	10,788,908
Effective tax rate	$ 1,535	$ 1,625

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The tax effects of temporary differences that give rise to significant components of the deferred tax assets are as follows:

	2024	2023
Deferred tax assets:		
Net operating loss	$ 67,009,000	$ 57,255,000
Other accruals	1,058,000	870,000
Stock based compensation	693,000	457,000
Credit carryforwards	3,054,000	2,473,000
Intangible assets	10,709,000	12,343,000
Research & development capitalization	7,820,000	4,816,000
Fixed assets	80,000	39,000
Total deferred tax assets	90,423,000	78,253,000
Deferred tax liability		
Fixed assets	-	-
Total deferred tax liability	-	-
Net deferred tax asset before valuation allowance	90,423,000	78,253,000
Valuation allowance	(90,423,000)	(78,253,000)
Net deferred tax assets	$ -	$ -

As of December 31, 2024, the Company recorded the portion of its deferred tax assets that were determined to meet the more likely than not threshold. Significant judgment is required in determining the Company's provision for income taxes, recording valuation allowances against deferred tax assets and evaluating the Company's uncertain tax positions. Due to net losses since inception and the uncertainty of realizing the deferred tax assets, the Company has a full valuation allowance against its net deferred tax assets. To the extent that the Company generates positive income and expects, with reasonable certainty, to continue to generate positive income, the Company may release all, or a portion of, the valuation allowance in a future period. This release would result in the recognition of all, or a portion of, the Company's deferred tax assets, resulting in a decrease to income tax expense for the period such release is made. As of December 31, 2024, the Company's valuation allowance was $90,423,000, which increased by $12,170,000 for the year ended December 31, 2024.

On August 16, 2022, the United States enacted the Inflation Reduction Act (IRA), which introduces, among other items, an excise tax that would impose a 1% surcharge on stock repurchases, net of stock issuances which began in 2023. The IRA also introduced a 15% book minimum tax on Companies with average adjusted financial statement earnings that exceed $1 billion. As the Company's average adjusted financial statement earnings do not exceed this threshhold, the Company is not an "Applicable Corporation". These provisions do not impact the Company based on the current financial positions.

The Company does not meet the Pillar II consolidated annual revenue threshold of EUR 750 million and as such is not expected to be subject to any Pillar II top up taxes.

Net operating loss ("NOL") carryforwards and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and may become subject to annual limitation due to ownership changes that have occurred previously or that could occur in the future under Section 382 of the Internal Revenue Code, as amended and similar state provisions. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed, and any limitation is known, no amounts are being presented as an uncertain tax position.

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As of December 31, 2024, the Company had federal NOL carryforwards of $219,902,011 available to reduce taxable income, of which $45,622,855 expire beginning 2027 and $174,279,156 do not expire. As of December 31, 2024, the Company had state NOL carryforwards of 217,271,254 available to reduce future state taxable income of which $214,379,681 expire beginning 2028 and $2,891,573 do not expire.

As of December 31, 2024, the Company had federal and state research and development credit carryforwards of $2,236,314 and $2,126,254, respectively. The federal research and development credit carryforwards expire beginning in 2035 and the state credit carryforwards do not expire.

The Company files income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. In the normal course of business, the Company is subject to examination by taxing authorities throughout the world. Due to NOL carryforwards not being utilized, all periods are open to potential examinations.

The Company's policy is to classify interest and penalties related to unrecognized tax benefits, if and when required, as a component of interest expense, in the accompanying consolidated statements of operations. The Company had not recorded any interest or penalties for the years ended December 31, 2024 and 2023.

As of December 31, 2024, the Company's uncertain tax positions totaled $1,308,770, which are netted against the underlying deferred tax assets. The entire balance in uncertain tax positions would cause a decrease in the effective income tax rate upon recognition.

The following is a roll-forward of the Company's liability related to uncertain tax positions as of December 31, 2024 and 2023:

	2024	2023
Balance as of January 1	$ 1,059,676	$ 1,012,850
Increase for current period tax positions	249,094	287,704
Decrease for release of FIN 48 reserves	-	(240,878)
Balance as of December 31	$ 1,308,770	$ 1,059,676

Note 13 – Net loss per share

The following tables sets forth the computation of basic and diluted net loss per share attributable to common stockholders at December 31, 2024 and 2023:

	2024	2023
Numerator – basic & diluted:		
Net loss attributable to common stockholders, basic and diluted	$ (40,798,272)	$ (35,036,888)
Denominator:		
Weighted-average number of shares outstanding, basic and diluted	324,995,419	288,875,373
Net loss per share attributable to common stockholders, basic and diluted	$ (0.13)	$ (0.12)

The following potentially dilutive shares were not included in the calculation of diluted shares outstanding for the periods presented as the effect would have been anti-dilutive at December 31, 2024 and 2023:

	2024	2023
Outstanding warrants	19,789,379	19,789,379
Outstanding stock options	41,918,671	38,214,582
Total dilutive shares	61,708,050	58,003,961

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

Note 14 - Segment information

An operating segment is defined as a component of an entity for which discrete financial information is available that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's Chief Executive Officer is the CODM. The CODM reviews financial information on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. The Company is currently in the pre-revenue development stage and its primary activity is the development of its leadless cardiac pacing system, WiSE CRT. Thus, the total Company's consolidated results represent only the results of the WiSE CRT Segment. The Company currently conducts its operations primarily in the United States. Operations in countries outside of the U.S. are limited to Australia and Europe and are not significant. Business activity conducted in the U.S and in our international locations are similar in nature and economic characteristics and are consolidated for reporting purposes. As such, management has determined that the Company operates as one operating and reportable segment that is currently focused exclusively on the advancement of the Company's WiSE CRT System.

The Company's operating expenses and net loss are the primary measures of the segment's performance used by the Company's CODM. The segment is in the pre-revenue operating stage, and therefore the CODM primarily focuses on research and development expenses, general and administrative expenses, and the net loss as the primary measure of the segment's performance used by the Company's CODM. In addition to the segment's expenses that are presented on the consolidated statement of operations, the information about the segment's expenses is disaggregated into significant expenses, which are not separately presented on the Company's consolidated statement of operations, as included below.

The table below reports information about the segment loss for the years ended December 31, 2024 and 2023.

	2024	2023
Research and development expenses		
Personnel-related expenses	$ 17,769,916	$ 14,278,125
Clinical expenses	2,022,952	3,383,567
Quality assurance and regulatory approval expense	272,128	126,522
Contract manufacturing, materials and components	5,340,641	7,854,132
Facility-related and other expenses	1,659,790	1,503,680
Total research and development expenses	27,065,427	27,146,026
General and administrative expenses		
Personnel-related expenses	4,634,579	3,515,789
Professional services expenses	4,219,946	1,805,484
Corporate Expense	1,967,149	1,543,021
Facility-related and other expenses	431,927	538,627
Total general and administrative expense	11,253,601	7,402,921
Loss from operations	(38,319,028)	(34,548,947)
Other (expense) income		
Interest expense	(6,029,668)	(4,483,731)
Interest income	3,180,984	3,281,440
Other Income, net [(a)]	370,975	715,975
Total other (expense), net	(2,477,709)	(486,316)
Income tax (expense)	(1,535)	(1,625)
Consolidated Net Loss	$ (40,798,272)	$ (35,036,888)

[(a)] Other Income (Expense) includes gain/(loss) on foreign currency, reimbursements of clinical trial expenses as well as refundable tax incentives from the Australian Taxation Office

EBR SYSTEMS, INC.
Notes to the Consolidated Financial Statements

Note 15 – Commitments and contingencies

Purchase commitments

The Company purchases raw materials, manufacturing equipment, and various services from a variety of vendors. During the normal course of business, in order to manage manufacturing lead times and help ensure an adequate supply of certain items, we enter into agreements with suppliers that either allow us to procure goods and services when we choose or that establish purchase requirements over the term of the agreement. In certain instances, our purchase agreements allow us to cancel, reschedule, or adjust our purchase requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our purchase commitments are firm and noncancelable. As of December 31, 2024, the Company's obligations under such arrangements were approximately $14,404,767.

Contingencies

The Company is party to various legal proceedings from time to time. A liability is accrued when a loss is both probable and can be reasonably estimated. Management believes that the probability of a material loss with respect to any currently pending legal proceeding is remote. However, litigation is inherently uncertain, and it is not possible to definitively predict the ultimate disposition of any of these proceedings. The Company does not believe that there are any pending legal proceedings or other loss contingencies that will, either individually or in the aggregate, have a material adverse impact on the Company's consolidated financial statements.

Accrued warranty reserves

The Company accrues for the estimated cost of product warranties based on historical experience at the time a patient enrolls in the clinical trial. Adjustments to initial obligations for warranties are made as changes to the obligations become reasonably estimable. Accrued warranty reserves are included in accrued expenses and other liabilities in the accompanying consolidated balance sheets.

Changes in accrued warranty reserves were as follows for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Beginning of period	$ 826,924	$ 734,400
Warranty reserve accrued during the period	-	280,808
Settlement of warranty claims	(134,520)	(188,284)
End of period	$ 692,404	$ 826,924

Note 16 – Related party transactions

On September 25, 2024, the Company issued 55,856,325 shares of common stock at a price to the public of $0.56 per share in connection with an institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement offer on the ASX. Host-Plus, a beneficial owner of more than 5% of our common stock, participated in the institutional placement and purchased 7,868,138 CDIs for the aggregate purchase price of $4,403,403.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15(d)-15(e) under the Exchange Act as of the end of the period covered by this Annual Report on Form 10-K. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2024.

Management's Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of SEC for newly public companies.

Attestation report of the registered public accounting firm.

This annual report does not include an attestation report of the Company's registered public accounting firm due to the established rules of the Securities and Exchange Commission.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues within a company are detected. The inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this item will be contained in the Company's Proxy Statement for its 2025 Annual Stockholder Meeting, to be filed with the SEC within 120 days after December 31, 2024 (the "2025 Proxy Statement"), under the headings "Proposal 1 — Election of Directors" and "Executive Officers" and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a code of conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. If we make any substantive amendments to the code of conduct or grant any waiver from a provision of the code of conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. The full text of our code of conduct is on the investor relations portion of our website at ebrsystemsinc.com/investor-center. The inclusion of our website address in this Annual Report on Form 10-K does not include or incorporate by reference into this Annual Report on Form 10-K the information on or accessible through our website.

Securities Trading Policy

We have adopted a Securities Trading Policy which governs the purchase, sale and/or any other dispositions of our securities by the Company and its directors, officers and employees and is reasonably designed to promote compliance with insider trading laws, rules and regulations and applicable exchange listing standards. A copy of our Securities Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item will be contained in the Company's 2025 Proxy Statement, under the heading "Executive Compensation," and is incorporated herein by reference.

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

The information required by this item will be contained in the Company's 2025 Proxy Statement, under the heading "Security Ownership of Certain Beneficial Owners and Management," and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item will be contained in the Company's 2025 Proxy Statement, under the heading "Transactions with Related Persons and Indemnification," and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in the Company's 2025 Proxy, under the heading - Principal Accountant Fees and Services," and is incorporated herein by reference.

Part IV

Item 15. Exhibits, Financial Statements and Schedule

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

1. Financial Statements. Our consolidated financial statements are listed in the "Index to Consolidated Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.
2. Financial Statement Schedules. The financial statement schedules have been omitted as they are either not applicable or the required information is otherwise included.
3. Exhibits. The exhibits required to be filed as part of this report are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Number	Description	Filed Herewith	Incorporated by Reference			
			Schedule/Form	File No.	Exhibit	Filing Date
3.1*	Amended and Restated Certificate of Incorporation of EBR Systems, Inc.		10-12G	000-56671	3.1	11/21/2024
3.2*	Amended and Restated Bylaws of EBR Systems, Inc.		8-K	000-56671	3.1	03/20/2025
4.2*	Amended and Restated Investors' Rights Agreement dated October 13, 2021, between the EBR Systems, Inc. and the parties thereto.		10-12G	000-56671	4.2	11/21/2024
4.3*	Form of Warrant to Purchase Stock issued on March 25, 2020		10-12G	000-56671	4.3	11/21/2024
4.4*	Warrant to Purchase Stock, dated October 30, 2017, between the Company and M.H. Carnegie Co. Pty Ltd		10-12G	000-56671	4.4	11/21/2024
4.5*	Form of Warrant to Purchase Stock issued between August 16, 2019, and October 4, 2021		10-12G	000-56671	4.5	11/21/2024
4.6*	Form of Warrant to Purchase Stock issued between October 6, 2015, and February 28, 2018.		10-12G	000-56671	4.6	11/21/2024
4.7	Description of Capital Stock	X				
10.1*†	Loan and security Agreement, dated June 28, 2022, between the Company and Runway Growth Finance Corp.		10-12G	000-56671	10.1	11/21/2024
10.2	First Amendment to Loan and Security Agreement, dated March 21, 2025, between the Company and Runway Growth Finance Corp.	X				
10.3*†	Standard Industrial/Commercial Multi-Tenant Lease, dated March 30, 2017, between the Company and 480 Oakmead Properties, LLC (the "Oakmead Lease")		10-12G	000-56671	10.2	11/21/2024

10.4*†	Addendum "B" to the Oakmead Lease, dated January 2024, between the Company and 480 Oakmead Properties, LLC.		10-12G	000-56671	10.3	11/21/2024
10.5*†	Addendum "C" to the Oakmead Lease, dated March 2024, between the Company and 480 Oakmead Properties, LLC.		10-12G	000-56671	10.4	11/21/2024
10.6*†	Addendum "D" to the Oakmead Lease, dated July 2024, between the Company and 480 Oakmead Properties, LLC.		10-12G	000-56671	10.5	11/21/2024
10.7	Lease Agreement, dated January 17, 2025, between the Company and Drawbridge 4600 Patrick Henry, LLC	X				
10.8*+	Offer Letter entered into between the Company and John McCutcheon, dated May 29, 2019		10-12G	000-56671	10.6	11/21/2024
10.9*+	Offer Letter entered into between the Company and Allan Will, dated August 21, 2019		10-12G	000-56671	10.7	11/21/2024
10.10*+	Offer Letter entered into between the Company and Gary Doherty, dated August 29, 2023		10-12G	000-56671	10.8	11/21/2024
10.11*+	Offer Letter entered into between the Company and Michael Hendricksen, dated October 27, 2021		10-12G	000-56671	10.9	11/21/2024
10.12*+	Form of Severance and Change of Control Agreement entered into between the Company and each of its executive officers#		10-12G	000-56671	10.10	11/21/2024
10.13*+	2021 Equity Incentive Plan, as amended#		10-12G	000-56671	10.11	11/21/2024
10.14*+	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Equity Incentive Plan (Australian Grants)#		10-12G	000-56671	10.12	11/21/2024
10.15*+	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Equity Incentive Plan (United Kingdom Grants)#		10-12G	000-56671	10.13	11/21/2024
10.16*+	Australian Sub-Plan under the 2021 Equity Incentive Plan#		10-12G	000-56671	10.14	11/21/2024
10.17*+	United Kingdom Sub-Plan under the 2021 Equity Incentive Plan#		10-12G	000-56671	10.15	11/21/2024
10.18*+	2013 Equity Incentive Plan, as amended		10-12G	000-56671	10.16	11/21/2024

10.19*+	Form of Stock Option Grant Notice and Stock Option Amendment under the 2013 Equity Incentive Plan		10-12G	000-56671	10.17	11/21/2024
10.20*+	Form of Indemnification Agreement entered into between the Company and each of its directors and executive officers		10-12G	000-56671	10.19	11/21/2024
19.1	Securities Trading Policy	X				
21.1*	List of Subsidiaries		10-12G	000-56671	21.1	11/20/2024
23.1	Consent of Deloitte and Touche, LLP, an Independent Registered Public Accounting Firm	X				
24.1	Power of Attorney (included on the signature page to this report)	X				
31.1	Chief Executive Officer Certification Pursuant to Rule 13a-14(a) of the Exchange Act.	X				
31.2	Chief Financial Officer Certification Pursuant to Rule 13a-14(a) of the Exchange Act.	X				
32.1	Chief Executive Officer and Chief Financial Officer Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					

* Filed previously.

\+ Indicates a management contract or compensatory plan, contract or arrangement.

† Certain exhibits and schedules to this exhibit have been omitted in accordance with Item 601(a)(5) of Regulation S-K. The registrant hereby agrees to furnish supplementally a copy of any omitted exhibit or schedule to the SEC upon its request.

§ Portions of this exhibit have been redacted in accordance with Regulation S-K Item 601(b)(10)(iv).

Item 16. Form 10-K Summary

None

SIGNATURES

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

EBR SYSTEMS, INC.

By:	*/s/John McCutcheon*
Name:	John McCutcheon
Title:	Chief Executive Officer (Principal Executive Officer)

By:	*/s/Gary Doherty*
Name:	Gary Doherty
Title:	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Date: March 24, 2025

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints John McCutcheon and Gary Doherty, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ John McCutcheon John McCutcheon	Chief Executive Officer and Director (Principal Executive Officer)	March 24, 2025
/s/ Gary Doherty Gary Doherty	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 24, 2025
/s/ Allan Will Allan Will	Executive Chairman of the Board	March 24, 2025
/s/ Karen Drexler Karen Drexler	Director	March 24, 2025

/s/ Bronwyn Evans, Ph.D., A.M. Bronwyn Evans, Ph.D., A.M.	Director	March 24, 2025
/s/ Trevor Moody Trevor Moody	Director	March 24, 2025
/s/ Christopher Nave, Ph.D. Christopher Nave, Ph.D.	Director	March 24, 2025
/s/ David Steinhaus, M.D. David Steinhaus, M.D.	Director	March 24, 2025