ASX ANNOUNCEMENT **18 September 2024**

Amendment to Form 10

Sunnyvale, California; 18 September 2024: EBR Systems, Inc. (ASX: **"EBR"**, **"EBR Systems"** or the "**Company**") advises that it has filed an amendment to its Form 10 Registration Statement (originally filed on 29 July 2024 in the U.S.) with the U.S. Securities and Exchange Commission (**SEC**). As previously stated by the Company, the Form 10 is not being used to conduct a U.S. initial public offering or a U.S. stock exchange listing and the Company does not intend to raise capital with the Form 10 filing.

The amendment to the Form 10 has been lodged today with the ASX, following the filing with the SEC. The amendment addresses certain minor additional edits and clarifications raised in the SEC review process, as well as the inclusion of financial information and comparisons for the quarters ended 30 June 2024 and 2023. This follows the standard process for the SEC review of such filings.

The Company expects the Form 10 to become effective on 30 September 2024.

This announcement has been authorised for release by General Disclosure Committee, a Committee of the Board.
ENDS

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About EBR Systems (ASX: EBR)

Silicon Valley-based EBR Systems (ASX: EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The patented proprietary Wireless Stimulation Endocardially (WiSE) technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications, effectiveness and reliability issues in cardiac rhythm disease management. The initial product is designed to eliminate the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring Cardiac Resynchronisation Therapy (CRT). Future products potentially address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

EBR Systems' WiSE Technology

EBR Systems' WiSE technology is the world's only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart's left ventricle. This has long been a goal of cardiac pacing companies since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location. WiSE technology enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice. The need for a pacing wire on the outside of the heart's left ventricle – and the attendant problems – are potentially eliminated. WiSE is an investigational device and is not currently available for sale in the US.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the

Company's control, subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. EBR does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. EBR may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Foreign Ownership Restriction

EBR's CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of EBR's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

As filed with the Securities and Exchange Commission on September 17, 2024.
File No. 000-56671

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

Amendment No. 1
to
FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g)
of the Securities Exchange Act of 1934

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 number)
480 Oakmead Parkway **Sunnyvale, CA**	**94085**
(Address of principal executive offices)	(Zip code)

(408) 720-1906
(Registrant's telephone number, including area code)

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

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

Title of Each Class to be Registered
Common Stock, par value $0.0001 per share

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. (Check one):

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. ☐

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Explanatory Note

EBR Systems, Inc., a Delaware corporation (the "Company"), is filing this Registration Statement on Form 10-12G (as may be amended from time to time, the "Registration Statement") with the Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), on a voluntary basis to register our common stock, par value $0.0001 per share, or common stock. The common stock is publicly traded on the Australian Securities Exchange, or ASX under the ticker "EBR", in the form of Clearing House Electronic Subregister System ("CHESS") Depositary Interests, or CDIs. CDIs are units of beneficial ownership in our shares of common stock held by CHESS Depositary Nominees Pty Limited, or CDN, a wholly owned subsidiary of ASX Limited, the company that operates the ASX. In this Registration Statement, unless otherwise noted, each of the "Company," "we," "us," "our," and "EBR" refers to EBR Systems, Inc. and its consolidated subsidiaries.

This registration statement will become effective automatically by lapse of time 60 days from the date of its filing pursuant to Section 12(g)(1) of the Exchange Act. As of the effective date of the registration statement, we

will be subject to the requirements of Regulation 13(a) under the Exchange Act and will be required to file annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K, and we will be required to comply with all other obligations of the Exchange Act applicable to issuers filing registration statements pursuant to Section 12(g) of the Exchange Act.

"EBR Systems" and the "EBR Systems" logo, "WiSE" and the "WiSE" logo, "WICS" and the "WICS" logo are registered trademarks of the Company. All other trademarks, trade names and service marks mentioned in this registration statement are the property of other organizations.

The market data and other statistical information contained in this registration statement are based on independent industry publications, government publications, reports by market research firms and other publicly available information. Some data is also based on our good faith estimates, which are derived from other relevant statistical information. Although we believe these sources are reliable, we have not independently verified the accuracy and completeness of such information, nor did we commission any third-party data presented in this registration statement.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies. These provisions include, but are not limited to:

- being exempt from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act (the "Sarbanes-Oxley Act");
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board (the "PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements and proxy statements; and
- being exempt from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved by stockholders.

We have elected to take advantage of certain reduced disclosure obligations in this registration statement and may elect to take advantage of other reduced reporting requirements in future filings. In addition, the JOBS Act permits us, as an emerging growth company, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

We will remain an emerging growth company until the earliest of (i) the last day of our fiscal year 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 of 1933, as amended (the "Securities Act"), (ii) the first fiscal year after our annual gross revenues exceed $1.235 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.00 billion in non-convertible debt securities or (iv) the end of any fiscal year in which the aggregate worldwide market value of our voting and non-voting common equity held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year and have filed at least one annual report and be subject to Section 13(a) or 15(d) of the 1934 Act for at least 12 months.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" (as we do as of the filing date of this registration statement), which would allow us to take advantage of

many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Disclosure Regarding Forward-Looking Statements

This Form 10 contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Form 10, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans, and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this Form 10 include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and effectiveness of our WiSE system;
- 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;
- our expectations with respect to entry into clinical trial agreements with potential collaborators for our clinical trials;
- 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, effectiveness of our products;
- our ability to obtain and maintain regulatory approval of or Conformité Européene ("CE") Certificates of Conformity for our products;
- our plans relating to the further development and commercialization of our products, including additional indications we may pursue;
- the potential effects of public health crises on our clinical programs and business;
- 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.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Form 10 and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Form 10. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by

applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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 Form 10, and while 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 an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Where You Can Find More Information

We will be subject to the requirements of Section 13(a) under the Exchange Act, which requires us to file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and proxy statements with the SEC. We will also be required to comply with all other obligations of the Exchange Act applicable to issuers filing registration statements pursuant to Section 12(g) of the Exchange Act.

Electronic copies of the materials we file with the SEC will be available to the public at the web site maintained by the SEC at http://www.sec.gov.

We also maintain a website at www.ebrsystemsinc.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this Form 10. We have included our website address as an inactive textual reference only.

Item 1. Business.

Overview and Company History

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. 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 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. For a more comprehensive discussion of the conventional CRT market, see "Overview of Leadless Pacemakers for Cardiac Pacing" below.

EBR has developed the WiSE® CRT System, the only leadless left ventricular pacing device in clinical development. If approved by the FDA, our system would allow clinicians to provide CRT for patients where an left ventricular ("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. Please see the discussion in the sections below following "WiSE CRT Clinical Program" and "Patients with No Current Available Options" for further information about our clinical studies of the WiSE® CRT System.

The WiSE® CRT System employs ultrasound energy for leadless pacing, a significant advancement over traditional CRT systems currently available that are constrained by leads.

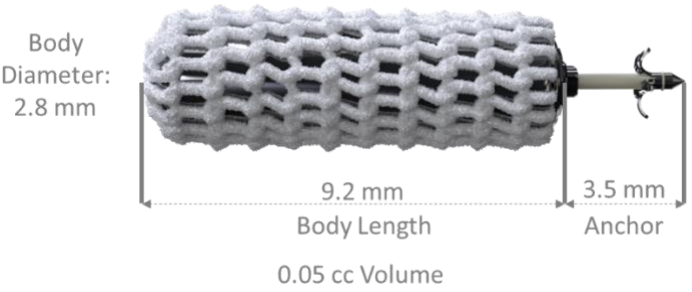


Figure 1.1: WiSE Electrode

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 Food and Drug Administration ("FDA") which provides the Company 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. Within 45 days of our submission date, the FDA will notify us if our PMA has been filed and will communicate its review timeline. Under standard review, the FDA has 180 days to review the PMA. Thus, subject to FDA review and approval, and pre-commercial activities described under "Commercial Strategy" section below, we expect to commercially launch the WiSE CRT System in the U.S. in 2025.

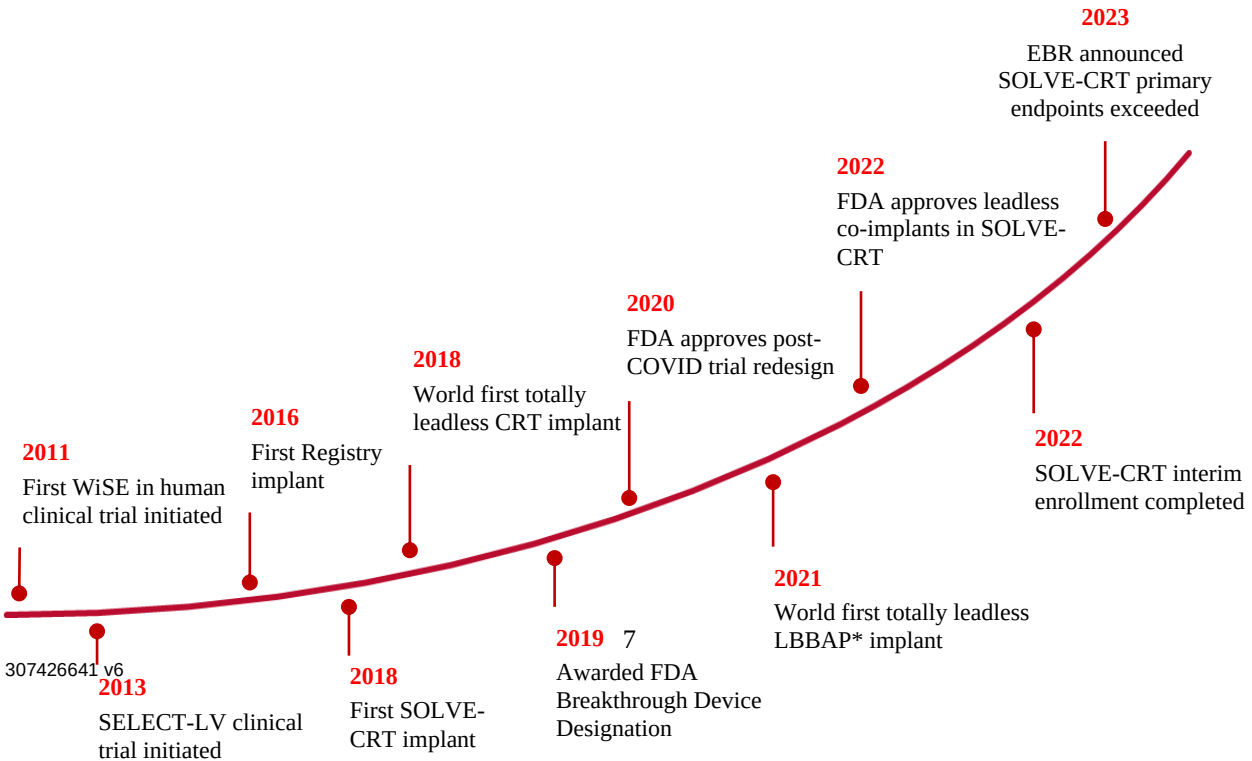


Figure 1.2: Timeline of key milestones achieved for EBR
*****Left Bundle Branch Area Pacing

Opportunity

Heart Failure

Our leadless WiSE CRT system is designed for use in patients with moderate to severe heart failure who require CRT. The initial patient population is for those whom CRT leads have failed previously, or who are at high risk to receive CRT using existing lead-based devices because of potential complications from the use of leads due to the patients' anatomy or disease condition. According to a Journal of American Heart Association publication in 2015 "*Venous Stenosis After Transvenous Lead Placement: A Study of Outcomes and Risk Factors in 212 Consecutive Patients"*, patients with multiple leads have a greater than 62% chance of having venous occlusion (where a vein is blocked, narrowed, or compressed, which can cause blood to pool and flow backward) and 59% of the upgrade population has at least two existing leads. Based on the study *"Infection after pacemaker implantation: infection rates and risk factors associated with infection in a population-based cohort study of 46299 consecutive patients"* published in the *European Health Journal* and results from the National Cardiovascular Data Registry, patients who had a pacemaker or implantable cardioverter defibrillator ("ICD") battery pocket reopened within 12 months of the original implant have a 3-times higher risk of surgical site infection. Additionally, the study *"Risk Factors for Infections Involving Cardiac Implanted Electronic Devices"* published in the *Journal of American College of Cariology* found that patients under the age of 60 years old undergoing any device upgrade, or those with more than one previous battery replacement, face a six-fold increased risk of surgical site infection, as younger patients are more likely to require additional procedures over their lifetime, increasing cumulative exposure to infection risks.

Failed implants due to left ventricular lead placement in the coronary sinus are high, with reported rates in the 5% to 10% range, with many patients have suboptimal lead locations, as reported in a study published in the *New England Journal of Medicine* in 2002. Based on the combined results of over 2,000 patients from a multicenter study program, as published in the *Journal of the American College of Cardiology*, left ventricular lead-based issues include inability to access the coronary sinus due to anatomical constraints or venous occlusion, infection, phrenic nerve stimulation, and lead dislodgement.

Prevalence and Incidence of Heart Failure

Heart failure belongs to a group of diseases called cardiovascular diseases. Heart failure is a complex clinical syndrome that results from functional or structural impairment of the heart that results in the dysfunction of the LV.

Heart failure is a significant public health problem with an estimated current prevalence in 2020 of 6.2 million people in the U.S. (with approximately one million new cases of heart failure diagnosed in the U.S. each year) and around 64 million people worldwide, based on a Cardiovascular Res. 2023 publication by *Savarese G, Lund LH. "Global public health burden of heart failure"*. According to report published by American Heart Association in 2020, it is expected that 8 million people in the United States will suffer heart failure by 2030, with a 5-year survival rate of 52.6% once diagnosed. Further, the European Society of Cardiology ("ESC") guidelines suggest 5-10% of all heart failure patients meet the criteria for CRT, due to the ventricles of the heart contracting at slightly different times (dyssynchronous contractions).

Cardiac Rhythm Management Devices

The first cardiac pacing device was developed in the 1950s and formed the foundation for the medical device company, Medtronic. Since then, cardiac pacing devices have continued to play a key role in the clinical management of patients with heart disease.

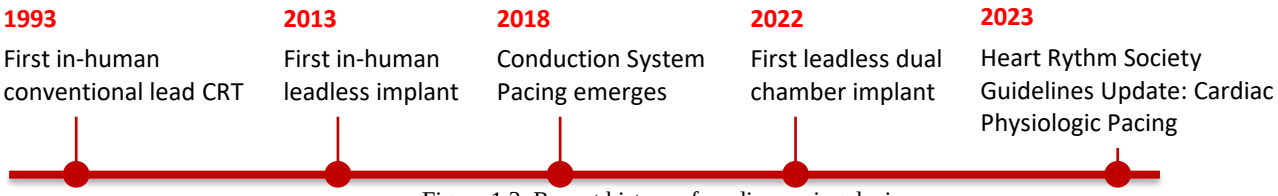


Figure 1.3: Recent history of cardiac pacing devices

CRM devices are devices that monitor a patient's heart rhythm and normalize different types of irregularities by delivering electrical stimulation to the heart tissue. The three most common therapeutic CRM devices are:

***Pacemakers**:* which stimulate contractions of the heart if it slows or becomes irregular;

Implantable Cardioverter Defibrillators ("ICDs"): which deliver an electric shock to reset the heart rhythm when certain types of cardiac arrhythmia occur; and

CRT devices: which synchronize the contraction of the left and right sides of the heart.

Pacemaker Technologies Today

Pacemakers have been a cornerstone in treating bradycardia, a condition where the heart rate slows down due to disease, tissue damage, or the effects of medication. These devices deliver electrical impulses to stimulate heart contractions, ensuring the heart maintains an adequate rate. The necessity for pacemakers varies among patients, with some entirely dependent on these devices, while others require occasional pacing. Implantation techniques and device types have evolved:

- Single lead for right-ventricle pacing,
- Duel leads for right atrial and right ventricle pacing, or
- Leadless pacemakers, (all-in-one-device) for right-sided single or dual chamber pacing.

The United States sees over 200,000 pacemaker implantations annually, reflecting the widespread reliance on these devices for managing bradycardia per the *American College of Cardiology. (March 23, 2016). Permanent leadless cardiac pacing.*

Understanding the Evolution of CRT in Heart Failure Management

CRT represents a critical advancement in the treatment of heart failure, particularly for patients with dyssynchronous heart contractions that can result in an enlarged left ventricle. While traditional pacemakers, both lead and leadless, primarily address arrhythmias within the right side of the heart, CRT devices extend this therapeutic approach. By synchronizing the contractions of both the left and right ventricles through electrical stimulation, CRT enhances the heart's efficiency and overall function.

Technical Insights into CRT Implementation

To stimulate the left ventricle, conventional CRT devices utilize a 3rd lead, a method that would ideally involve direct pacing within the left ventricle, akin to procedures for the right ventricle. However, the direct placement of leads in the left ventricle (endocardial – inside surface of the heart) raises significant concerns regarding thromboembolism (the formation of blood clots), prompting the standard practice of situating the lead within the

coronary sinus ("CS") — a vein on the heart's outer surface (epicardial – outside surface of the heart). This approach to left ventricular pacing has two main challenges:

- ***Anatomical Constraints*:** The feasibility of lead placement relies on the specific anatomical features of a patient's heart, potentially limiting physicians' options and impacting the lead's optimal positioning.

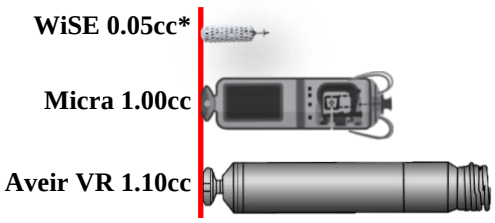
  For example, research studies on epicardial LV lead positions in the CS have shown that apical or non-lateral epicardial positions are seen as unfavorable.[1,2] Further, an acute human study showed that optimizing the left ventricular pacing site was the primary determinant in hemodynamic response in non-ischemic dilated cardiomyopathy patients and that pacing in the coronary sinus was rarely optimal.[3] Other studies have shown that concordance of the left ventricular lead position with the site of latest activation was associated with improved CRT response and revere remodeling.[4-7] In addition, Leyva and co-workers reported that left ventricular pacing at a scar-free site is key to ensure improvement in left ventricular function in CRT patients.[8-9] While recent data suggest patient-specific tailoring of left ventricular lead position based on site of latest activation may provide improved clinical response to CRT, the LV lead position of a transvenous coronary sinus lead is limited by the accessibility and path of the coronary veins.[10,11]

- ***Physiological Considerations*:** Traditional epicardial (surface) pacing, while effective, does not mimic the heart's natural endocardial (inner) pacing pathway. Endocardial pacing is more physiological, promoting a more natural progression of electrical stimulation from the inside of the heart to the outside.[1-3]

The applicability of CRT is considerably shaped by the current technological scope and restrictions of the devices available on the market.

Leadless Pacemakers (see Emerging leadless market for cardiac pacing *section)*

Leadless devices address the common complications associated with traditional pacemaker leads. These devices combine the pulse generator and electrode lead into a single unit implanted directly into the right ventricle of the heart. Current leadless devices, despite their innovative design and effectiveness in pacing the right ventricle of the heart, are too large for placement inside the left ventricle. This is due to the physiological difference between the left and right ventricles. The right ventricle is the chamber of the heart that drives venous, non-oxygenated blood to the lungs. The left ventricle is the chamber of the heart that drives arterial, oxygenated blood through that patient's body including areas that are particularly vulnerable to clots, such as the brain and other major organs. Foreign objects are thrombogenic (clot forming). Some small foreign objects are completely covered by the body's tissue, rendering them inert and non-thrombogenic. This process in the heart is called endothelization. EBR's WiSE implant has been shown to be completely endothelialized within 30-45 days, thus rendering it inert and suitable for left-ventricle use. On the other hand, leadless pacemakers are too large to completely endothelialize and are not indicated for use in the left ventricle.



Actual Relative Device Volume Comparison

Figure 1.4: Current leadless device illustration of relative physical sizes

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

1. *Singh JP, Klein HU, Huang DT, et al. Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. Circulation 2011;123(11):1159-66.*
2. *Thebault C, Donal E, Meunier C, et al. Sites of left and right ventricular lead implantation and response to cardiac resynchronization therapy observations from the REVERSE trial. Eur Heart J 2012;33(21):2662-71.*
3. *Derval N, Steendijk P, Gula LJ, et al. Optimizing hemodynamics in heart failure patients by systematic screening of left ventricular pacing sites: the lateral left ventricular wall and the coronary sinus are rarely the best sites. J Am Coll Cardiol 2010;55(6):566-75.*
4. *Becker M, Franke A, Breithardt OA, et al. Impact of left ventricular lead position on the efficacy of cardiac resynchronisation therapy: a two-dimensional strain echocardiography study. Heart 2007;93(10):1197-203.*
5. *Gold MR, Birgersdotter-Green U, Singh JP, et al. The relationship between ventricular electrical delay and left ventricular remodelling with cardiac resynchronization therapy. Eur Heart J 2011;32(20):2516-24.*
6. *Polasek R KP, Nedbal P, Roubicek T, Belza T, Hanuliakova J, Horak D, Wichterle D, Kautzner J. Local electrogram delay recorded from left ventricular lead at implant predicts response to cardiac resynchronization therapy: Retrospective study with 1 year follow up. BMC Cardiovascular Disorders 2012;12(34).*
7. *Ypenburg C, van Bommel RJ, Borleffs CJ, et al. Long-term prognosis after cardiac resynchronization therapy is related to the extent of left ventricular reverse remodeling at midterm follow-up. J Am Coll Cardiol 2009;53(6):483-90.*
8. *Chalil S, Foley PW, Muyhaldeen SA, et al. Late gadolinium enhancement-cardiovascular magnetic resonance as a predictor of response to cardiac resynchronization therapy in patients with ischaemic cardiomyopathy. Europace 2007;9(11):1031-7. (In eng). DOI: 10.1093/europace/eum133.*
9. *Taylor RJ, Umar F, Panting JR, Stegemann B, Leyva F. Left ventricular lead position, mechanical activation, and myocardial scar in relation to left ventricular reverse remodeling and clinical outcomes after cardiac resynchronization therapy: A feature-tracking and contrast-enhanced cardiovascular magnetic resonance study. Heart Rhythm 2016;13(2):481-9.*
10. *Khan FZ, Virdee MS, Palmer CR, et al. Targeted left ventricular lead placement to guide cardiac resynchronization therapy: the TARGET study: a randomized, controlled trial. J Am Coll Cardiol 2012;59(17):1509-18. DOI: 10.1016/j.jacc.2011.12.030.*
11. *Kydd AC, Khan FZ, Watson WD, Pugh PJ, Virdee MS, Dutka DP. Prognostic benefit of optimum left ventricular lead position in cardiac resynchronization therapy: follow-up of the TARGET Study Cohort (Targeted Left Ventricular Lead Placement to guide Cardiac Resynchronization Therapy). JACC Heart Fail 2014;2(3):205-12.*

Patients with No Currently Available Options

For many patients, CRT provides a lifeline, stabilizing or reversing progressive heart failure. However, there are a subset of patients with limited options:

a) Inability to Provide CRT

Most of the limitations that prevent patients from being provided with effective CRT arise from the use of leads. According to *Biventricular Pacing for Atrioventricular Block and Systolic Dysfunction* published by the New England Journal of Medicine (NEJM) in 2013:

- The successful placement of an effective lead in the coronary sinus is not achieved in approximately 6.3% of patients due to the patient's anatomy or disease condition.
- For the population of patients who initially received effective CRT, 4.9% each year will have their leads subsequently fail, move position, or develop other chronic problems.

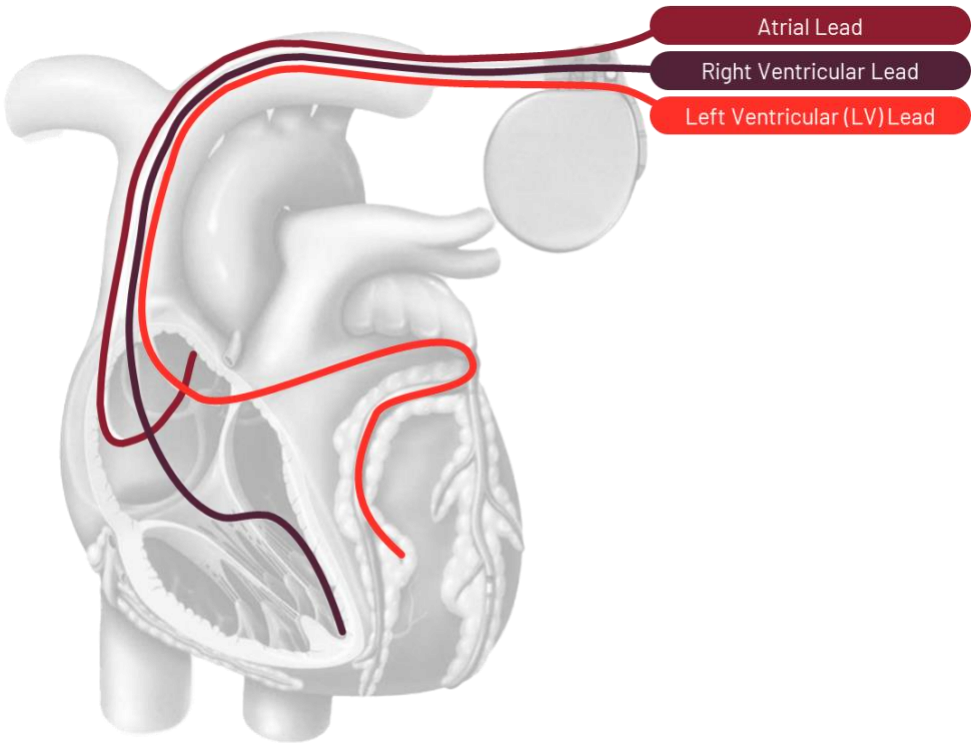


Figure 1.5: Placement of leads for lead-based CRT systems

Without a functional LV lead to stimulate the left ventricle, these patients are unable to receive effective CRT using existing devices.

b) High Risk for Conventional Upgrade

Patients with pacemakers and implantable cardioverter defibrillators (ICDs), may eventually develop heart failure necessitating BiV pacing. Approximately 25% of all CRT implants are classified as upgrades from other cardiac pacing devices. Based on studies published in the American Heart Association Journal and the Heart Rhythm Journal, approximately 60% of these upgrades are considered high risk, which translates to 15% of all CRT implants being high risk upgrades.

WiSE CRT – Overview and Clinical Program

Background

Heart failure (HF) was designated as an emerging epidemic in 1997; more than two decades later, it remains a clinical problem of major proportions associated with significant mortality, morbidity, and expenditure, particularly

among the aging population. More patients are living with HF than ever before given the reduction in short-term mortality and improvement in long-term survival as a result of advances in treatment. Yet, the prognosis for HF patients remains poor, with approximately 50% dying within five years, based on a 2020 report by the American Heart Association. The 2021 American Heart Association Heart Disease and Stroke Statistics based their HF prevalence estimates on the National Health and Nutrition Examination Survey (NHANES) data collected between 2015 and 2018. Around six million Americans aged > 20 years had HF, which increased from around 5.7 million according to data collected between 2009 and 2012. According to a publication in Cardiovascular Res. 2023 by *Savarese G, Lund LH. "Global public health burden of heart failure*", the prevalence of HF in the US was 2.4% in 2012, which is projected to rise to 3.0% in 2030. Further, costs attributed to HF are expected to increase to $53.1 billion in 2030, with the highest increase in costs expected in HF patients 65 years and older.

Cardiac resynchronization therapy (CRT) is a well-established treatment for HF and has been shown to improve clinical status and reduce HF hospitalizations (HFHs) and mortality. However, 30% to 40% of patients do not respond to the conventional approaches to CRT,[1-7] and 5% to 10% of patients cannot be treated with a transvenous lead-based CRT system largely due to a persistent rate of left ventricular (LV) lead issues.[1-9] As a result, there is a significant unmet clinical need to provide an alternative for stimulating the left ventricle for CRT. The WiSE CRT System was developed to address the challenges of conventional CRT and help this at-risk patient population by performing BiV pacing via a wireless or commonly known as leadless LV endocardial pacing (LVEP) electrode.

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3. Cleland JG, Daubert JC, Erdmann E, et al. The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med 2005;352(15):1539-49. DOI: 10.1056/NEJMoa050496.
4. McAlister FA, Ezekowitz J, Hooton N, et al. Cardiac resynchronization therapy for patients with left ventricular systolic dysfunction: a systematic review. Jama 2007;297(22):2502-14. (In eng). DOI: 10.1001/jama.297.22.2502.
5. Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-resynchronization therapy for the prevention of heart-failure events. N Engl J Med 2009;361(14):1329-38. DOI: 10.1056/NEJMoa0906431.
6. Auricchio A, Prinzen FW. Non-responders to cardiac resynchronization therapy: the magnitude of the problem and the issues. Circ J 2011;75(3):521-7. (In eng). DOI: 10.1253/circj.cj-10-1268.
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8. Sieniewicz BJ, Gould J, Porter B, et al. Understanding non-response to cardiac resynchronisation therapy: common problems and potential solutions. Heart Fail Rev 2019;24(1):41-54. DOI: 10.1007/s10741-018-9734-8.

Rationale Behind the WiSE CRT Approach

In contrast to the strategy adopted by many major cardiac rhythm management device companies, which have focused on miniaturizing pacemakers to make them leadless, the WiSE CRT System is designed to decouple the lead from the battery and operational core. This design philosophy has enabled the LV endocardial implant to be minimized to a fraction of the size of its counterparts, approximately 95% smaller by volume compared to devices like Medtronic's Micra or Abbott's Aveir. This novel configuration facilitates leadless LVEP and could potentially broaden the spectrum of patients who could benefit from CRT.

WiSE CRT System

The WiSE CRT System 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. A subcutaneously implanted ultrasound Transmitter initiates an ultrasonic energy pulse that travels through the tissue to intersect an Electrode implanted in the heart. The Electrode 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 a right ventricular (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 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 (Error! Reference source not found.**.6**).

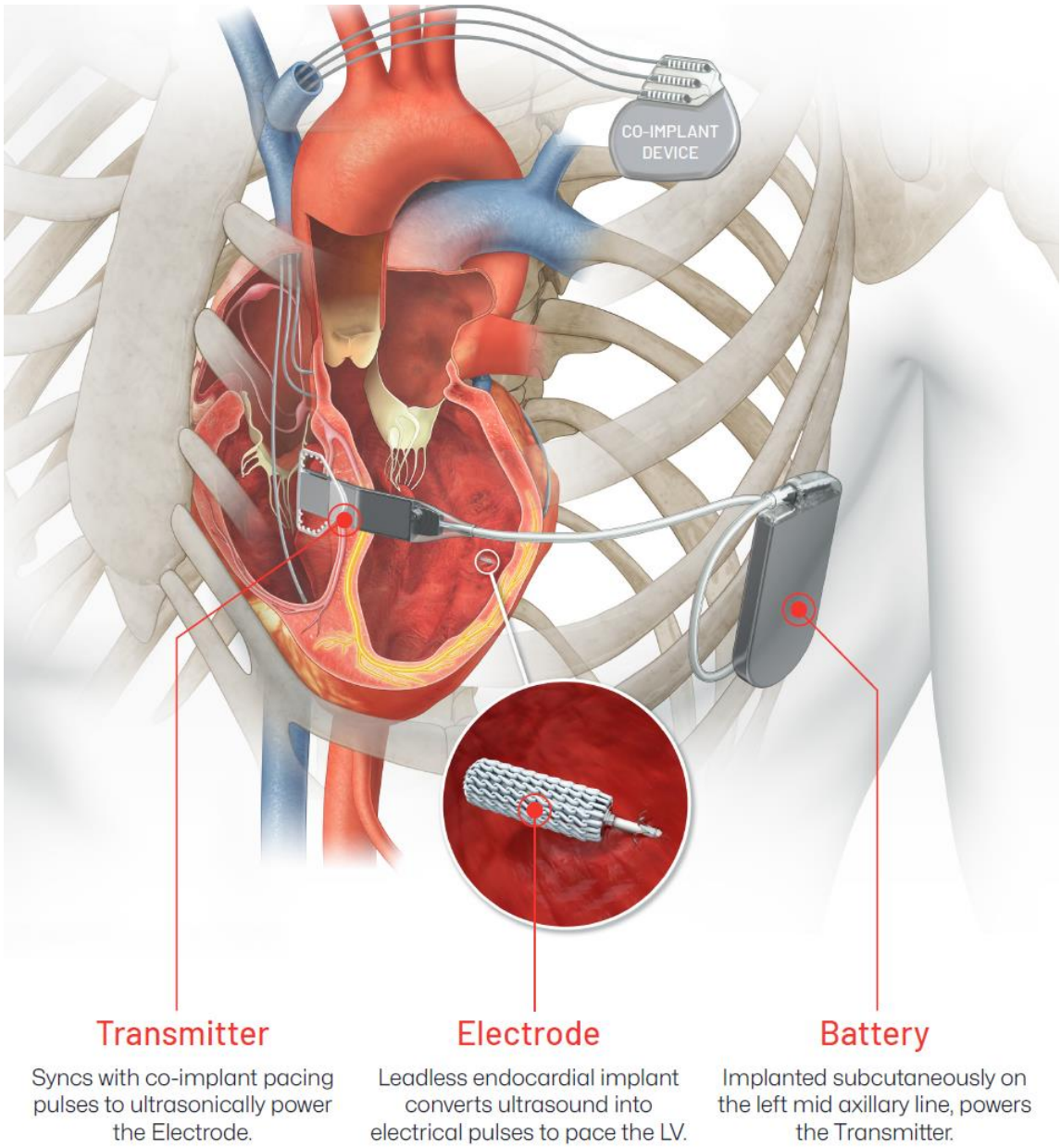

Figure 1.6 How WiSE CRT System Provides Leadless Cardiac Pacing

The final submission of information garnered from our pivotal trial, SOLVE-CRT, was provided to the FDA on August 28, 2024, in support of the premarket review of the WiSE CRT System by the FDA which is intended to assess the safety and efficacy of the system. The FDA will review the safety and efficacy data from SOLVE-CRT to evaluate whether to approve a premarket approval application, or PMA, for the system. Until FDA approval is received, we do not have regulatory approval to market WiSE in the United States.

WiSE CRT Clinical Program

The WiSE CRT System was used in the premarket European WiSE-CRT and the Safety and Performance of Electrodes implanted in the Left Ventricle ("SELECT-LV") studies, the Post Market Surveillance (PMS) WiSE CRT System Registry, and the pivotal SOLVE-CRT Investigational Device Exemption (IDE) studies as well as a number of studies published in the clinical literature. **Table 1** provides an overview of the EBR-sponsored clinical studies that have been conducted to date to evaluate the safety and efficacy of the WiSE CRT System, including the number of implants, number of implanting sites, and geographic region for each study. Subsequent sections provide summaries of each EBR-sponsored study of the WiSE CRT System.

	WiSE-CRT	**SELECT-LV**	**PMS Registry**	**SOLVE-CRT**
Study Design	Single-arm safety and feasibility	Single-arm safety and efficacy	Real-world safety and performance	Multi-arm pivotal trial*
Timeframe	2011 to 2016	2013 to 2019	2015 – 2022	2018 to 2022
Number of Patients	13	34	153	183
Number of Sites	11	7	19	68
Geographic Regions	EU	EU	EU, UK	US, EU, AU, UK

Table 1. Overview of the WiSE CRT Clinical Study Program

*Randomized trial converted to Single-Arm study during the Coronavirus Disease ("COVID") pandemic

WiSE-CRT Premarket European Clinical Study

The European WiSE-CRT study was a multicenter, prospective, single-arm first-in-man study in HF patients indicated for CRT. Primary objectives were to evaluate device-related complications (24 hours and one month) and BiV pacing capture at one month. The study included a six-month safety and performance analysis for preliminary efficacy and a five-year registry follow-up period. The first study participant was enrolled on February 15, 2011. The study was terminated on March 15, 2012, due to a third procedure-related serious adverse event (SAE). The last five-year follow-up visit took place on October 13, 2016.

The population enrolled in the study was comprised of patients with advanced HF and multiple cardiac comorbidities. The majority had previous unsuccessful treatment attempts using standard CRT systems for reasons such as the coronary sinus (CS) lead could not be implanted, the CS lead failed after implant, or the patient did not respond to treatment. Seventeen (17) patients were enrolled and underwent a WiSE CRT System implant attempt. Of those, 13 patients had successful implants and 12 received pacing therapy and completed the one- and six-month follow-up endpoints. In addition, 11 participants completed the one-year follow-up and nine (9) completed the two-year follow-up in the registry.

Adverse events (AEs) were adjudicated by a clinical events committee (CEC). There were 19 SAEs within the first six months, with seven (7) procedure-related events in six (6) participants (35%). One (1) SAE was adjudicated to be procedure- and device-related, and one (1) other SAE was adjudicated to be device related. In addition, there were 14 non-serious AEs within six months in six (6) participants, with four (4) adjudicated as procedure related and none adjudicated to be device related. One (1) patient died within six months of implant due to a periprocedural pericardial effusion.

The primary performance endpoint of successful BiV pacing at one month was present in 10 of 12 participants (83%), and the secondary performance endpoint of successful BiV pacing at six months was present in 11 of 12

participants (92%). In addition, the QRS duration ("QRSd") during BiV pacing was reduced compared to RV pacing at one (41 ms; $p = 0.0002$) and six (42 ms; $p = 0.0011$) months. The QRS complex is a pattern seen in an electrocardiogram (ECG) that indicates the pulses in a heartbeat and their duration.

Preliminary efficacy was assessed by New York Heart Association (NYHA) functional class, the participant's global assessment, and echocardiographic indices. There was an improvement in NYHA of approximately one class at three months ($p = 0.001$), six months ($p = 0.0004$), and one year ($p = 0.0007$). Global assessment at six months was markedly improved in three (3) participants, moderately improved in three (3), mildly improved in two (2), unchanged in three (3), and slightly worse in one (1) participant. The ejection fraction (EF) significantly improved from a mean of 25% to a mean of 31% ($p = 0.01$). Changes in LV end diastolic ("LVEDV") and LV end systolic ("LVESV") volumes did not reach significance at six months.

Over a three-year follow-up period, six (6) additional participants died due to causes unrelated to the device or the procedure.

SELECT-LV Premarket Clinical Study

The European SELECT-LV study was a multicenter, prospective, open label, and non-comparative clinical investigation in HF patients indicated for CRT. Primary objectives were to evaluate device-related complications at 24 hours and one month and BiV pacing capture at one month. The study included a six-month safety and performance analysis for efficacy and a five-year registry follow-up period. The first patient was implanted on July 26, 2013, and the study was completed on February 25, 2015.

The population enrolled in the study had previous unsuccessful treatment attempts using standard CRT systems because a CS lead could not be implanted or failed after implant, or the participant did not respond to treatment. Thirty-nine (39) patients were enrolled and 35 underwent a WiSE CRT System implant attempt. The implant was successful in 34 patients (97%); all 34 received pacing therapy and completed the one-month follow-up. At the six-month follow-up, 33 participants had active implanted Systems. In addition, 31 participants completed the one-year follow-up in the registry and 24 completed the two-year follow-up.

Adverse events through six months were adjudicated by a Clinical Events Committee (CEC). There were 26 SAEs in 17 participants. Procedure- and device-related events occurred in 13 participants. One (1) periprocedural death occurred following a spontaneous episode of ventricular fibrillation (VF) with failure to recover. One (1) device embolization occurred following a device- and procedure-related event. Three (3) device-related SAEs were attributed to circuit board failures in the Transmitter. Corrective actions were taken, and participants received replacement Transmitters. There were no pericardial effusions or electrode dislodgements and no unanticipated AEs (UAEs). One (1) patient died within six months of implant due to a periprocedural episode of VF with prolonged resuscitation; the Electrode was not implanted in this patient.

The primary performance endpoint of successful BiV pacing at one month was present in 33 of 34 evaluable participants (97%), and the secondary performance endpoint of successful BiV pacing at six months was present in 30 of 31 evaluable participants (97%). The clinical composite score (CCS) was evaluated for the 33 participants completing the six-month follow-up: 27 participants were improved (81.8%), three (3) were unchanged (9.1%), and three (3) were worsened (9.1%).

For the participants completing the echocardiographic analysis at six months, EF improved from a mean of $25 \pm 6.4\%$ pre-implant to $33.0 \pm 10.3\%$ at the six-month follow-up ($p < 0.00001$). In addition, LVEDV improved from 243.1 ± 70.7 ml pre-implant to 222.4 ± 77.0 ml at six months ($p = 0.02$), and LVESV improved from 183.8 ± 62.9 ml pre-implant to 157.0 ± 75.7 ml at six months ($p = 0.007$).

Over a five-year follow-up period, 11 additional participants died due to causes unrelated to the device or the procedure.

WiSE CRT European Post Market Surveillance Registry

The European Post Market Surveillance (PMS) Registry was designed to collect data about the safety and performance of the CE-marked WiSE CRT System under conditions of normal use in real-world settings. The objective of the Registry is to track device- and procedure-related complications as well as major complications, SAEs, and AEs at various time points up to six months and BiV pacing capture at three, six, and twelve months. The Registry follows participants for five years. Use of the WiSE CRT System in the PMS Registry is in adherence to device Instructions for Use.

There were 174 patients enrolled in the Registry through July 19, 2022; 153 were implanted with the WiSE CRT System. Of those 153 patients, 103 have exited the Registry and 50 remain in follow-up. The implant success rate for the Registry is 98.6%.

Performance of the WiSE CRT System has been defined as biventricular pacing capture documented on 12-lead ECG at three, six, and twelve months. The performance objective of the Registry is to achieve biventricular pacing success in at least 70% of participants. At three months, BiV pacing was successful in 121 of 126 participants (96.3%). At six months, it was successful in 113 of 114 participants (99.1%), and at one year, it was successful in 92 of 97 participants (94.8%). In addition, results from the Registry show a high average rate (> 90%) of LV pacing attempts following RV detections at three months post implant and beyond, including the expected stability over time.

Significant adverse events (AEs) are tracked in the Registry. Rates are determined based on the total number of patients enrolled. Patients are considered enrolled after they sign the consent form. A total of 50 AEs were reported through September 30, 2023. All AEs were assessed by the Site and Sponsor for device and procedure relatedness as well as whether the event was known or unknown per the device instruction for use. That assessment showed that no unknown serious device- or procedure-related AEs were identified among Registry patients through 30 September 2023.

Mortality rates observed in the PMS Registry through September 30, 2023, were 9.0% at six months: 12.5% at twelve months, and 22.9% at twenty-four months. These rates are consistent with the poor prognosis of enrolled patients, which have been reported to have a ~50% mortality rate at five years. In addition, mortality rates in the PMS Registry are consistent with those from the Alternate Site Cardiac ResYNChronization (“ALSYNC”) study which enrolled an identical patient population. Estimated mortality rates for that study were 8.3% at six months, 14.4% at twelve months: and 18.4% at twenty-four months.

SOLVE-CRT Investigational Device Exemption Clinical Trial

The SOLVE-CRT 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 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 Investigational Device Exemption (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 (KCCQ).

We are seeking to demonstrate with the SOLVE-CRT study that leadless 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 two premarket clinical studies (WiSE CRT and SELECT-LV Studies), a PMS Registry, a pivotal clinical trial (SOLVE-CRT), 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, as stated previously, 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.

Commercial strategy

We have a three-stage commercial strategy comprising a pre-commercial stage, initial commercial stage, and an expansion stage.

Overview of anticipated commercial pathway for WiSE

1. All five modules for our PMA application have been submitted.
2. PMA approval is now dependent on the successful completion of the following FDA-mandated items:

a. A BiMo (Bioresearch Monitoring) audit: an audit of the SOLVE-CRT study documents and sites by the FDA;
b. Pre-Approval Inspection audit: an audit of the WiSE CRT Quality and Manufacturing Systems by the FDA; and
c. Resolution of any queries that may arise from FDA's review of the submitted modules

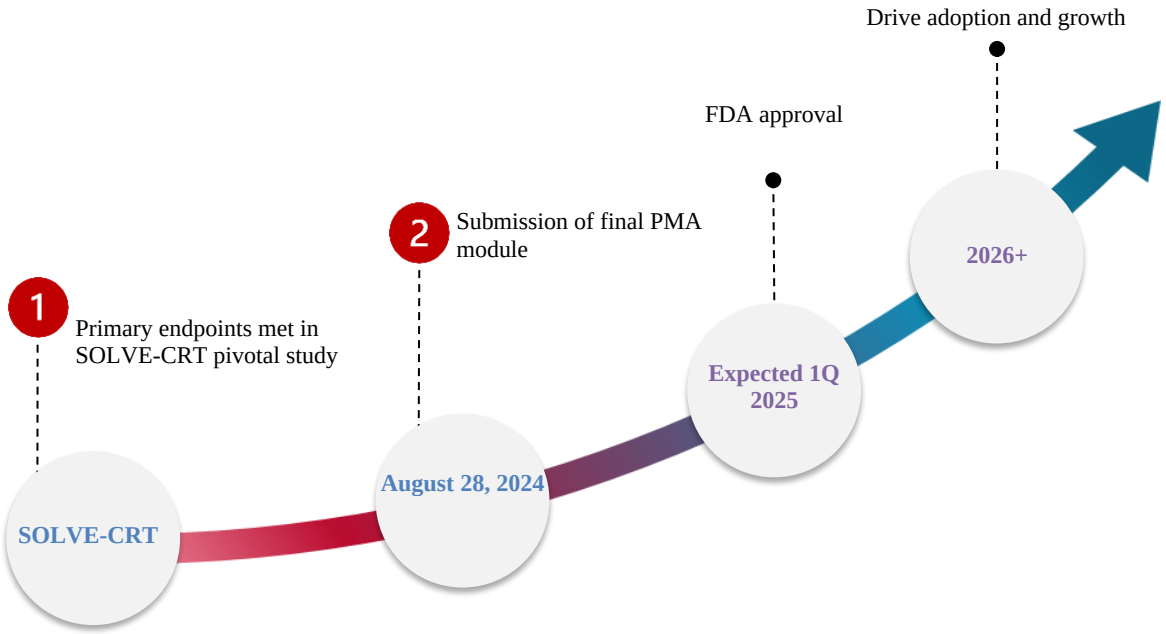

Figure 1.7: Anticipated Commercial Pathway for WiSE System

Initial Commercial Phase

We intend to commercially launch WiSE, subject to successful regulatory review. If we receive FDA approval, the initial commercial launch will 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

EBR plans to implement a phased Limited Market Release (LMR) process. We believe this is crucial when launching a novel medical technology for several reasons:

- **Risk Mitigation:** Targeting a limited number of initial sites helps closely monitor safety and address any unforeseen issues before broader release.
- **Operational Refinement:** Moving from a clinical to commercial company requires real-world feedback to refine functions such as production, logistics, and customer support.
- **Building Expertise:** The LMR phase enables the field team to provide high-quality support and training as the market expands, offering insights for Full Market Release.

LMR Phase 1: Initial Target Accounts

- Launch in target accounts from the SOLVE-CRT 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.

We currently anticipate our average selling price (ASP) for WiSE CRT in the U.S., if approved, 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. See discussion below for further details on potential reimbursement in the U.S.

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 UK, and the EU. 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.

Future clinical growth and R&D opportunities

The WiSE CRT System is our only product candidate, and the Company has no immediate plans to add further products to its pipeline. In addition to the commercial strategy described above, we expect growth opportunities for the Company will come from the areas described below.

Enhancing Physician Experience and Adoption

Physicians are integral to the successful adoption and implementation of this therapy. Utilizing the WiSE CRT technology involves a learning curve, as it requires the use of common catheters in innovative ways, particularly for placing the leadless endocardial device within the LV—a procedure unique to our technology.

Insights from pivotal trials, registries, and case studies have highlighted opportunities for design modifications to the delivery system. EBR is actively pursuing these modification concepts to make WiSE CRT more intuitive for physicians. Our goal is to reduce procedural complexity and accelerate the physician's journey from novice to experienced user, ultimately enhancing their experience and encouraging broader adoption of our technology.

Physicians undergo a mandatory training program to receive certification to implant the WiSE CRT System. The comprehensive curriculum consists of educational modules based on procedural best practices and hands-on training activities. Educational elements are delivered in the form of didactic materials, training videos, bench model training, and practical sessions which include hands-on surgical training condensed into a one-day training and certification event. The training program is structured in a modular approach to provide a deep understanding of WiSE

technology, patient screening procedures, and post-implantation device follow-up, while also imparting the necessary clinical skills and watchouts associated with device implantation.

Enhancing Patient Experience

The Company envisions a series of R&D efforts over time designed to improve and enhance the performance of our system. These efforts are currently in their nascent stages of development and internal review and will be undertaken as resources permit.

Target markets for WiSE CRT

The WiSE CRT system targets patients unable to receive traditional lead-based CRT systems, focusing on those with lead failures or patients who are considered at risk for a CRT upgrade from a previously implanted pacemakers/ICD. We believe the addressable market opportunity to be approximately $3.6 billion in the U.S based on the distinct patient groups, that include (i) patients whose existing CRT system leads to the left heart have either been deactivated or become ineffective, due to malfunction and/or failure (Chronic Lead Failure), (ii) where lead placement to pace the LV such as via the coronary sinus (CS), was not achievable due to anatomical or disease-related barriers (Acute Lead Failure), (iii) patients with pre-existing pacemaker systems often need upgrades to biventricular pacing as their heart failure progresses (High Risk Upgrade), and (iv) subset of patients using leadless pacemakers that may require biventricular pacing, which traditional systems cannot provide (Leadless Upgrades):

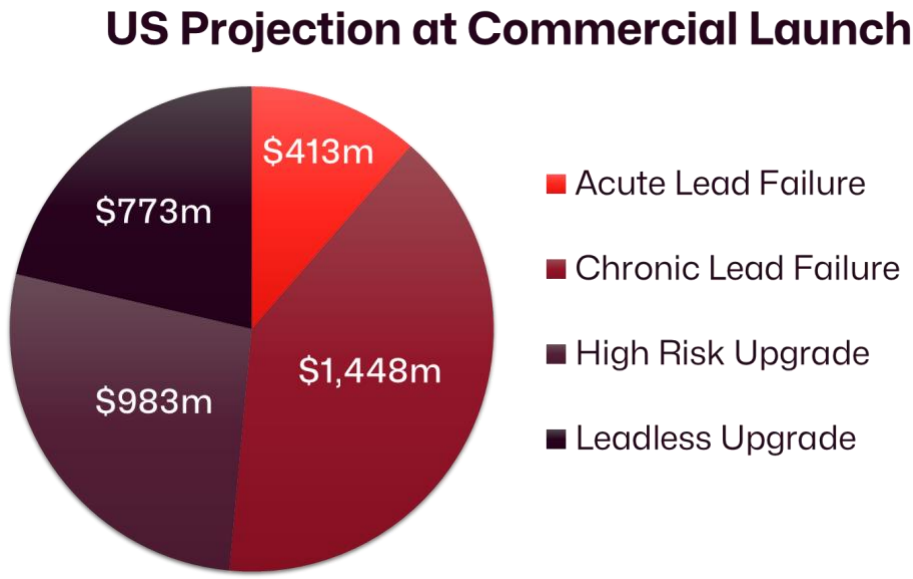

Figure 1.8: Initial Patient Groups for WiSE and US Market Projection

Upgrading Patients with Leadless Pacemakers

Leadless pacemakers represent a rapidly expanding category within CRM devices, highlighted by the swift market uptake of Medtronic's Micra and Abbott's Aveir. Combining these technologies with WiSE CRT System will potentially offer a totally leadless solution for CRT.

A retrospective study in eight patients demonstrated the WiSE CRT System's capability to synchronize with a leadless pacemaker in the right ventricle, confirming the feasibility of totally leadless CRT pacing. WiSE CRT is currently the only system that is able to provide leadless LVEP, subject to regulatory approval.

Carabelli and colleagues (2021) described the technical feasibility and first insights into the safety and efficacy of the combination of Micra and the WiSE CRT System in Europe. This was a retrospective, observational, non-randomized, single-group, and multicentric European study. The intention was to describe the technical feasibility and to depict first insights into the safety and efficacy of the WiSE CRT System and the Micra co-implantation. The authors concluded, "The Micra and WiSE CRT Systems can successfully operate together to deliver total leadless CRT to a patient. Moreover, the WiSE CRT System provides the only means to upgrade the large population of Micra patients to CRT capability without replacing the Micra."

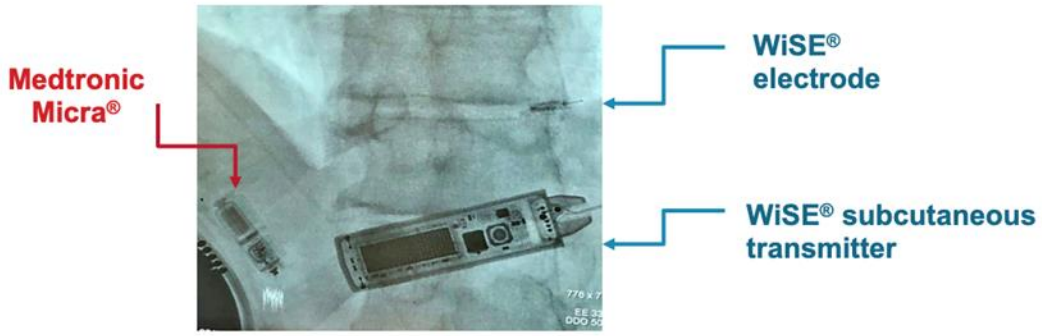

Figure 1.9: X-Ray from Patient Receiving Leadless CRT Using Micra and WiSE

As more patients are implanted with leadless pacemakers, these patients are likely to become an increasingly important part of the market. Thus, the growing adoption of leadless pacemakers represents a current pool of patients that may require leadless upgrades to CRT and this pool will continue to grow as the leadless pacemaker market expands. Based on our market research report and a clinical report (Ponnusamy 2023) citing the annual incidence of pacing induced heart failure in patients with existing right ventricular pacing, this provides a $773 million total available US market.

Government Regulation of Medical Devices and Regulatory Strategy

We filed the final module of our PMA for the WiSE CRT System in the U.S. on August 28, 2024. We intend to seek regulatory approval and certification 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

The WiSE CRT System is not currently approved for commercial sale in the U.S. In 2016, we secured an IDE approval which allowed the WiSE CRT System to be used in human clinical trials in the United States. WiSE CRT has concluded its SOLVE-CRT clinical trial which was designed to support a PMA application in the U.S. As the WiSE CRT System has been granted BDD, any regulatory filings with the FDA, including the Company's proposed PMA application, will be given a prioritized review.

Under the revised design for the SOLVE-CRT clinical trial (due to the effects of COVID-19), the single-arm phase of the trial enrolled patients classified as lead failure ("LF") LF-acute, LF-chronic, or high-risk upgrades ("HRU") The PMA application submitted to the FDA for WiSE during August 2024 covered our use in these patients. Per the FDA document, "MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027", section IIB, page 6, "For Original PMAs, PDPs, Panel-Track Supplements, and Premarket Reports that do not require Advisory Committee input, FDA will issue a MDUFA decision within 180 FDA Days for 90% of submissions." Based on this timeline, if our PMA application for the WiSE CRT System is successful, we anticipate the device to be approved by the FDA during the first quarter of 2025 and be available for commercial sale in the U.S. shortly thereafter.

Regulation of Medical Device Products 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 to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed.

Generally, 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," as defined in the statute, 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. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. 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 (as EBR has done), 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 and by regulation, 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. The PMA process can be expensive, uncertain, and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

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 cleared under a 510(k) notification, 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

The FDA granted the WiSE CRT System BDD in July 2019. FDA grants this designation to those devices that intend 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 us with 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.

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We received a CE Certificate of Conformity permitting us to CE mark the WiSE CRT System in 2015. The CE Certificate of Conformity is a certification provided by a Notified Body for products that have met the design, safety, and quality requirements required to allow their use and sale within the E.U. The intended use for which the WiSE CRT System was CE Marked was the leadless, endocardial stimulation of the left ventricle in patients indicated for CRT. Our application for CE Mark was supported with data from the 35 patient SELECT-LV study that was completed in 2015 and the 17 patient WiSE-CRT study completed in 2011. We elected to allow CE Mark to lapse during 2024 as we are required to reapply under new Medical Device Regulation ("MDR") regulations, and we prioritized our FDA PMA submission.

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 a refined responsibility of economic operators. We would also be required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the Regulation may cause us to incur substantial costs. We may be unable to fulfill these obligations, or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations to merit the continued use of CE Certificate of Conformity under the MDR or the issuance of a CE Certificate of Conformity under the MDR for our WiSE CRT system.

Following the result of a referendum in 2016, the UK left the EU on January 31, 2020, commonly referred to as Brexit. A Trade and Cooperation Agreement ("TCA") was signed between the EU and the UK and entered into force on May 1, 2021. This Agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods but does not specifically address medical devices. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a "third country," a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland will continue to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods, and including the Medical Devices Regulation, at least in the short to medium term. In light of the fact that the CE Marking process is set out in EU law, which no longer applies in the UK, 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 at least for

the present.

For a medical device to be sold and marketed in Australia, it must be included in the Australian Register of Therapeutic Goods ("ARTG"). As the WiSE CRT System will be classified as 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. As previously noted, we prioritized our FDA PMA submission and intend to initially commercialize in the U.S. before evaluating expansion OUS.

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.

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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 the U.K., once appropriate certification has been received and the related marking has been affixed to a medical device, new medical devices are reviewed for health benefits, cost, and cost effectiveness, and then reimbursement levels are established. In the EU some countries require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact, and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States.

In Australia, medical devices must be listed on the ARTG to be eligible for any form of reimbursement. Reimbursement is differentiated between those treated under private health insurance and those within the public hospital system under Medicare. Public hospitals are reimbursed for activity under the Australian Refined Diagnosis-Related Groups (**AR-DRG**) scheme. For medical devices to be reimbursed within the private system, they must appear on the Prostheses List. Applications to be included on the Prostheses List are submitted to the Prostheses List Advisory Committee (**PLAC**) which makes recommendations to the Australian Government Minister for Health as to which products should be included on the Prostheses List and the appropriate benefit for those products. The Prostheses List specifies the benefits that private health insurers are required to pay for the listed prostheses to appropriately insured persons.

Key market players in CRT

Medtronic

In 2018, Medtronic held the leading position in the CRT market with a share of approximately 50%. The company offers a wide range of products for the treatment of heart failure. The company offers CRT devices under brand names such as Claria MRI CRT-D Surescan, Amplia MRI CRT-D Surescan, Compia MRI CRT-D Surescan, Viva CRT-P, Consulta CRT-P, and Syncra CRT-P, among others.

Abbott

Abbott accounted for a market share of approximately 23% of the CRT market in 2018. The company is engaged in the research, development, production, and distribution of a diversified range of healthcare products, including drugs, diagnostics, branded generics, vascular, and nutritional products. Abbott offers CRT devices for the treatment of heart failure under the brand names— Quadra Allure MP CRT-P, Allure RF, Unify Assura, Aveir, and Promote Plus CRT-D, among others.

Boston Scientific

Boston Scientific Corporation accounted for a market share of approximately 19% of the CRT market in 2018. The company offers CRT devices through the CRM subsegment under the brand names— Visionist X4 CRT-P, Valitude X4 (CRT-P), Momentum CRT-D, Resonate X4 CRT-D, and Vigilant X4 CRT-D, among others.

Emerging leadless market for cardiac pacing

The most recent advance in the evolution of pacemakers has been the advent of leadless cardiac pacing systems. Most of the complications associated with pacemakers have been due to the leads. Leadless pacing systems have the pulse generator and the stimulating electrode in a single unit that can be fully implanted inside the heart chamber.

Overview of Leadless Pacemakers for Cardiac Pacing

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. Leadless devices are expected to play an increasingly important role in the future pacemaker market. This has been reflected in the rapid growth of sales demonstrated by Medtronic's Micra device since it received FDA approval in 2016.

Leadless Cardiac Rhythm Management Landscape

Figure 1.10: Current Leadless Pacemakers for Cardiac Pacing*
*CAUTION: The WiSE CRT System is an investigational device. Limited by Federal (US) law to investigational use only.

Medtronic – Micra Implant

Medtronic's Micra implant was the first leadless pacemaker to become commercially available. In 2020, the FDA approved a second leadless pacemaker for Medtronic, Micra AV, which is also implanted in the right ventricle but has an additional capability of being able to sense the contraction of the right atrium to create atrioventricular synchrony. Both versions of Micra can only be implanted in the right ventricle due to their size.

Medtronic announced that the quarterly sales of Micra in the March 2021 quarter had grown by 74% and were annualized at $400M. For the June 2021 quarter, Medtronic reported Micra sales had increased by over 30% from the preceding quarter.

Abbott – Aveir Implant

Abbott has received approval for its leadless pacemaker Aveir™ VR single chamber in April 2022 and the DR dual-chamber leadless pacemaker system was approved July 2023. Now with the VR and DR systems, Abbott is the world's first dual-chamber leadless pacing system, aiming to compete directly against Medtronic Micra which only has a single chamber device. The Aveir DR system is similar in size, with each pacemaker being smaller than a AAA battery. As with Micra, Aveir can only be implanted in the right atrium and right ventricle due to its size.

Boston Scientific – Empower Implant

Boston Scientific announced the successful results of their 300-patient, MODULAR ATP, trial of their leadless Empower pacemaker in May 2024. They also announced that they expect FDA approval in 2025.

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.

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. 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 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.

Business operations

Manufacturing

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.

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 June 30, 2024, our WiSE CRT System and related technologies are covered by an extensive portfolio of patents which includes 61 granted U.S. patents, 56 granted non-U.S. patents, and 17 patent applications across 21 different patent families. These patent families 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.

WiSE CRT System Patent Families

We own at least seven patent families directed to the WiSE CRT System. The patent assets in these patent families are all utility patents and utility patent applications, and are solely owned by the Company.

Patent Family 1 is directed to leadless cardiac systems for pacing, implantable transducer devices, and associated methods. As of June 30, 2024, this patent family includes eight U.S. patents, two European patents (validated in three states), and three Japanese patents. The various patents in this patent family expire late 2025 to 2027, without taking into account a potential patent term extension.

Patent Family 2 is directed to devices, systems, and methods for efficiently delivering acoustic stimulation energy to tissue and expires between 2026 and 2030, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes five U.S. patents.

Patent Family 3 is directed to devices, systems, and methods implantable wireless acoustic stimulators with high energy conversion efficiencies and expires between 2029 and 2030, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes nine U.S. patents, three European patents (validated in three states), and one pending U.S. application.

Patent Family 4 is directed to devices, systems, and methods for optimizing energy transmission in a leadless tissue stimulation system and expires between 2027 and 2030, without taking into account a potential patent term

extension. As of June 30, 2024, this patent family includes four U.S. patents, 1 European patent (validated in three states), and two issued Japanese patents.

Patent Family 5 is directed to systems and methods for heart failure prevention and treatments using ultrasound and leadless implantable devices and expires between 2026 and 2029, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes four U.S. patents and one pending U.S. application.

Patent Family 6 is directed to devices, systems, and methods for electromechanical sensing and mapping and expires in 2039, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes one U.S. patent, 1 European patent (validated in three states), and one pending U.S. application.

Patent Family 7 is directed to pulse delivery devices including slew rate detectors and associated systems and methods and expires in 2040, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes one U.S. patent, one European patent (validated in three states), and one pending U.S. application.

Additional Patent Families

We own fourteen patent families directed to the variations of and modifications to the WiSE CRT system, devices and systems that can be used in conjunction with the WiSE CRT System and/or components thereof, and next generation systems and devices. The patent assets in these patent families are solely owned by the Company.

Patent Family 8 is directed to systems and methods for vibrational treatment of arrythmias and expires in 2025, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes two U.S. patents.

Patent Family 9 is directed to systems and methods for determining cardiac stimulation sites using hemodynamic data and expires in 2027, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes one U.S. patent and one European patent (validated in three states).

Patent Family 10 is directed to acoustically powered wireless defibrillators and expires in 2027, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes one U.S. patent.

Patent Family 11 is directed to systems and methods for leadless stimulation at various non-cardiac treatment sites (e.g., spine, ear, brain, bone, gastrointestinal tract) and expires in 2027, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes fourteen U.S. patents.

Patent Family 12 is directed to systems and methods for optimizing the size of implantable medical devices by isolating the power source and expires between 2028 and 2029, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes one U.S. patent and one European patent (validated in three states).

Patent Family 13 is directed to implantable wireless acoustic stimulators with high energy conversion efficiencies and expires in 2028, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes one U.S. patent and one European patent (validated in three states).

Patent Family 14 is directed to systems and methods for temporary electrode connections for wireless pacing systems and expires in 2029, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes four U.S. patents and one European patent (validated in three states).

Patent Family 15 is directed to systems and methods for selectively locating implantable devices and expires in 2033, without taking into account a potential patent term extension. As of June 30, 2024, this patent family includes one U.S. patent and one European patent (validated in three states).

Patent Family 16 is directed to devices, systems, and methods for cardiac resynchronization therapy and expires in 2040, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes two U.S. patents, and one pending application in Australia, Europe, and the U.S.

Patent Family 17 is directed to implantable stimulation assemblies having tissue engagement mechanisms and expires in 2042, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes one U.S. patent and one pending U.S. application.

Patent Family 18 is directed to systems and methods for sensing endocardial tissue for cardiac pacing and expires in 2042, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes one pending U.S. application.

Patent Family 19 is directed to tissue stimulation systems and methods for pacing cardiac tissue and expires in 2042, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes one pending application in Australia, Europe, Japan, and the U.S.

Patent Family 20 is directed to systems and methods for wireless endocardial stimulation of the left ventricular septal wall and expires in 2041, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes one pending application in Australia, Europe, Japan, and the U.S.

Patent Family 21 is directed to systems and method for direct visualization of endocardial tissue locations and expires in 2043, assuming all fees are paid and without taking into account potential patent term adjustment or patent term extension. As of June 30, 2024, this patent family includes one pending application the U.S.

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

Employees

As of June 30, 2024, we had 88 full-time employees including 77 in research and development and 11 in general and administrative. As of June 30, 2024, we had 78 employees located in the U.S., 6 in Europe, and 4 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.

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; and
- Our current capital reserves may not be adequate.

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 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 the Company's headquarters in California. There are inherent risks in relying on third-party suppliers for the Company's 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 and their 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.

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. The Company expects that its current manufacturing capabilities will be sufficient to support its projected growth profile only through to the end of 2027. If the Company gains significant market share over and above its current short-term expectations and, in any case, from 2027 onwards, it will need to expand its manufacturing capacity, including additional facilities, and invest in systems and processes to support the development of the business. The failure of

the Company to address projected growth in a timely, robust, and efficient manner may negatively impact the Company's financial performance.

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 the assumed prices at which we can sell products for markets that have 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 successfully complete necessary clinical trials, submit PMA to the FDA and 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 the 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 the Company, the demand for the Company's 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, EBR's 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 EBR operates its business, and its 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, EBR 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. EBR Systems 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. The Company's 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 its 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, 2023, we had U.S. federal and state net operating loss, or NOL, carryforwards of approximately $191.3 million and $173.1 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 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.

EBR is currently at the pre-commercialization phase. The Company intends to move into the initial commercial phase if it receives FDA approval of our WiSE CRT System. As is common with companies at the pre-commercialization stage, EBR has incurred net losses since its inception, has never been profitable and can give no assurance that the Company will be profitable or cash-flow positive in the future. In assessing EBR's 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 EBR's 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 the Company reduces its prices because of consolidation in the medical device industry, its future revenue will decrease, which could have a material adverse effect on its 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, the Company 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 six months ended June 30, 2024, and the year ended December 31, 2023, we had a net loss of $20.6 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 June 30, 2024, and December 31, 2023, we had an accumulated deficit of $333.3 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 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 will also initially be 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 will be 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.

Furthermore, the current lease for our manufacturing facility expires at the end of December 2026, and we may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve 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 61 issued U.S. patents and 56 corresponding granted foreign patents. In addition, as of June 30, 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 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 will be 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 and in this Form 10, 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 May 1, 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 will 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 2. Financial Information.

Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our audited and unaudited consolidated financial statements and the related notes included elsewhere in this Form 10. This discussion and analysis and other parts of this Form 10 contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties, and assumptions, such as statements regarding our intentions, plans, objectives, and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth in the section titled "*Item 1A. Risk Factors*." See also the section titled "*Disclosure Regarding Forward-Looking Statements*."

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.

We initially developed the WiSE CRT System for use in conjunction with another implanted pacemaker to provide CRT to patients who are unable to receive CRT from a traditional lead-based system or are at high risk of complications from an upgrade procedure. WiSE CRT technology is engineered to benefit patients who have not seen success with conventional CRT or face high complication risks. By eliminating lead requirements for left ventricular pacing, WiSE CRT introduces a novel approach to cardiac pacing, with the potential to transform CRT delivery.

We completed interim enrollment in the pivotal SOLVE study in July 2022, and subsequently stopped enrollment as a result of early trial success. The results, presented during a Late Breaking Clinical Trial session at the 2023 Heart Rhythm Society Conference, showed the study met both its primary efficacy and safety end points. We have submitted all required five modules to the FDA for our Pre-Market Approval submission and will plan to begin commercialization upon final FDA approval. We plan to commercialize the device in Australia and certain European

countries following our U.S. launch and upon obtaining local regulatory approvals and securing reimbursement coverage.

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, 2023, we had $73.4 million in cash, cash equivalents, and marketable securities and an accumulated deficit of $312.7 million. As of June 30, 2024, we had $54.1 million in cash, cash equivalents, and marketable securities and an accumulated deficit of $333.3 million.

In November 2021, we issued 101,851,851 CDIs (equivalent to 101,851,851 shares of common stock) in connection with an initial public offering ("IPO") on the Australian Securities Exchange ("ASX") and a parallel private placement under Regulation D of the Securities Act ("Parallel Placement"). We raised a total of approximately $75 million, net of issuance costs of approximately $5.1 million. Of this amount, $73.6 million were net cash proceeds directly from the IPO, and $1.4 million were cash proceeds from the Parallel Placement. In connection with the IPO, all of our existing shares of preferred stock were converted into common stock.

On June 30, 2022, we entered into a loan and security agreement with Runway Growth Finance Corp. As of June 30, 2024, the outstanding principal balance under this loan and security agreement was $41,800,000, which included the principal borrowings under tranche one and tranche two of the loan facility, as well as the final payment of 4.5% of the principal borrowings to date. 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 CDIs in connection with a Security Purchase Plan ("SPP") on the ASX. We raised a total of approximately $20.6 million from these transactions, 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.

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 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 end markets. assurance that our efforts will increase the use of our products

- ***Sales force size and effectiveness***. 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 continue 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.

- ***Competition***. Our industry is intensely competitive and, in particular, we compete with a number of large, well-capitalized companies on multiple fronts. We must strive to be successful in light of our

competitors' existing and future products and related pricing and their resources to successfully market to the physicians who use our products.

- ***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 highly uncertain and 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 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 Term Loan. 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, or 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, 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.

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 Australian Securities Exchange ("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% and 0.01% for the years ended December 31, 2023 and 2022, respectively. 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 sections titled "Summary of Significant Accounting Policies—Recently issued accounting pronouncements" in Note 2 to our audited consolidated financial statements and our unaudited condensed consolidated financial statements included elsewhere in this Form 10.

Results of Operations

The following discussion analyzes our operating results for the year ended December 31, 2023, and compares those results to results for the year ended December 31, 2022. We also discuss our operating results for the three and six-month periods ended June 30, 2024, and compare those results to the three and six-month periods ended June 30, 2023. We suggest that you read the following information in conjunction with our audited consolidated financial statements years ended December 31, 2023, and 2022, as well as the unaudited interim consolidated financial statements for the six months ended June 30, 2024, and 2023 contained elsewhere in this Form 10.

Comparison of the Years Ended December 31, 2023, and 2022

We recorded a net loss of $35.0 million in 2023, an increase of $2.0 million, or 5.9%, from 2022. The increased loss in 2023 was due to an increase in general and administrative expenses in 2023, as discussed below, partially offset by a decrease in research and development expenses. Interest expense also increased in 2023, which was offset partially by an increase in other income, as discussed below. We expect to continue reporting losses until such time as we obtain FDA approval, commercialize WiSE, and generate revenue and gross margin sufficient to offset our operating expenses.

The following table summarizes our operating results for 2023 and 2022:

(in thousands)	Year Ended December 31, 2023	2022	Change Amount	%
Operating expenses:				
Research and development	$ 27,146	$ 27,786	$ (640)	(2.3%)
General and administrative	7,403	6,240	1,163	18.6%
Total operating expenses	34,549	34,026	523	1.5%
Other (expense) income, net	(486)	940	(1,426)	(151.7%)
Loss before income tax	(35,035)	(33,086)	(1,949)	5.9%
Income tax expense	(2)	(2)	-	-
Net Loss	$ (35,037)	$ (33,088)	$ (1,949)	5.9%

Operating Expenses

Research and Development

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

(in thousands)	Year Ended December 31, 2023	2022	Change Amount	%
Research and development expenses:				
R&D personnel expense	$ 14,278	$ 12,637	$ 1,641	13.0%
Clinical expenses	3,384	5,896	(2,512)	(42.6%)
Quality assurance	126	49	77	157.1%
Contract manufacturing, materials & components	7,854	7,896	(42)	(0.5%)
Facility allocation & depreciation	1,504	1,308	196	15.0%
Total research and development expense	$ 27,146	$ 27,786	$ (640)	(2.3%)

Research and development expenses decreased by $0.6 million, or 2.3%, during the year ended December 31, 2023, as compared to the year ended December 31, 2022. Clinical trial related expenses decreased $2.5 million, primarily due to completing enrollment in the SOLVE-CRT Study in July 2022. This decrease was offset by a $1.6 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 $1.2 million, or 18.6%, during the year ended December 31, 2023, as compared to the year ended December 31, 2022. Personnel-related expenses, including salaries, bonuses and certain fringe benefits increased by $0.5 million as a result of the expansion of our workforce to support our business needs. In addition, stock-based compensation increased by $0.3 million related to new option grants issued to new hires and existing employees. Professional fees increased $0.3 million, primarily resulting from higher audit, legal, regulatory, and tax-related services. Travel and related expenses increased by $0.1 million, resulting from a decrease in global travel restrictions due to COVID-19 measures.

Other (expense) income, net

Other (expense) income, net decreased by $1.4 million during the year ended December 31, 2023, as compared to the year ended December 31, 2022. The change was caused by increased interest expense, decreased reimbursement income, and increased refundable tax incentives in 2023 as compared to 2022. These changes were offset by increased interest income. Interest expense increased $3.0 million, which resulted from an additional $20 million in borrowings and higher interest rates, as a result of the U.S. Federal Reserve raising interest rates. Reimbursement income decreased by $0.8 million in 2023, compared to 2022. Refundable tax incentives increased by $0.2 million in 2023, compared to 2022. During the year ended December 31, 2023, we earned interest income,

including the accretion of discounts, from investment in marketable securities of $3.3 million, an increase of $2.2 million as compared to the year ended December 31, 2022.

Comparison of the Three Months Ended June 30, 2024, to the Three Months Ended June 30, 2023

We recorded a net loss of $11.5 million in the three-month period ended June 30, 2024, an increase of $3.4 million, or 41.3%, from the three-month period ended June 30, 2023. The increased loss in 2024 was due to an increase in research and development and general and administrative expenses in 2024, as discussed below. Other (expense) income, net also increased in 2024 due to an increase in interest expense and decrease in other income, which were offset partially by an increase in interest income, as discussed below.

The following table summarizes our operating results for the three months ended June 30, 2024, and 2023:

	Three Months Ended June 30,		Change	
(in thousands)	2024	2023	Amount	%
Operating expenses:				
Research and development	$ 7,472	$ 6,663	$ 809	12.1%
General and administrative	3,270	1,615	1,655	102.5%
Total operating expenses	10,742	8,278	2,464	29.8%
Other (expense) income, net	(753)	140	(893)	(637.6%)
Loss before income tax	(11,495)	(8,138)	(3,357)	41.3%
Income tax expense	-	-	-	-
Net Loss	$ (11,495)	$ (8,138)	$ (3,357)	41.3%

Operating Expenses

Research and Development

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

	Three Months Ended June 30,		Change	
(in thousands)	2024	2023	Amount	%
Research and development expenses:				
R&D personnel expense	$ 4,432	$ 3,573	$ 859	24.0%
Clinical expenses	546	820	(274)	(33.4%)
Quality assurance	64	10	54	540.0%
Contract manufacturing, materials & components	1,992	1,893	99	5.2%
Facility allocation & depreciation	438	367	71	19.3%
Total research and development expense	$ 7,472	$ 6,663	$ 809	12.1%

Research and development expenses increased by $0.8 million, or 12.1%, during the three months ended June 30, 2024, as compared to the three months ended June 30, 2023. The increase was primarily due to a $0.9 million increase in personnel-related expenses, including salaries, bonuses, and certain fringe benefits, resulting from an expansion in our workforce to support the final development testing of the last module of our PMA submission for the WiSE CRT System. This increase was offset by a $0.3 million decrease in clinical trial expenses as a result of completing enrollment in the SOLVE-CRT Study in July 2022.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million, or 102.5%, during the three months ended June 30, 2024, as compared to the three months ended June 30, 2023. Professional fees increased $1.1 million, primarily resulting from higher accounting and legal related services in connection with preparation for this Form 10

filing. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $0.6 million as a result of the expansion of our workforce to support our growth.

Other (expense) income, net

Other (expense) income, net decreased by $0.9 million during the three months ended June 30, 2024, as compared to the three months ended June 30, 2023. Interest expense increased by $0.8 million during the three months ended June 30, 2024, as compared to the three months ended June 30, 2023, which resulted from borrowing tranche 2 in June 2023, under a loan and security agreement as discussed below. This increase was offset by a $0.2 million increase in interest income, including the accretion of discounts on marketable securities. Additionally, other income has decreased by $0.3 million, primarily resulting from the decrease in refundable tax incentives.

Comparison of the Six Months Ended June 30, 2024, to the Six Months Ended June 30, 2023

We recorded a net loss of $20.6 million in the six-month period ended June 30, 2024, an increase of $5.0 million, or 32.4%, from the six-month period ended June 30, 2023. The increased loss in 2024 was due to an increase in research and development and general and administrative expenses in 2024, as discussed below. Other (expense) income, net also increased in 2024 due to an increase in interest expense and decrease in other income, which were offset partially by an increase in interest income, as discussed below.

The following table summarizes our operating results for the six months ended June 30, 2024, and 2023:

	Six Months Ended June 30,		Change	
(in thousands)	2024	2023	Amount	%
Operating expenses:				
Research and development	$ 13,873	$ 12,276	$ 1,597	13.0%
General and administrative	5,443	3,304	2,139	64.7%
Total operating expenses	19,316	15,580	3,736	24.0%
Other (expense) income, net	(1,329)	(16)	(1,313)	8206.3%
Loss before income tax	(20,645)	(15,596)	(5,049)	32.4%
Income tax expense	-	-	-	-
Net Loss	$ (20,645)	$ (15,596)	$ (5,049)	32.4%

Operating Expenses

Research and Development

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

	Six Months Ended June 30,		Change	
(in thousands)	2024	2023	Amount	%
Research and development expenses:				
R&D personnel expense	$ 8,292	$ 6,993	$ 1,299	18.6%
Clinical expenses	838	1,512	(674)	(44.6%)
Quality assurance	124	28	96	342.9%
Contract manufacturing, materials & components	3,724	3,024	700	23.1%
Facility allocation & depreciation	895	719	176	24.5%
Total research and development expense	$ 13,873	$ 12,276	$ 1,597	13.0%

Research and development expenses increased by $1.6 million, or 13.0%, during the six months ended June 30, 2024, as compared to the six months ended June 30, 2023. The increase was primarily due to a $1.3 million increase in personnel-related expenses, including salaries, bonuses, and certain fringe benefits resulting from an expansion in our workforce to support research, design, testing and development of our WiSE CRT System. Contract manufacturing, materials and components increased by $0.7 million resulting from increased component testing to

complete the final Pre-Market Approval submission to the FDA. This increase was offset by a $0.7 million decrease in clinical trial related expenses, primarily due to completing enrollment in the SOLVE-CRT Study in July 2022.

General and Administrative Expenses

General and administrative expenses increased by $2.1 million, or 64.7%, during the six months ended June 30, 2024, as compared to the six months ended June 30, 2023. Professional fees increased $1.2 million, primarily resulting from higher accounting and legal related services. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $0.9 million as a result of the expansion of our workforce to support our growth.

Other (expense) income, net

Other (expense) income, net decreased by $1.3 million during the six months ended June 30, 2024, as compared to the six months ended June 30, 2023. Interest expense increased by $1.6 million, which resulted from borrowing tranche 2 in June 2023, under a loan and security agreement, as discussed below. This increase was offset by a $0.6 million increase in interest income, including the accretion of discounts on marketable securities. Additionally, other income has decreased by $0.3 million, primarily resulting from a decrease in refundable tax incentives.

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 its 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 June 30, 2024, and December 31, 2023, we had approximately $54.1 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% - 2%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 June 30, 2024, and December 31, 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 June 30, 2024, and December 31, 2023, we were in compliance with all debt covenants.

Recent Financings

In November 2021, we issued 101,851,851 CDIs (equivalent to 101,851,851 shares of common stock) in connection with an initial public offering ("IPO") on the Australian Securities Exchange ("ASX") and a parallel private placement under Regulation D of the Securities Act ("Parallel Placement"). We raised a total of approximately $75 million, net of issuance costs of approximately $5.1 million. Of this amount, $73.6 million were net cash proceeds directly from the IPO, and $1.4 million were cash proceeds from the Parallel Placement. In connection with the IPO, all of our existing shares of preferred stock were converted into common stock.

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.

Contractual Obligations and Commitments

As of June 30, 2024, and December 31, 2023, we had $0.8 million and $1.9 million in operating lease obligations, respectively, for our corporate headquarters and laboratory space, located in Sunnyvale, California. As of June 30, 2024, and December 31, 2023, 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 June 30, 2024, and December 31, 2023, the outstanding principal balance was $82,029 and $21,496, respectively. 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 June 30, 2024, and December 31, 2023, our obligations under such arrangements were approximately $12.5 million and $3.5 million, respectively.

Working Capital

December 31, 2023, Compared to December 31, 2022

As of December 31, 2023, we had working capital of $68.0 million, comprised of current assets of $74.4 million and current liabilities of $6.4 million. Current assets, consisting of cash and cash equivalents, marketable securities, prepaid expenses, non-trade receivables and other current assets, increased by $7.8 million as of December 31, 2023, compared to December 31, 2022. Current liabilities, consisting primarily of accounts payable, accrued liabilities, lease obligations, the current portion of notes payable and interest payable, increased by approximately $0.5 million as of December 31, 2023, compared to December 31, 2022. The sale of common stock and the borrowings under tranche 2 of the loan and security agreement discussed above contributed to the increase in cash, cash equivalents, and marketable securities as of December 31, 2023, as compared to December 31, 2022.

June 30, 2024, Compared to December 31, 2023

As of June 30, 2024, we had working capital of $49.1 million, comprised of current assets of $55.7 million and current liabilities of $6.6 million. Current assets, consisting of cash and cash equivalents, marketable securities, prepaid expenses, non-trade receivables and other current assets, decreased by $18.7 million as of June 30, 2024, compared to December 31, 2023. Current liabilities, consisting primarily of accounts payable, accrued liabilities, lease obligations, the current portion of notes payable and interest payable, increased by approximately $0.2 million as of June 30, 2024, compared to December 31, 2023. The sale of common stock and the borrowings under tranche 2 of the loan and security agreement discussed above contributed to the increase in cash, cash equivalents, and marketable securities during the second half of 2023, resulting in an increase in working capital as of December 31, 2023.

Cash Flows

December 31, 2023, Compared to December 31, 2022

The following table summarizes our cash flows for the years ended December 31, 2023, and 2022

(in thousands)	Year Ended December 31, 2023	2022
Net cash used in operating activities	$ (32,698)	$ (30,356)
Net cash used in investing activities	(8,641)	(49,348)
Net cash provided by financing activities	40,466	17,014
Effect of exchange rate change on cash	(5)	(96)
Beginning cash balance	15,456	78,242
Ending cash balance	$ 14,578	$ 15,456

Operating Activities

Net cash used in operating activities during the year ended December 31, 2023, was $32.7 million, compared to $30.4 million during the year ended December 31, 2022, representing an increase in use of $2.3 million. This increase was primarily attributed to an increase in net loss of $1.9 million, a decrease in cash from changes in working capital of $0.5 million, and offset by a $0.1 increase in non-cash adjustments.

- The increase in net loss of $1.9 million primarily resulted from increases in personnel costs due to the expansion of our workforce, as well as increases in interest expense, resulted from an additional borrowings and higher interest rates as further described under "—Results of Operations" above.

- The key drivers that caused the decrease in cash from working capital primarily consisted of a $1.0 million decrease in accrued expenses and other liabilities primarily driven by a $0.7 million decrease in accrued development expenses pertaining to the clinical trial, and a $0.3 million decrease in the accrued warranty reserve. Also attributing to the decrease in cash from working capital was a $0.8 million decrease in accounts payable due to the timing of vendor payments, and a $0.4 million decrease in non-trade receivables due to the timing of collections. These decreases were partially offset by a $0.8 million increase in prepaids expenses due to increased vendor prepayment requirements for research and development materials and professional services, a $0.7 million increase in other assets due to refundable tax incentives from the Australian Taxation Office, and a $0.3 million increase in interest payable as a result of additional borrowing during the year ended December 31, 2023.

- Non-cash items primarily consisted of increases in share-based compensation of $0.4 million driven by new employee stock options granted to new and existing employees, an increase of $0.3 million from the amortization of deferred loan costs and discount on notes payable as a result additional borrowings, and a $0.1 million increase in the adjustment to depreciation and amortization due to an increase in property and equipment. These increases were offset by a $0.7 million decrease in accretion of discount on marketable securities driven by fluctuating interest rates and maturity terms.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2023, was $8.6 million, compared to $49.3 million the year ended December 31, 2022, representing a decrease in cash used of $40.7 million. The decrease was attributable to a $26.8 million increase in the purchase of marketable securities and offset by a $67.2 million increase in the maturities and sales of marketable securities during the year ended December 31, 2023, as compared to the year ended December 31, 2022. Cash used in investing activities was significantly higher during the year ended December 31, 2022, as we began investing surplus cash in marketable securities during 2022. During the years ended December 31, 2023, and 2022, we invested approximately $0.4 million and $0.7 million, respectively, in the acquisition of property and equipment.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2023, was $40.5 million, compared to $17.0 million during the year ended December 31, 2022, representing an increase of $23.5 million. As discussed above, we raised approximately $20.6 million, net of offering costs, from the sale of CDIs during the year ended December 31, 2023, resulting in a substantial increase in cash generated from financing activities in that year.

Additionally, we drew down $20 million in term debt, as discussed above, during the years ended December 31, 2023, and 2022.

June 30, 2024, Compared to June 30, 2023

The following table summarizes our cash flows for the six months ended June 30, 2024, and 2023:

	Six Months Ended June 30,	
(in thousands)	2024	2023
Net cash used in operating activities	$ (20,386)	$ (15,572)
Net cash provided by investing activities	13,989	16,161
Net cash provided by financing activities	195	35,468
Effect of exchange rate change on cash	(12)	(44)
Beginning cash balance	14,579	15,456
Ending cash balance	$ 8,365	$ 51,557

Operating Activities

Net cash used in operating activities during the six months ended June 30, 2024, was $20.4 million, compared to $15.6 million during the six months ended June 30, 2023, representing an increase in use of $4.8 million. This increase is primarily attributed to an increase in net loss of $5.0 million, a decrease in non-cash adjustments of $0.2 million, and offset by an increase in cash from changes in working capital of $0.4 million.

- The increase in net loss of $5.0 million resulted from ongoing research and development efforts and increases in personnel costs due to the expansion of our workforce as further described under "Results of Operations" above.

- Non-cash items primarily consisted of increases in share-based compensation of $0.3 million due to new options issuance to new hires and existing employees, an increase of $0.1 million from the amortization of deferred loan costs and discount on notes payable as a result additional borrowings, offset by a decrease in accretion of discount on marketable securities of $0.6 million driven by fluctuating interest rates and maturity term.

- The increase in changes from working capital activities primarily consisted of a $1.5 million increase in accounts payable due to the timing of invoice payments. This increase was partially offset by $0.3 million decrease in other assets mainly due to the receipt of refundable tax incentives from the Australian Taxation Office in 2023, a $0.5 million decrease in prepaids expenses due to decreased vendor prepayment requirements for research and development materials and professional services, and a $0.3 million decrease in non-trade receivables due to the timing of collections.

Investing Activities

Net cash provided by investing activities during the six months ended June 30, 2024, was $14.0 million, compared to $16.2 million the six months ended June 30, 2023, representing a decrease in cash provided of $2.2 million. The decrease was attributable to a $12.5 million decrease in the maturities and sales of marketable securities, which were partially offset by a $10.3 million decrease in the purchase of marketable securities during the six months ended June 30, 2024, as compared to the six months ended June 30, 2023.

Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2024, was $0.2 million, compared to $35.5 million during the six months ended June 30, 2023, representing a decrease of $35.3 million. This decrease is primarily attributed to the $19.7 million borrowing, net of issuance cost, under tranche 2 of the loan and security, as well as $15.6 million capital raise, net of issuance cost, during the quarter ended June 30, 2023, resulting in a substantial increase in cash generated from financing activities during the year ended December 31, 2023.

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 required under this item.

Item 3. 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. While we believe these premises are suitable for our current needs, we are exploring alternatives for new or additional facilities for our office, laboratory, and manufacturing space requirements in order to meet potential future commercial demand for the WiSE CRT System.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth information regarding beneficial ownership of our common stock, and common stock held as CDIs, as of June 30, 2024, by:

- each person, or group of affiliated persons, whom we know to beneficially own more than 5% of any class of our voting securities;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

In accordance with the rules of the SEC, beneficial ownership includes voting or investment power with respect to securities and includes the shares issuable pursuant to stock options and warrants that are exercisable within 60 days of June 30, 2024. Shares issuable pursuant to stock options and warrants are deemed outstanding for computing the percentage of the person holding such options but are not outstanding for computing the percentage of any other person.

We have based our calculation of the percentage of beneficial ownership on 308,113,383 shares of our common stock outstanding as of June 30, 2024.

Unless otherwise indicated, the address for each listed stockholder is c/o EBR SYSTEMS, INC., 480 Oakmead Parkway, Sunnyvale, CA 94085. To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

Name and address of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned (%)
Named Executive Officers and Directors:		
John McCutcheon [(1)]	8,559,978	2.70%
Gary W. Doherty [(2)]	—	0.00%
Michael Hendricksen [(3)]	1,146,875	0.37%
Frank Hettmann [(4)]	1,000,000	0.32%
Allan Will [(5)]	9,453,982	3.04%
Bronwyn Evans [(6)]	317,606	0.10%
Trevor Moody [(7)]	1,168,844	0.38%
Christopher Nave [(8)]	21,237,952	6.89%
David Steinhaus [(9)]	317,606	0.10%
Karen Drexler [(10)]	317,606	0.10%
All directors and executive officers as a group (9 persons)[(11)]	42,520,449	13.15%
All Other Greater than 5% Owners:		
Entities Affiliated with HESTA [(12)]	26,191,146	8.42%
Entities Affiliated with HOSTPLUS [(13)]	31,061,471	10.01%
Entities Affiliated with Brandon Capital Partners [(14)]	21,237,952	6.89%
Entities Affiliated with M.H. Carnegie Funds [(15)]	44,304,280	14.19%
Entities Affiliated with Split Rock Partners [(16)]	29,375,659	9.45%

(1) Consists of 8,559,978 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024.

(2) In connection with his commencement of employment, Mr. Doherty was granted an option to purchase 3,618,062 shares of common stock with an exercise price of $0.54, expiring on September 14, 2033. None of these option shares are exercisable within 60 days of June 30, 2024.

(3) Consists of 1,146,875 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024.

(4) Consists of 1,000,000 CDIs.

(5) Consists of (a) 5,827,224 CDIs held by Allan R. Will Trust U/A Dtd 6/14/2012, Allan R. Will TTEE, (b) 628,000 CDIs held by Matthew S. Will Special Needs Trust Dtd 1/16/2013, (c) 2,748,746 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024, and (d) 250,012 shares issuable upon exercise of certain warrants issued to Allan R. Will Trust U/A Dtd 6/14/2012, Allan R. Will TTEE.

(6) Consists of 317,606 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024.

(7) Consists of (a) 223,068 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024 (b) 91,758 shares issuable pursuant to a stock option exercisable within 60 days of June 30, 2024, held by Australian Medtech Services Pty Ltd, and (c) 854,018 shares issuable upon exercise of certain warrants issued to M. H. Carnegie & Co. Pty Ltd on behalf of Mr. Moody.

(8) Consists of (a) 314,826 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024, held of record by MRCF BTF Service (BCPIT) Pty Ltd as trustee for the MRCF BTF (BCP Investment) Trust, and (b) 20,923,126 CDIs held of record by Brandon Capital Partners.

(9) Consists of (a) 276,697 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024, held of record by David M. Steinhaus Revocable Trust dated January 20, 2004, as amended and restated (b) 40,909 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024.

(10) Consists of 317,606 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024.

(11) Consists of (a) 27,378,350 CDIs held by our current directors and executive officers, (b) 14,038,069 shares issuable pursuant to stock options exercisable within 60 days after June 30, 2024, and (c) 1,104,030 shares issuable upon exercise of certain warrants.

(12) Consists of (a) 15,875,392 CDIs held of record by H.E.S.T. Australia Limited as Trustee of Health Employees Superannuation Trust Australia (HESTA), (b) 7,243,522 CDIs held of record by Brandon Capital Partners, and (c) 3,072,232 shares issuable upon exercise of certain warrants issued to H.E.S.T. Australia Limited as Trustee of Health Employees Superannuation Trust Australia (HESTA). MRCF3 Services (H) Pty Ltd is the Registered Holder of H.E.S.T. Australia Limited as Trustee of Health Employees Superannuation Trust Australia (HESTA) and Brandon Capital Partners and as such may be deemed to have indirect beneficial ownership of an indeterminate amount of such CDIs. Christopher Nave (a member of our board of directors), and Henry Thompson are the members of MRCF3 Services (H) Pty Ltd and share voting and investment power over the CDIs held by H.E.S.T. Australia Limited as Trustee of Health Employees Superannuation Trust Australia (HESTA) and Brandon Capital Partners. Mr. Nave does not have voting or investment power over the CDIs held by MRCF3 Services (H) Pty Ltd. The address for MRCF3 Services (H) Pty Ltd is Level 9 31 Queen Street, Melbourne VIC 3000.

(13) Consists of (a) 26,551,391 CDIs held of record by HOST-PLUS Pty Ltd as Trustee of Hostplus Pooled Superannuation Trust (HOSTPLUS), (b) 2,415,200 CDIs held of record by Brandon Capital Partners, and (c) 2,094,880 shares issuable upon exercise of certain warrants issued to HOST-PLLUS Pty Ltd as Trustee of Hostplus Pooled Superannuation Trust (HOSTPLUS). MRCF3 Services (HP) Pty Ltd/MRCF3(HP) Pty Ltd is the Registered Holder of HOST-PLUS Pty Ltd as Trustee of Hostplus Pooled Superannuation Trust (HOSTPLUS) and Brandon Capital Partners and as such may be deemed to have indirect beneficial ownership of an indeterminate amount of such CDIs. Christopher Nave (a member of our board of directors), and Henry Thompson are the members of MRCF3 Services (HP) Pty Ltd/MRCF3(HP) Pty Ltd and share voting and investment power over the CDIs held by HOST-PLUS Pty Ltd as Trustee of Hostplus Pooled Superannuation Trust (HOSTPLUS) and Brandon Capital Partners. Mr. Nave does not have voting or investment power over the CDIs held by MRCF3 Services (HP) Pty Ltd/MRCF3(HP) Pty Ltd. The address for MRCF3 Services (HP) Pty Ltd/MRCF3(HP) Pty Ltd is Level 9 31 Queen Street, Melbourne VIC 3000.

(14) Consists of (a) 20,923,126 CDIs held of record by Brandon Capital Partners, and (b) 314,826 shares issuable pursuant to a stock option exercisable within 60 days after June 30, 2024, held of record by MRCF BTF Service (BCPIT) Pty Ltd as trustee for the MRCF BTF (BCP Investment) Trust. MRCF3 Services (H) Pty Ltd, MRCF3 Services (HP) Pty Ltd, MRCF3 Services (AS) Pty Ltd, MRCF3 Services (SW) Pty Ltd, MRCF3 Services (CSL) Pty Ltd and MRCF3 Pty Ltd are the Registered Holders of Brandon Capital Partners and as such may be deemed to have indirect beneficial ownership of an indeterminate amount of such CDIs. Christopher Nave (a member of our board of directors), and Henry Thompson are the members of MRCF3 Services (H) Pty Ltd, MRCF3 Services (HP) Pty Ltd, MRCF3 Services (AS) Pty Ltd, MRCF3 Services (SW) Pty Ltd, MRCF3 Services (CSL) Pty Ltd and MRCF3 Pty Ltd and share voting and investment power over the CDIs held by Brandon Capital Partners. Mr. Nave does not have voting or investment power over the CDIs held by MRCF3 Services (H) Pty Ltd, MRCF3 Services (HP) Pty Ltd, MRCF3 Services (AS) Pty Ltd, MRCF3 Services (SW) Pty Ltd, MRCF3 Services (CSL) Pty Ltd and MRCF3 Pty Ltd. The address for MRCF3 Services (H) Pty Ltd, MRCF3 Services (HP) Pty Ltd, MRCF3 Services (AS) Pty Ltd, MRCF3 Services (SW) Pty Ltd, MRCF3 Services (CSL) Pty Ltd and MRCF3 Pty Ltd is Level 9 31 Queen Street, Melbourne VIC 3000.

(15) Consists of (a) 14,952,663 CDIs held of record by Carnegie Healthcare Fund, (b) 14,162,839 CDIs held of record by Carnegie Innovation Fund No.2 L.P., (c) 3,323,193 CDIs held of record by MHC Fund Services 2A Pty Ltd atf Carnegie Private Opportunities Fund No. 2A, (d) 7,833,287 CDIs held of record by MHC Fund Services B Pty Ltd atf MHC HOSTPLUS Co Investment Trust, (e) 2,401,671 shares issuable upon exercise of certain warrants issued to Carnegie Healthcare Fund, (f) 448,526 shares issuable upon exercise of certain warrants issued to Carnegie Innovation Fund No. 2 L.P., and (g) 1,182,101 shares issuable upon exercise of certain warrants issued to MHC Fund Services B Pty Ltd aft MHC HOSTPLUS Co Investment Trust. Mark Carnegie and Catherine Thompson are the members of Carnegie Healthcare Fund, Carnegie Innovation Fund No.2 L.P., MHC Fund Services 2A Pty Ltd atf Carnegie Private Opportunities Fund No. 2A and MHC Fund Services B Pty Ltd aft MHC HOSTPLUS Co Investment Trust and share voting and investment power over the CDIs. The address for MHC Fund Services 2A Pty Ltd is 52 Victoria Street, Paddington NSW 2021 and MHC Fund Services B Pty Ltd is 120B Underwood Street, Paddington NSW 2021, Australia.

(16) Consists of (a) 6,996,473 CDIs held of record by SPVC VI, LLC, (b) 19,732,458 CDIs held of record by Split Rock Partners, LP, (c) 656,806 shares issuable upon exercise of certain warrants issued to SPVC VI, LLC, and (d) 1,989,922 shares issuable upon exercise of certain warrants issued to Split Rock Partners, LP. Split Rock Partners Management, LLC is the general partner of Split Rock Partners, LP, and as such may be deemed to have indirect beneficial ownership of an indeterminate amount of such CDIs. SPVC Management VI, LLC is the managing member of SPVC VI, LLC and as such may be deemed to have indirect beneficial ownership of an indeterminate amount of such CDIs. The principal business address of Split Rock Partners LP and SPVC VI, LLC is 16526 West 78th Street, Suite 504, Eden Prairie, Minnesota 55346.

Item 5. Directors and Executive Officers.

The following table sets forth information regarding our executive officers and directors as of June 30, 2024:

Name	Age	Position(s) with the Company
Executive Officers		
John McCutcheon	63	President, Chief Executive Officer, Director
Gary W. Doherty	58	Chief Financial Officer
Michael Hendricksen	51	Chief Operating Officer
Non-Employee Directors		
Allan Will	69	Executive Director and Chairman
Christopher Nave, PhD	49	Director
Trevor Moody	58	Director
Bronwyn Evans, PhD	63	Director – Chairperson of Audit & Risk Committee
David Steinhaus, MD	72	Director
Karen Drexler	64	Director – Chairperson of Nomination and Remuneration Committee
Significant Employees		
Madhuri Bhat	52	Chief Regulatory Officer
Erik Strandberg	46	Chief Commercial Officer
Parker Willis, PhD	58	Chief Technology Officer
Spencer Kubo, MD	69	Chief Medical Officer
Andrew Shute	51	Senior Vice President, Global Field Operations

Our board of directors is divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Each of our directors is serving a term which expires at the next annual meeting of stockholders at which his or her class is up for election until his or her successor is elected and qualifies or until such individual resigns or is removed. The officers serve at the will of the Board of Directors. There are no arrangements or understandings with major stockholders, customers, suppliers, or others pursuant to which any of our executive management or our directors were selected.

Executive Officers and Directors

John McCutcheon

Mr. McCutcheon has served as our President, Chief Executive Officer and director since June 2019, and has 40 years of sales, marketing, and general management experience in medical devices. Mr. McCutcheon started his career at American Hospital Supply (acquired by Baxter International) followed by DVI (acquired by Eli Lily), Perclose (acquired by Abbott Laboratories), Emphasys Medical (acquired by Pulmonx), Ventus Medical and Ceterix Orthopaedics (acquired by Smith & Nephew). Mr. McCutcheon has also served on numerous boards of private companies in the medical device industry. Mr. McCutcheon holds B.A. degrees in Economics and Psychology from

the University of California, Los Angeles ("UCLA"), and an M.B.A. from the UCLA Anderson Graduate School of Management.

We believe Mr. McCutcheon is qualified to serve as a member of our Board of Directors because of his leadership experience in various executive roles, particularly his experience in publicly traded companies and capital markets.

Gary W. Doherty

Mr. Doherty has served as our Chief Financial Officer ("CFO") since September 2023 and brings over 30 years of international expertise in technology, healthcare, finance, and operations. Mr. Doherty's previous roles include serving as CFO of Mikuna Foods, Inc. from July 2021 to October 2022, in various roles at Acutus Medical, Inc. (Nasdaq: AFIB) including CFO from October 2015 to June 2021, and in various leadership positions at Volcano Corporation (acquired by Philips NV) from August 2003 until October 2015. Prior to this, he served as the Director of Financial Management with Digirad, Inc., and served as Corporate Controller for Palomar Technologies, Inc. Mr. Doherty received a B.S. in Business Administration, Finance from San Diego State University.

Michael Hendricksen

Mr. Hendricksen has served as our Chief Operating Officer since November 2021 and has over 25 years of medical device product development and manufacturing experience. Prior to joining EBR Systems, from February 2018, Mr. Hendricksen served as Chief Operating Officer at Ceterix Orthopaedics where he led the development of the NOVOSTITCH Pro Meniscal Repair System. Ceterix was acquired in 2019 by Smith+Nephew at which time Michael assumed the role of Site Leader, scaling and integrating operations not only for Ceterix but also for Tusker Medical, another Smith+Nephew acquisition. Before Ceterix, Mr. Hendricksen was Vice President of R&D at Foundry NewcoXI and served in engineering roles of increasing responsibility at Emphasys Medical, Cardica, and IDEO Product Development. Mr. Hendricksen is an inventor on over 80 issued patents, and he holds an MS in Mechanical Engineering from Stanford University and a BS in Mechanical Engineering from Northwestern University.

Allan Will

Mr. Will served as our Chairman, President and Chief Executive Officer from October 2011 until June 2019 and has served in the role of Executive Chair since June 2019. Mr. Will is a seasoned executive with extensive experience founding, funding, operating, and selling medical device companies. In addition to his role with our company, Mr. Will has served as Chair of the board of Fractyl Health, Inc., (Nasdaq: GUTS) a metabolic therapeutics company, since August 2012, and SetPoint Medical, Inc., a privately held clinical-stage bioelectronics medicine company dedicated to treating patients with chronic autoimmune disease, since March 2011. Since 2014, he has served as a director of Fogarty Innovation, a not-for-profit organization dedicated to advancing human health worldwide. Prior to these roles, Mr. Will served as founding Managing Director of Split Rock Partners' (and its predecessor, St. Paul Venture Capital's) Silicon Valley venture capital office, focusing on the therapeutic medical device field. Previously, Mr. Will founded The Foundry, an incubator dedicated to transforming medical device concepts into companies, where he also served as Chair and Chief Executive Officer from 1998 to 2002 and Chair until 2010, co-founding eleven companies including, among others, Ardian, Inc., a medical device company focused on treating hypertension, which was subsequently acquired by Medtronic plc, and Evalve Inc., a company treating heart failure by repairing mitral valves percutaneously, now a wholly owned subsidiary of Abbott Laboratories. Mr. Will is an inventor on more than 30 issued patents, is a University of Maryland Distinguished Alumnus and a recipient of the ASTIA/Deloitte Excellence in Mentoring Women Executives Award. He served on the MIT Entrepreneurship Center Shareholders' Board and the University of Maryland President's Committee on Innovation and Entrepreneurship. Mr. Will received his M.S. in management from MIT and his B.S. in zoology from the University of Maryland.

We believe Mr. Will is qualified to serve as Executive Chairman of our Board of Directors because of his extensive experience as an investor and leader in medical technology companies and as a member of the boards of directors of multiple public and private companies.

Christopher Nave, PhD

Dr. Nave has served as a Director of EBR since 2017. Dr. Nave is a Founder and Managing Director of Brandon Capital Partners and the CEO of the Medical Research Commercialization Fund. Dr. Nave previously served as the Director of Commercialization at the Baker Heart Research Institute. Dr. Nave is currently a director of The Australian Investment Council and the following privately held companies; Azura Ophthalmics, Inc., Certa Therapeutics Pty Ltd., Global Kinetics Corporation Ltd., PolyActiva Pty Ltd., and Pathios Plc. Dr. Nave was Chairperson of Fibrotech Therapeutics Pty Ltd. at the time of its successful sale to Shire Plc and a director of Spinifex Pharmaceuticals, Inc. at the time of its sale to Novartis International AG. Dr. Nave holds a B.Sc. (Honours) and a Ph.D. in Endocrinology and Physiology from the University of Melbourne.

We believe Dr. Nave is qualified to serve as a member of our Board of Directors due to his strong business and investment acumen, and extensive experience advising companies in the healthcare industry.

Trevor Moody

Mr. Moody has served as a Director of EBR since 2017. He served as Medical Device Partner at M.H. Carnegie & Co. (from October 2013 to April 2022), where he made investments in medical device companies. He has also served since January 2010 as President of TM Strategic Advisors LLC, a management consultancy. Mr. Moody was previously a General Partner at Frazier Healthcare Ventures, a large U.S. based private equity and venture capital firm. Mr. Moody is currently a Director of ElectroCore, Inc., Australian Medtech Services Pty Ltd., Cardiac Dimensions Pty Ltd., Renew Medical Pty Ltd., Serene Medical Pty Limited, The Brain Protection Company Pty Ltd., and CurvaFix, Inc. Mr. Moody also serves on the board of Angel Flight West, a not-for-profit that provides free air transport for patients requiring long distance travel for medical treatment. Mr. Moody was a Director of Simplify Medical Pty Ltd. at the time of its sale to NuVasive, Inc. Mr. Moody holds a B.Eng. from the University of Southern Queensland, and a M.S. in Management from the Massachusetts Institute of Technology (Sloan School).

We believe Mr. Moody is qualified to serve as a member of our Board of Directors due to his business experience and experience servicing as a director at various life science companies.

Bronwyn Evans, PhD

Dr. Evans has served as our Director since October 2021 and is an experienced leader and CEO with a broad technical background across multiple industry sectors including medical technology, manufacturing, power generation and distribution, and technical regulation and standards. Dr. Evans is currently the CEO of Engineers Australia, the Chair of Building 4.0 CRC, and the Director at GME Pty Ltd. Prior to her role with Engineers Australia, Dr. Evans was the CEO of Standards Australia. Dr. Evans has previously held positions in innovation initiatives, including as Chair of MTPConnect (the Industry Growth Center for Medical Technologies and Pharmaceuticals) and was a member of the Industry 4.0 Advanced Manufacturing Forum Leadership group. She has also held various senior engineering roles, including at Cochlear and GE Healthcare. Dr. Evans has been recognized as one of Australia's 100 most influential engineers and recognized as a 100 Women of Influence. Dr. Evans holds a BE (Honors I) and a Ph.D. in Electrical Engineering from the University of Wollongong. She also has an Honorary Doctorate from Swinburne University and is an Honorary Fellow of the University of Wollongong and Engineers Australia and a Fellow of the Australian Academy of Technological Sciences and Engineering.

We believe Dr. Evans is qualified to serve as a member of our Board of Directors due to her broad leadership and corporate governance experience.

David Steinhaus, MD

Dr. Steinhaus has served as our Director since October 2021. He retired in 2019 as Vice President and General Manager of the Heart Failure Business for the Cardiac Rhythm and Heart Failure Division at Medtronic plc. Dr. Steinhaus joined Medtronic in 2005, after 20 years of cardiology (electrophysiology) practice. In his initial capacity as Medical Director, Dr. Steinhaus' responsibilities at Medtronic included bringing the physician voice to CRHF, identifying future opportunities in new product development, and serving as a liaison to government agencies, professional societies and medical groups. Subsequently, he took on more managerial roles including strategy,

business development, R&D, and ultimately general manager of the Heart Failure Business. Closely associated with research and academia, performing extensive clinical studies in implantable cardiac devices and leads, he served as Chair of the Department of Cardiology, and Director of the Electrophysiology Department at the Mid America Heart Institute and St. Luke's Hospital and Director of the Electrophysiology Fellowship Program at the University of Missouri at Kansas City School of Medicine. Since leaving Medtronic, he has served as a consultant and board member to multiple established and early-stage medical device companies. Dr. Steinhaus graduated magna cum laude from Harvard College and received his medical doctorate from Harvard Medical School as part of the Harvard-M.I.T. program in Health Sciences and Technology, with AOA honors.

We believe Dr. Steinhaus is qualified to serve as a member of our Board of Directors due to his background as a physician and his extensive experience in medical device companies.

Karen Drexler

Ms Drexler is a serial entrepreneur with expertise in the fields of digital health, medical devices, and diagnostics. Currently serving on the boards of three other public companies, ResMed, Inc. (NYSE: RMD), a global leader in connected medical devices and out of hospital software, where she chairs the compensation committee and serves on the nominating and governance committee, Outset Medical Inc. (Nasdaq: OM), a Medtech company innovating dialysis treatment, where she is a member of both the compensation and nomination and governance committees; and Tivic Health Systems, Inc.(Nasdaq: TIVC), a bioelectric medicine company focused on relief of congestion and sinus pain, where she chairs the compensation and nomination and governance committees and serves on the audit committee Ms. Drexler also serves on the boards of two private companies: VIDA Diagnostics Inc. and Huma.ai. She also acts as a senior strategic advisor for other early-stage companies and spent 11 years on the board of the Keller Center for Innovation in Engineering Education at Princeton University. Ms. Drexler has extensive operating experience including as CEO of Amira Medical (sold to Roche Diagnostics) and Sandstone Diagnostics (sold to LabCorp.) Ms. Drexler is an active mentor and advisor to Astia, a global nonprofit that supports high-potential female founders, as well as a mentor for StartX, the Stanford University incubator. She graduated magna cum laude with a Bachelor of Science in Chemical Engineering from Princeton University and earned an MBA with Honors from the Stanford University Graduate School of Business.

Ms. Drexler's executive and board experience in the medical diagnostics and medical device industries, particularly her experience in digital health, technology, and data security, and out-of-hospital care models, led our board to conclude she should serve as a director.

Significant Employees

Madhuri Bhat

Ms. Bhat has served as our Chief Regulatory Officer since February 2019 and has over 20 years of experience in public affairs, public policy, clinical, quality, and regulatory roles in medical devices. She led several successful pivotal clinical trials and multiple registries and secured regulatory approvals and clearances in the US and internationally for Class II and III cardiovascular systems. Most recently, from November 2011 until January 2019, Ms. Bhat served as Consulting Vice-President RA/Clinical for companies in the reproductive, GI, neurological, urological, and cardiovascular domains such as Kyma Medical (acquired by Zoll) as the Founder/ Principal of her own consulting company. Prior to that, Ms. Bhat was the VP of RA/QC at Barrx Medical (acquired by Covidien, then Medtronic), VP of RA/Clinical at Corventis (acquired by Medtronic) and held management positions at Guidant and Abbott Vascular. Ms. Bhat is a book author on child advocacy and serves as visiting faculty at San Jose State University. She has a B.S. in Biology from University of Mumbai, a diploma in Mass Communications from Sophia Polytech, and a Master's in Public Policy from Duke University.

Erik Strandberg

Mr. Strandberg has served as our Chief Commercial Officer since April 2024 and has over two decades of medical device industry sales experience and has developed relationships across a broad spectrum of physicians, C-

suite hospital executives and medical professionals. He has demonstrated exceptional strategic sales planning, contract negotiation, operational oversight, and leadership expertise. Prior to joining EBR, Mr. Strandberg was the Senior Vice President of the Hybrid Therapies Division at AtriCure (NASDAQ: ATRC), where from July 2018 to April 2024 he led the promotion and sales initiatives for a prestigious product portfolio targeting the treatment of Atrial Fibrillation and related conditions. Before that, Mr. Strandberg was at Boston Scientific from August 2015 to July 2018 (NYSE: BSX) where he helped execute the commercial launch strategy of the Watchman Left Atrial Appendage Closure device. He previously held leadership roles at St Jude Medical and Guidant Corporation focused on the areas of Cardiac Rhythm Management, EP, and Heart Failure.

Parker Willis, PhD

Dr. Willis has served as our Chief Technology Officer since September 2011 and has with extensive experience in signal processing applications and has worked in medical devices for over 20 years, all in technical leadership capacities for development of novel technologies for cardiac electrophysiology. He previously held senior positions at Boston Scientific and Cardiac Pathways. Dr. Willis is an inventor on more than 28 issued patents. He earned his Bachelor of Science in Electrical Engineering from the University of California, San Diego, and his Master of Science and Ph.D. from the University of Illinois Urbana-Champaign.

Spencer Kubo, MD

Dr. Kubo has served as our Chief Medical Officer since January 2019 and holds the same position at Heart Leaflet Technologies, where he oversees clinical trials for a next-generation Transcatheter Aortic Valve Replacement. Dr. Kubo's career also includes roles as Executive Director of Merck's Academic and Professional Affairs department, Professor of Medicine, Co-Director of Clinical Cardiology, and Medical Director of the Heart Failure-Heart Transplantation Program at the University of Minnesota. Dr. Kubo earned his undergraduate degree in biology from Dartmouth College and his MD from Cornell University Medical College3. He is a Fellow of both the American College of Cardiology and the American Heart Association.

Andrew Shute

Mr. Shute has served as our Senior Vice President, Global Field Operations since July 2015 and has over 20 years of medical device experience and has led the successful commercialization of new technologies and products working in the corporate, start-up and distributor settings. He brings strong business, clinical training and sales management background to the team, including positions at St. Jude Medical, Endocardial Solutions and Getz Brothers. Mr. Shute received his B.S. from the University of Wollongong, Australia. Mr. Shute currently holds the position of Chairman of the Cardiac Rhythm Management section of the Association of British Healthcare Industries Ltd (ABHI).

Family Relationships

There are no family relationships among any of our current executive officers or directors.

Executive Officers

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal.

Board of Directors

Our board of directors currently consists of seven members. The current members of our board of directors were elected pursuant to our current Amended and Restated Certificate of Incorporation.

Our Amended and Restated Certificate of Incorporation provides that our board of directors is divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of

stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors are divided among the three classes as follows:

- the Class I directors are Mr. Will and Mr. Moody, and their terms will expire at the annual meeting of stockholders to be held in 2025;
- the Class II directors are Mr. McCutcheon, Dr. Evans, and their terms will expire at the annual meeting of stockholders to be held in 2026; and
- the Class III directors are Dr. Nave, Dr. Steinhaus, and Ms. Drexler and their terms will expire at the annual meeting of stockholders to be held in 2027.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our Amended and Restated Certificate of Incorporation. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of our directors.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Director Independence

Our Board has determined that the following Board members can be considered independent:

- Bronwyn Evans, PhD
- David Steinhaus, MD
- Karen Drexler
- Trevor Moody

We consider that a director is an independent director where that director is free from any business or other relationship that could materially interfere with, or be perceived to interfere with, the independent exercise of the director's judgment. While we are not currently seeking a listing on Nasdaq or any other U.S. securities exchange and do not intend to do so in the foreseeable future, we have assessed the independence of our directors with respect to the definition of independence prescribed by Nasdaq and the SEC. Although we may seek a listing on Nasdaq in the future, there is no guarantee that we will do so or that we will achieve a listing on Nasdaq or any other exchange in any particular timeframe or at all.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Dr. Evans, Dr. Steinhaus, Ms. Drexler, and Mr. Moody representing four of our seven directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

Corporate Governance

Our board of directors is currently chaired by Mr. Will. As a general policy, our board of directors believes that separation of the positions of Chair of our board of directors and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole. As such, Mr. McCutcheon serves as our President and Chief Executive Officer while Mr. Will serves as the Executive Chair of our board of directors but is not an officer. We currently expect and intend the positions of Chair of our board of directors and President and Chief Executive Officer to continue to be held by two individuals in the future.

Board Committees

Our board of directors has an audit & risk committee, and nomination & remuneration committee, each of which has the composition and the responsibilities described below.

Audit & Risk Committee

The members of our audit & risk committee are Dr. Evans, Ms. Drexler, and Dr. Steinhaus. Ms. Drexler serves as our audit & risk committee "financial expert" as defined in the Nasdaq rules, given her experience as a CEO that had financial oversight responsibilities. Our audit & risk committee oversees our corporate accounting and financial reporting process and assists our board of directors in monitoring our financial and risk management systems. Our audit & risk committee also:

- selects and hires the independent registered public accounting firm to audit our consolidated financial statements;
- helps to ensure the independence and performance of the independent registered public accounting firm;
- approves audit and non-audit services and fees;
- reviews our consolidated financial statements and discusses with management and the independent registered public accounting firm our annual audited and quarterly consolidated financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal control over financial reporting and disclosure controls;
- reviews reports and communications from the independent registered public accounting firm;
- reviews the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- reviews our policies on risk assessment and risk management;
- reviews and monitors conflicts of interest situations, and approves or prohibits any involvement in matters that may involve a conflict of interest or taking of a corporate opportunity;
- reviews related party transactions; and
- establishes and oversees procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit and risk committee operates under a written charter, which has been prepared having regard to the recommendations set out in the ASX Corporate Governance Principles and Recommendations.

Nomination and Remuneration Committee

The members of our nomination and remuneration committee are Ms. Drexler and Dr. Moody. Ms. Drexler is the chair of our nomination and remuneration committee. Our nomination and remuneration committee oversees and assists our board of directors in reviewing and recommending nominees for election as directors plus our compensation policies, plans, and benefits programs. The nomination and remuneration committee also:

- oversees our overall compensation philosophy and compensation policies, plans, and benefit programs;
- reviews and approves or recommends to the board of directors for approval compensation for our executive officers and directors;
- administers our equity compensation plans.
- identifies, evaluates, and makes recommendations to our board of directors regarding nominees for election to our board of directors and its committees;

- considers and makes recommendations to our board of directors regarding the composition of our board of directors and its committees;
- reviews developments in corporate governance practices;
- evaluates the adequacy of our corporate governance practices and reporting; and
- evaluates the performance of our board of directors and of individual directors.

Our corporate governance and nominating committee operates under a written charter, which has been prepared having regard to the recommendations set out in the ASX Corporate Governance Principles and Recommendations.

Code of Business Conduct

Our board of directors has adopted a code of business conduct that applies to all of our employees, officers, and directors, including those officers responsible for financial reporting. Our code of business conduct is available on our website at https://ebrsystemsinc.com/.

Item 6. Executive Compensation.

This section discusses the material components of the executive compensation program for our named executive officers (NEOs.) In fiscal year 2023, our NEOs and their positions were as follows:

- John McCutcheon, President, and Chief Executive Officer;
- Gary W. Doherty, Chief Financial Officer[(1)];
- Michael Hendricksen, Chief Operating Officer; and
- Frank Hettmann, Former Chief Financial Officer.[(2)]

(1) Mr. Doherty has served as our Chief Financial Officer since September 11, 2023

(2) Mr. Hettman ceased serving as our Chief Financial Officer on September 11, 2023, and his employment with us terminated effective November 30, 2023.

Summary Compensation Table

This discussion contains forward looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The following table sets forth information concerning the compensation awarded to or earned by our NEOs during the fiscal year ended December 31, 2023:

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) [1]	Non- Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)	Total ($)
John McCutcheon *President and Chief Executive Officer*	2023	493,750	—	—	209,250	241,727	—	944,727
Gary W. Doherty [3] *Chief Financial Officer*	2023	108,647	43,351[4]	—	1,338,693	—	—	1,490,691
Michael Hendricksen *Chief Operating Officer*	2023	311,250	—	—	69,000	76,817	—	457,067
Frank Hettmann [5] *Former Chief Financial Officer*	2023	332,678	—	—	115,460	—	271,728[6]	719,866

[1] Amounts do not reflect dollar amounts actually received by our Named Executive Officers and instead, in accordance with SEC rules, represent the aggregate grant date fair values of option awards granted in 2023 as computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718. See Note 13, Stock-based compensation to our consolidated financial statements included elsewhere in this Form 10 for a discussion of the assumptions used in the calculation of these amounts.

[2] Amounts disclosed under the "Non-Equity Incentive Plan Compensation" column represent the portion of the annual performance-based bonuses earned pursuant to objective performance criteria established as part of our annual performance-based bonus plan for the indicated year for the achievement of pre-established corporate and other goals. For further discussion on performance-based bonuses paid for 2023, see the sub-section entitled "2023 Annual Performance-Based Bonuses."

[3] Mr. Doherty has served as our Chief Financial Officer since September 11, 2023.

[4] Amount disclosed under the "Bonus" column represents Mr. Doherty's guaranteed bonus for 2023.

[5] Mr. Hettmann ceased serving as our Chief Financial Officer on September 11, 2023, and continued to provide services to us in a non-executive capacity through November 30, 2023.

[6] Amount disclosed under the "All Other Compensation" column for Mr. Hettmann represents amounts paid in connection with his termination of employment, including (i) a cash severance payment of $175,100, representing six months of base salary, (ii) $70,040, representing 50% of his target bonus amount for 2023, and (iii) six months of Consolidated Omnibus Budget Reconciliation Act ("COBRA") coverage valued at $26,588.

Narrative to Summary Compensation Table

Annual Base Salary

Our named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. The base salary of our named executive officers is generally determined and approved by our board of directors in connection with the commencement of employment of the named executive officer and may be adjusted from time to time thereafter as the board of directors determines appropriate. The 2023 annual base salary rates for our named executive officers were as follows: (1) for Mr. McCutcheon, $500,000; (2) for Mr. Doherty, $350,000 (determined in connection with the commencement of his employment with us in September 2023); (3) for Mr. Hendricksen, $315,000; and (4) for Mr. Hettman, before his termination of employment, $350,200.

2023 Annual Performance-Based Bonuses

We generally provide each of our executive officers an opportunity to receive an annual cash incentive payment under our short-term cash incentive program. The amount of any cash incentive payable under this program is based on a target incentive amount for each named executive officer. The amount of the cash bonus will depend on the plan participant's performance during the relevant financial year and will be calculated as a percentage (between 0% to 110%) of the participant's target bonus amount. For example, a participant with a target bonus amount of $50,000 could be entitled to a bonus of, depending on performance, between $0 to $55,000. This target bonus amount will be determined by the Nomination and Remuneration Committee at the start of each year. Mr. McCutcheon's non-equity incentive opportunity for 2023 was based 70% on company-wide performance objectives, 20% individual performance objectives, and 10% on total shareholder return. Mr. Hendricksen's non-equity incentive opportunity for 2023 was based 80% on company-wide performance objectives, 15% on individual performance objectives, and 5% on total shareholder return.

The annual cash bonuses awarded to each named executive officer for 2023 performance are set forth above in the Summary Compensation Table in the column titled "Non-Equity Incentive Plan Compensation," provided, however, that if, in the Board's discretion, an amount is paid over and above the amounts earned by meeting the performance measures in the plan, such excess amount (if any) shall be set forth above in the Summary Compensation Table in the column titled "Bonus."

For 2023, the target incentive amounts and actual payments for our Named Executive Officers under our 2023 bonus plan, as determined by the Board based on its assessment of individual and company achievements throughout the year, were as follows:

Named Executive Officer	Target Award ($)	Actual Award ($)
John McCutcheon	300,000	241,727
Gary W. Doherty [(1)]	—	—
Michael Hendricksen	94,500	76,817
Frank Hettmann [(2)]	140,080	—

[(1)] Mr. Doherty's bonus for 2023 was guaranteed at target for the prorated portion of the year during which he was employed by the Company, or $43,351, and accordingly, such amount is reported in the "Bonus" column of the Summary Compensation Table.

[(2)] Mr. Hettmann received 50% of his target bonus for 2023, or $70,040, as part of his severance package. Such amount is reported in the "All Other Compensation" column of the Summary Compensation Table.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our named executive officers' interests with those of our stockholders and to retain and incentivize our named executive officers over the long term. Our board of directors is responsible for approving equity grants. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Our named executive officers generally are awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize our named executive officers with respect to achieving certain corporate goals or to reward our named executive officers for exceptional performance.

We currently grant equity incentive awards pursuant to our 2021 Equity Incentive Plan, or 2021 Plan, and previously granted awards under our 2013 Equity Incentive Plan, or 2013 Plan. The terms of our equity plans are described below under "—Equity Incentive Plans." Generally, our option awards vest over a four-year period from the date of grant, subject to the holder's continuous service to us, as further described under "—Outstanding Equity Awards as of December 31, 2023" below.

In May 2023, our board of directors granted Mr. McCutcheon, Mr. Hendricksen, and Mr. Hettmann options to purchase 675,000, 150,000, and 251,000 shares of our common stock, respectively, vesting in 48 equal monthly installments over the four years from the vesting commencement date. In connection with Mr. Doherty's commencement of employment, our board of directors granted Mr. Doherty an option to purchase 3,618,062 shares

of our common stock in September 2023, vesting 25% on the first anniversary of the vesting commencement date and the remainder in 36 equal monthly installments thereafter. Vesting of the options is subject to the named executive officer's continued service through each applicable vesting date.

Outstanding Equity Awards as of December 31, 2023

The following table sets forth information regarding outstanding stock options and stock awards held by our named executive officers as of December 31, 2023:

		Option Awards[1]			
Name	**Vesting Start Date**	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price[2] ($)**	**Option Expiration Date**
John McCutcheon	06/17/2019	5,996,154	—	0.14	11/12/2029
	10/26/2020	811,458	213,542[3]	0.12	10/27/2030
	01/28/2021	1,185,184	320,988[3]	0.12	01/27/2031
	11/22/2021	158,707	146,012[3]	0.80	11/21/2031
	05/22/2023	98,437	576,563[3]	0.44	04/03/2033
Gary W. Doherty	09/11/2023	—	3,618,062[4]	0.54	09/13/2033
Michael Hendricksen	11/15/2021	833,333	766,667[3]	0.49	02/23/2032
	05/22/2023	21,875	128,125[3]	0.66	05/21/2033
Frank Hettmann[5]	09/01/2021	1,197,900	—	0.10	08/31/2031
	05/22/2023	31,375	—	0.66	05/21/2033

(1) Each of the outstanding equity awards was granted pursuant to our 2013 Plan or 2021 Plan (each as defined below).
(2) The exercise price for each option is the fair market value of our common stock on the date of grant, as determined by our board of directors.
(3) This option vests over four years from the vesting commencement date in 48 equal monthly installments, subject to continued service through each such vesting date.
(4) This option vests over four years from the vesting commencement date, with 1/4 vesting on the first anniversary of the vesting commencement date, and the remainder vesting in 36 equal monthly installments, subject to continued service through each such vesting date.
(5) Mr. Hettmann forfeited the unvested portion of all outstanding option awards in connection with his termination of employment.

Employment Agreements with Our Named Executive Officers

John McCutcheon

We are party to an employment offer letter dated as of May 29, 2019, with Mr. McCutcheon, our President and Chief Executive Officer. The offer letter does not have a specific term and provides that Mr. McCutcheon is an at-will employee.

Mr. McCutcheon's current annual base salary is $525,000 and his current annual target under our annual cash incentive program is 60% of his annual base salary. Mr. McCutcheon is eligible for severance benefits under his current severance and change of control agreement, subject to his execution of a general release in our favor, as more fully described in "—Potential Payments upon Termination or Change of Control."

Gary W. Doherty

We are party to an employment offer letter dated as of August 29, 2023, with Mr. Doherty, our Chief Financial Officer. The offer letter does not have a specific term and provides that Mr. Doherty is an at-will employee.

Mr. Doherty's current annual base salary is $354,270 and his current annual target under our annual cash incentive program is 40% of his annual base salary. The offer letter also states that for 2023, Mr. Doherty would be entitled to a guaranteed bonus for the prorated portion of the year during which he was employed by the Company. Mr. Doherty will be eligible for severance benefits under his severance and change of control agreement, subject to his execution of a general release in our favor, as more fully described in "—Potential Payments upon Termination or Change of Control."

Michael Hendricksen

We are party to an employment offer letter dated as of October 18, 2021, with Mr. Hendricksen, our Chief Operating Officer. The offer letter does not have a specific term and provides that Mr. Hendricksen is an at-will employee.

Mr. Hendricksen's current annual base salary is $327,600 and his current annual target under our annual cash incentive program is 35% of his annual base salary. Mr. Hendricksen is eligible for severance benefits under her current severance and change of control agreement, subject to her execution of a general release in our favor, as more fully described in "—Potential Payments upon Termination or Change of Control."

Frank Hettmann

We entered into an employment offer letter dated as of April 8, 2021, with Mr. Hettmann, our former Chief Financial Officer. The offer letter did not have a specific term and provided that Mr. Hettmann was an at-will employee.

Pursuant to his offer letter, Mr. Hettmann was entitled to an initial annual base salary of $300,000 and an initial annual target under our annual cash incentive program of 15% of his annual base salary. In connection with his termination of employment in November 2023, Mr. Hettmann received certain severance benefits under his severance and change of control agreement, subject to his execution of a general release in our favor, as more fully described in "—Potential Payments upon Termination or Change of Control."

Potential Payments upon Termination or Change of Control

We provide the following severance benefits to our named executive officers in the event of a qualifying termination of employment under the terms of their employment agreements.

John McCutcheon

We have entered into a severance and change of control agreement with Mr. McCutcheon providing for (i) in the event of a termination without cause or resignation following a material change in position in the absence of a change in control, six months of base salary severance, 50% of the target bonus for the year in which the termination occurred, and six months of paid COBRA continuation premiums, or (ii) in the event of a termination without cause or resignation following a material change in position in connection with or following a change in control, six months of base salary and paid COBRA continuation premiums, along with 50% of target bonus for the year of termination, and accelerated vesting of any outstanding option and restricted stock awards that are assumed or substituted by the acquiring company, all subject to Mr. McCutcheon's general release of the Company and its affiliates. For purposes of this agreement, "material change in position" means a material reduction in Mr. McCutcheon's duties or responsibilities (other than a change in title), a relocation of Mr. McCutcheon's primary worksite more than 50 miles away from its current location, or a greater than 5% reduction in Mr. McCutcheon's base salary, target bonus, or incentive payments (other than an across-the-board reduction applicable to similarly situated employees).

Gary W. Doherty

We have entered into a severance and change of control agreement with Mr. Doherty providing for (i) in the event of a termination without cause or resignation following a material change in position in the absence of a change in control, six months of base salary severance, 50% of the target bonus for the year in which the termination occurred, and six months of paid COBRA continuation premiums, or (ii) in the event of a termination without cause or resignation following a material change in position in connection with or following a change in control, six months of base salary and paid COBRA continuation premiums, along with 50% of target bonus for the year of termination, and accelerated vesting of any outstanding option and restricted stock awards that are assumed or substituted by the acquiring company, all subject to Mr. Doherty's general release of the Company and its affiliates. For purposes of this agreement, "material change in position" is as defined above with respect to Mr. McCutcheon.

Michael Hendricksen

We have entered into a severance and change of control agreement with Mr. Hendricksen providing for (i) in the event of a termination without cause or resignation following a material change in position in the absence of a change in control, six months of base salary severance, 50% of the target bonus for the year in which the termination occurred, and six months of paid COBRA continuation premiums, or (ii) in the event of a termination without cause or resignation following a material change in position in connection with a change in control, six months of base salary and paid COBRA continuation premiums, along with 50% of target bonus for the year of termination, and accelerated vesting of any outstanding option and restricted stock awards that are assumed or substituted by the acquiring company, all subject to Mr. Hendricksen's general release of the Company and its affiliates. For purposes of this agreement, "material change in position" is as defined above with respect to Mr. McCutcheon.

Frank Hettmann

In September 2023, we entered into a transition separation agreement with Mr. Hettmann, pursuant to which his employment with the Company terminated effective November 30, 2023. In connection with the termination of Mr. Hettmann's employment with the Company, Mr. Hettmann received (i) six months of base salary severance, (ii) 50% of his target bonus for 2023, and (iii) six months of paid COBRA continuation premiums.

Equity Awards

In the event of a merger or change in control in which the successor does not assume or substitute for an option or other award outstanding under our 2021 Plan, then each option or other award outstanding under our 2021 Plan will become fully vested. In addition, our board of directors has broad discretion under the 2013 Plan and 2021 Plan with respect to the treatment of awards outstanding under that plan in connection with a merger or change in control.

Other Compensation and Benefits

Each of our named executive officers is eligible to participate in our employee benefit plans, including our medical, dental, vision, life, and long-term disability plans, in each case on the same basis as all of our other employees. We pay the premiums for the medical, dental, vision, and life insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

In addition, we provide our employees, including each of our named executive officers, the opportunity to participate in a defined contribution retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Internal Revenue Code of 1986, as amended, or the Code. Individual contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. We may elect, at our discretion, to make matching employee contributions.

Equity Incentive Plans

The material terms of our equity plans are summarized below.

2021 Equity Incentive Plan

In October 2021, our board of directors adopted, and our stockholders approved, our 2021 Plan. The 2021 Plan is the successor to and continuation of our 2013 Plan. As of the effective date of the 2021 Plan, no further grants have been made under our 2013 Plan.

Types of Awards. The 2021 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code, nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards, which are collectively referred to as stock awards. Additionally, the 2021 Plan provides for the grant of performance cash awards. Incentive stock options may be granted only to employees. All other awards may be granted to employees, directors and consultants.

Share Reserve. Subject to adjustment for certain changes in our capitalization and our "evergreen" provision, the aggregate number of shares of our common stock that may be issued under the 2021 Plan will not exceed 34,864,407 shares, as increased from time to time by any Returning Shares (as defined below) in an amount not to exceed 28,619,618 shares.

In addition, the number of shares of our common stock reserved for issuance under the 2021 Plan will automatically increase on January 1 of each year, beginning on January 1, 2023 and ending on (and including) January 1, 2031, in an amount equal to the lesser of (i) 4% of the total number of shares of our capital stock outstanding on December 31st of the preceding calendar year, and (ii) such number of shares of our capital stock determined by the plan administrator; provided, that the aggregate number of shares of our common stock that may be issued under the 2021 Plan will not exceed 18% of total number of shares of our capital stock on December 31st of the preceding calendar year. The aggregate maximum number of shares that may be issued upon the exercise of incentive stock options under the 2021 Plan is 191,052,675 shares.

The "Returning Shares" are shares of our common stock subject to outstanding stock options granted under the 2013 Plan that as of the effective date of the 2021 Plan: (i) expire or terminate for any reason prior to exercise or settlement; (ii) are forfeited or reacquired because of the failure to meet a contingency or condition required to vest such shares or are repurchased at the original issuance price; or (iii) are otherwise reacquired or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award.

If a stock award granted under the 2021 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, such expiration, termination, or settlement will not reduce (or otherwise offset) the number of shares that may be available for issuance under the 2021 Plan. In addition, the following types of shares under the 2021 Plan will revert to and again become available for issuance under the 2021 Plan: (i) shares that are forfeited to or repurchased by us prior to becoming fully vested; (ii) shares withheld to satisfy income or employment withholding taxes; or (iii) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2021 Plan may be previously unissued shares or reacquired shares bought by us on the open market.

Administration. Our board of directors, or a duly authorized committee of our board of directors, administers the 2021 Plan. Our board of directors may also delegate to one or more officers the authority to do one or more of the following: (i) designate recipients (other than officers) of specified awards and determine the terms of such awards, and (ii) determine the number of shares subject to such stock awards. Under our 2021 Plan, the plan administrator has the authority to, among other things, (i) determine award recipients, (ii) determine the numbers and types of awards to be granted, (iii) determine the terms and conditions of awards, (iv) approve the forms of award notices and agreements, (v) determine whether (and to what extent and under what circumstances) awards may be settled in cash, shares of our common stock, or other property, (vi) establish rules and regulations, and (vii) make any other determination and take any other action it deems appropriate for the administration of the 2021 Plan. Our board of

directors and nomination and remuneration committee are each considered to be a plan administrator for purposes of the 2021 Plan.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid, as applicable, by us to any individual for service as a non-employee director with respect to any calendar year, including awards granted under the 2021 Plan and cash fees paid by us to such non-employee director, will not exceed (i) $750,000 in total value or (ii) in the event such non-employee director is first appointed or elected to our board of directors during such calendar year, $1,000,000 in total value, in each case calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes.

Stock Options. ISOs and NSOs are evidenced by stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2021 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2021 Plan vest at the rate specified by the plan administrator.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our equity incentive plans may not exceed $100,000. Options or portions thereof that exceed such limit will be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are evidenced by restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (i) cash, check, bank draft or money order, (ii) services rendered to us or our affiliates or (iii) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule as determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards evidenced by restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration or for no consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Rights under a restricted stock units award may be transferred only upon such terms and conditions as set by the plan administrator. Restricted stock unit awards may be subject to vesting as determined by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are evidenced by stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount in cash or stock equal to (i) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (ii) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2021 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

Performance Awards. The 2021 Plan permits the grant of performance-based stock and cash awards. The plan administrator can structure such awards so that stock or cash will be issued or paid pursuant to such award only

after the achievement of certain pre-established performance goals during a designated performance period. The plan administrator will select one or more criteria for purposes of establishing the performance goals for a performance period. The performance criteria that will be used to establish such performance goals may be based on any measure of performance selected by the plan administrator.

The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the plan administrator in the applicable award agreement or in such other document setting forth the performance goals at the time the performance goals are established, the plan administrator will appropriately make adjustments in the method of calculating the attainment of performance goals for a performance period as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. in addition, the plan administrator retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of performance goals and to define the manner of calculating the performance criteria it selects to use for such performance period. partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the award agreement or the written terms of a performance cash award.

Other Stock Awards. The plan administrator may grant other stock awards valued in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such stock awards.

Changes to Capital Structure. In the event of certain capitalization adjustments or reorganizations of capital, the rights of the holder of a stock award will be changed to the extent necessary to comply with the listing rules applying to a reorganization of capital at the time of the reorganization, and the plan administrator will appropriately adjust: (i) the class(es) and maximum number of securities subject to the 2021 Plan; (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of ISOs; and (iii) the class(es) and number of securities and price per share of stock subject to outstanding stock awards.

Corporate Transaction and Change in Control. The following provisions will apply to stock awards in the event of a corporate transaction (as defined in the 2021 Plan and described below) unless otherwise provided in the instrument evidencing the stock award or in any other written agreement between us or one of our affiliates and the participant.

In the event of a corporate transaction, any surviving or acquiring corporation (or its parent company) may assume or continue any or all awards outstanding under the 2021 Plan, or may substitute similar awards for stock awards outstanding under the 2021 Plan (including, but not limited to, awards to acquire the same consideration paid to our stockholders pursuant to the corporate transaction), and any reacquisition or repurchase rights held by us in respect of shares of our common stock issued pursuant to stock awards under the 2021 Plan may be assigned by us to the our successor (or such successor's parent company, if any). The terms of any assumption, continuation or substitution will be set by the plan administrator.

In the event of a corporate transaction in which the surviving or acquiring corporation (or its parent company) does not assume or continue outstanding stock awards under the 2021 Plan, or substitute similar awards for such

outstanding stock awards under the 2021 Plan, then with respect to outstanding stock awards under the 2021 Plan that have not been assumed, continued or substituted and that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction (the "current participants"), the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of such corporate transaction (contingent upon the effectiveness of the corporate transaction) as the plan administrator determines (or, if the plan administrator does not determine such a date, to the date that is five days prior to the effective time of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such awards will lapse (contingent upon the effectiveness of the corporate transaction). With respect to the vesting of performance stock awards that will accelerate upon the occurrence of a corporate transaction and that have multiple vesting levels depending on the level of performance, unless otherwise provided in a participant's award agreement or unless otherwise provided by the plan administrator, the vesting of such performance stock awards will accelerate at 100% of the target level upon the occurrence of the corporate transaction. with respect to the vesting of stock awards that will accelerate upon the occurrence of a corporate transaction and are settled in the form of a cash payment, such cash payment will be made no later than 30 days following the occurrence of the corporate transaction.

In the event of a corporate transaction in which the surviving or acquiring corporation (or its parent company) does not assume or continue outstanding stock awards under the 2021 Plan or substitute similar awards for such outstanding stock awards, then with respect to stock awards under the 2021 Plan that have not been assumed, continued or substituted and that are held by persons other than the current participants, such stock awards will terminate if not exercised (if applicable) prior to the occurrence of the corporate transaction; *provided, however*, that any reacquisition or repurchase rights held by the Company with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

Notwithstanding the foregoing, in the event a stock award under the 2021 Plan held by a participant will terminate if not exercised prior to the effective time of a corporate transaction, the plan administrator may provide that the participant may not exercise such stock award but instead will receive a payment, in such form as may be determined by the plan administrator, equal in value, at the effective time, to the excess, if any, of (i) the value of the property the participant would have received upon the exercise of such stock award (including, at the discretion of the plan administrator), any unvested portion of such stock award), over (ii) any exercise price payable by the participant in connection with such exercise.

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in a participant's award agreement or as may be provided in any other written agreement or plan with us or one of our affiliates, but in the absence of such provision, no such acceleration will occur.

For purposes of the 2021 Plan, a corporate transaction generally will be deemed to occur in the event of the consummation of: (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of at least 90% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to the transaction are converted or exchanged into other property by virtue of the transaction.

For purposes of the 2021 Plan, except in connection with any initial public offering of our common stock, a change in control generally will be deemed to occur in the event: (i) a person, entity or group acquires, directly or indirectly, our securities representing more than 50% of the combined voting power of our then-outstanding securities, other than by virtue of a merger, consolidation, or similar transaction; (ii) there is consummated a merger, consolidation, or similar transaction involving us and, immediately after the consummation of such transaction, our stockholders immediately prior thereto do not own, directly or indirectly, more than 50% of the combined outstanding voting power of the surviving entity or the parent of the surviving entity in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; (iii) there is consummated a sale or other disposition of all or substantially all of our consolidated assets, other than a sale or other disposition to an entity in which more than 50% of the entity's combined voting power is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such sale or other

disposition; or (iv) a majority of our Board becomes comprised of individuals whose nomination, appointment, or election was not approved by a majority of the Board members or their approved successors.

Transferability. A participant may not transfer stock awards under our 2021 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2021 Plan.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate the 2021 Plan, provided that such action does not materially impair a participant's rights under his or her outstanding awards without such participant's written consent and provided further that certain types of amendments will require the approval of our stockholders. Unless terminated sooner by the Board, the 2021 Plan will automatically terminate on the day before the tenth anniversary of the date our board of directors adopted the 2021 Plan.

2013 Equity Incentive Plan

In June 2013, our board of directors adopted, and our stockholders approved, our 2013 Plan, which was subsequently amended from time to time. No further awards have been made under this plan since our 2021 Plan became effective.

Types of Awards. The 2013 Plan provided for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards. ISOs could be granted only to employees. All other awards could be granted to employees, directors, and consultants.

Share Reserve. The 2013 Plan provided for a maximum of 36,825,412 shares of common stock to be issued pursuant to stock awards. As of the effective date of the 2021 Plan described above, any shares of our common stock subject to awards under the 2013 Plan that (i) expire or terminate for any reason prior to exercise or settlement; (ii) are forfeited or reacquired because of the failure to meet a contingency or condition required to vest such shares or are repurchased at the original issuance price; or (iii) are otherwise reacquired or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award will become available for issuance under our 2021 Plan.

Administration. Our board of directors and our remuneration committee administer the 2013 Plan. Under our 2013 Plan, the plan administrator has the authority to, among other things, (i) determine award recipients, (ii) determine the numbers and types of awards to be granted, (iii) determine the terms and conditions of awards, (iv) approve the forms of award notices and agreements, (v) determine whether (and to what extent and under what circumstances) awards may be settled in cash, shares of our common stock, or other property, (vi) establish rules and regulations, and (vii) make any other determination and take any other action it deems appropriate for the administration of the 2013 Plan.

Changes to Capital Structure. In the event of certain capitalization adjustments, the plan administrator will appropriately adjust: (i) the class(es) and maximum number of securities subject to the 2013 Plan; (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of ISOs; and (iii) the class(es) and number of securities and price per share of stock subject to outstanding stock awards.

Corporate Transaction and Change in Control. In the event of a corporate transaction or change in control, the plan administrator has the discretion to take any of the following actions with respect to stock awards under the 2013 Plan:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for cash consideration; or

- make a payment equal to the excess of (i) the value of the property the participant would have received upon exercise of the stock award over (ii) the exercise price payable in connection with the stock award.

The plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Transferability. A participant generally may not transfer stock awards under the 2013 Plan other than by will, the laws of descent and distribution, except as the plan administrator may otherwise determine or provide in the award agreement or as otherwise provided under the 2013 Plan.

Termination. The 2013 Plan terminated as of June 17, 2023. No new stock awards have been granted under the 2013 Plan following its termination.

Director Compensation

Mr. McCutcheon does not receive compensation for his service as a director. His compensation for service as an executive officer during 2023 is disclosed in the 2023 Summary Compensation Table and related narrative disclosure.

Mr. Will is an employee director and received an annual salary of $62,400 for the year ended December 31, 2023, for his services as the Executive Chairman of the Board. Effective January 1, 2024, Mr. Will's annual salary increased to $75,000.

In April 2023, each director received an option to purchase 182,159 shares of our common stock. Each of these options was granted with an exercise price of $0.44 per share and vests in 12 equal monthly installments beginning May 22, 2023, subject to continued service with us on each applicable vesting date.

The following table sets forth information concerning the compensation for all of our directors (except Mr. McCutcheon) for the year ended December 31, 2023.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Allan Will [2]	109,900	—	56,469	—	166,369
Karen Drexler [3]	55,000	—	56,469	—	111,469
Bronwyn Evans [4]	55,000	—	56,469	—	111,469
Trevor Moody [5]	47,500	—	56,469	—	103,969
Christopher Nave [6]	55,000	—	56,469	—	111,469
David Steinhaus [7]	47,500	—	56,469	—	103,969

(1) The amounts shown represent the grant date fair values of option awards granted in 2023 as computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718. See Note 13, Stock-based compensation to our consolidated financial statements included elsewhere in this Form 10 for a discussion of the assumptions used in the calculation of these amounts.

(2) Mr. Will serves as our Executive Chairman of the Board and an annual salary for his service in addition to his board service fees. At December 31, 2023, Mr. Will had 2,717,344 outstanding options to purchase shares of common stock.

(3) At December 31, 2023, Ms. Drexler had 282,259 outstanding options to purchase shares of common stock.

(4) At December 31, 2023, Ms. Evans had 282,259 outstanding options to purchase shares of common stock.

(5) At December 31, 2023, Mr. Moody had 182,159 outstanding options to purchase shares of common stock.

(6) Mr. Nave has nominated his compensation and option awards to MRCF BTF Service (BCPIT) Pty Ltd as a trustee for MRCF BTF (BCP Investment) Trust. At December 31, 2023, Mr. Nave had 282,259 outstanding options to purchase shares of common stock.

(7) At December 31, 2023, Mr. Steinhaus had 282,259 outstanding options to purchase shares of common stock.

We have entered into a severance and change of control agreement with Mr. Will dated July 25, 2018, providing for six months of base salary severance, 50% of target bonus for the year in which the termination occurred, six months paid COBRA continuation premiums, and six months continued vesting of equity awards in the event of a termination without cause or resignation, all subject to Mr. Will's general release of the Company and its affiliates. In addition, upon a change of control Mr. Will will receive accelerated vesting of any outstanding equity awards.

Item 7. Certain Relationships and Related Transactions, and Director Independence.

There have been no transactions since January 1, 2022, to which we have been a party, in which the amount involved exceeded or will exceed $120,000 or 1% of the average of the Company's total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or beneficial owners of more than 5% of our preferred stock or common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements, which are described under "Executive Compensation" [and as described below].

Amended and Restated Investors' Rights Agreement

We are party to an Amended and Restated Investors' Rights Agreement, between, among other parties, the Company, and certain stockholders of the Company affiliated with Christopher Nave and Allan Will (a member of our board of directors and Executive Chairman).

Under the Amended and Restated Investors' Rights Agreement, the stockholder parties are entitled to customary U.S. demand, piggyback and Form S-3 registration rights with respect to certain of their shares of the Company. These rights are described in more detail below. In addition, we will pay certain expenses for those shares to be registered pursuant to the demand, piggyback and Form S-3 registration rights described below. The registration rights will expire on the date that is three years after the date of the Company's initial public offering on the ASX or at such other time as the relevant stockholder can sell all of their shares of the Company pursuant to Rule 144 or another similar exemption under the Securities Act, during a three-month period without registration.

Demand Registration Rights

The holders of at least a majority of the shares of the Company subject to the Amended and Restated Investors' Rights Agreement (the "Registrable Securities") may request that we file a registration statement under the Securities Act to register all of their Registrable Securities by means of an underwriting, the underwriters of such offering will have the right to limit the number of shares of the Company to be underwritten for reasons related to the marketing of the Registrable Securities. We will not be required to effect more than two such demand registrations. Depending on certain conditions, we may defer such registration for up to 120 days once in any 12-month period.

Piggyback Registration Rights

If we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of Registrable Securities will be entitled to certain 'piggyback' registration rights allowing them to include their Registrable Securities in such registration, subject to certain limitations. Subject to those limitations and certain other exceptions, this means that whenever we propose to file a registration statement under the Securities Act, the holders of Registrable Securities are entitled to notice of the registration and have the right to include their Registrable Securities in the registration.

Form S-3 Registration Rights

The holders of Registrable Securities will be entitled to certain Form S-3 registration rights. This means that, subject to certain qualifications, such stockholders of the Company may require us to file a Form S-3 registration statement to have their shares registered, provided that we are qualified to do so. We would not be required to effect

more than two such Form S-3 registrations in any 12-month period. Depending on certain conditions, we may defer such registration for up to 120 days once in any 12-month period.

Potential Impact of Registration Rights

Current stockholders could require us to register their shares of the Company for resale in the U.S. with their registration rights. Accordingly, such stockholders would have the opportunity to liquidate their shares in the U.S. markets, which could indirectly impact the trading price of the CDIs.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, setting forth the procedures for the identification, review, consideration, and approval or ratification of related party transactions. This policy covers any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. Transactions with related parties will also be subject to shareholder approval to the extent required by the ASX Listing Rules.

Director Independence

Information regarding the independence of our directors is described herein in the section titled "*Item 5.* Directors and Executive Officers—Director Independence."

Item 8. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising out of our operations in the normal course of business. No legal proceedings, government actions, administrative actions, investigations, or claims are currently pending against us or our officers and directors in which we are adverse.

Item 9. Market Price of, and Dividends on, the Registrant's Common Equity and Related Stockholder Matters.

Market Information

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.

Rule 144

In general, under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, a person who acquires our common stock in a transaction not registered under the Securities Act and has beneficially owned such shares for at least one year would be entitled to sell within any three-month period those shares subject to certain restrictions, including volume and manner of sale restrictions.

Under Rule 144(b) under the Securities Act, a person who is not deemed to have been one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares proposed to be sold for

at least one year, is entitled to sell the shares without complying with the volume and manner of sale restrictions of Rule 144.

We have not previously filed a registration statement under the Securities Act. Shares sold pursuant to exemptions from registration are deemed to be "restricted" securities as defined by the Securities Act. As of June 30, 2024, out of a total of 600,000,000 shares of common stock authorized, 308,113,383 shares of common stock are issued as restricted securities and can only be sold or otherwise transferred pursuant to a registration statement under the Securities Act or pursuant to an available exemption from registration. 110,077,115 (35.7%) shares are held by affiliates (directors, officers and 10% holders), with the balance of 198,036,268 (64.3%) shares being held by non-affiliates.

Holders

As of June 30, 2024, we had 308,113,383 shares of common stock outstanding, held of record by 28 stockholders. The holders included CHESS Depositary Nominees Pty Limited ("CDN"), which held 307,201,851 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 3,021 registered owners of our CDIs on June 30, 2024, a substantial majority of whom are non-U.S. holders. There were no shares of preferred stock outstanding.

Dividends

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, 2023:

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	38,214,582[(2)]	0.31	22,221,882[(3)]
Equity compensation plans not approved by security holders	—	—	—
Total	38,214,582	0.31	22,221,882

(1) The weighted-average exercise price is calculated based solely on the exercise prices of the outstanding stock options and warrants.
(2) Includes 22,155,837 stock options issued under the 2013 Stock Plan and 16,058,745 issued under the 2021 Stock Plan.
(3) Represents shares available for issuance under the 2021 Stock Plan.

Item 10. Recent Sales of Unregistered Securities.

Since July 29, 2021, we have issued the following securities that were not registered under the Securities Act:

1. From July 29, 2021, to July 29, 2024, we granted stock options to purchase an aggregate of 24,574,527 shares of common stock at exercise prices ranging from $0.33 to $0.80 per share to a total of 122 employees, consultants and directors under our 2021 Equity Incentive Plan. In addition, we granted stock options to purchase an aggregate of 709,633 shares of common stock at exercises prices ranging from $0.44 to $0.80 per share to a total of three directors under outside of our 2021 Equity Incentive Plan, and we granted stock options to purchase an aggregate of 2,871,640 shares of common stock at an exercise price of $0.10 per share to a total of nine employees, consultants and directors under our 2013 Equity Incentive Plan. Of these options, 1,266,102 shares have been exercised for cash consideration in the aggregate amount of $139,767, options to purchase 4,980,231 shares have been cancelled without being exercised and options to purchase 21,909,467 shares remain outstanding.
2. On November 23, 2021, we issued 101,851,851 shares of common stock in connection with an initial public offering (IPO) on the Australian Securities Exchange (ASX) and a concurrent private placement under Regulation D of the Securities Act (or Concurrent Placement). On November 19, 2021, we issued 147,566,974 shares of common stock in connection with the conversion of convertible bridge notes payable and related accrued interest. We raised a total of approximately $75 million, net of issuance costs of approximately $5.1 million. Of this amount, $73.6 million were net cash proceeds directly from the IPO, and $1.4 million were cash proceeds from the Concurrent Placement. In connection with the IPO, all our existing shares of preferred stock were converted into common stock. Our joint lead managers were Bell Potter Securities Limited, Morgans Limited and Wilsons Corporate Finance Limited.
3. On June 28, 2023, we issued 27,472,527 shares of common stock in connection with the first tranche of an institutional placement, and on July 10, 2023, we issued 5,494,506 shares of common stock 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.

The offers, sales and issuances of the securities described in paragraph 1 above were deemed to be exempt from registration under the Securities Act under Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

The offers, sales, and issuances of the securities described in paragraphs 2 and 3 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.

Item 11. Description of Registrant's Securities to be Registered.

The following summary describes our capital stock, including our common stock being registered hereby. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, copies of which have been filed as exhibits to this Form 10.

General

Our authorized capital stock consists of 600,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. We have no shares of preferred stock outstanding.

Common Stock

Outstanding Shares

As of June 30, 2024, we had 308,113,383 shares of common stock outstanding.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. For all matters submitted to a vote of the stockholders, the affirmative vote of a majority of the shares represented at the meeting and entitled to vote on the subject matter will be required to take such actions, including the election of directors.

Dividends

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.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights, Preferences, and Privileges

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences, and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Stock Options

As of June 30, 2024, we had outstanding options to purchase an aggregate of 39,953,154 shares of our common stock, with a weighted-average exercise price of $0.34 per share under our equity incentive plans. For additional information regarding terms of our equity incentive plans, see the section titled "*Executive and Director Compensation—Equity Incentive Plans*."

Registration Rights

The holders of our securities are entitled to certain registration rights, including 'piggyback' registration rights, which allow them to include their shares of the Company if we propose to register any of our securities under

the Securities Act; and Form S-3 registration rights, which means that, subject to certain qualifications, those stockholders may require us to file a Form S-3 registration statement to have their shares registered, provided that we are qualified to do so.

CDIs

In order for our shares of common stock in the form of CDIs to trade electronically on the ASX, we participate in the electronic transfer system known as the Clearing House Electronic Subregister System, or CHESS, operated by ASX Settlement Pty Limited, or ASX Settlement. ASX Settlement provides settlement services for ASX markets to assist participants and issuers to understand the operation of the rules and procedures governing settlement facilities. The ASX Settlement Operating Rules form part of the overall listing and market rules which we are required to comply with as an entity listed on ASX.

CHESS is an electronic system which manages the settlement of transactions executed on ASX and facilitates the paperless transfer of legal title to ASX quoted securities. CHESS cannot be used directly for the transfer of securities of companies domiciled in certain jurisdictions outside of Australia, such as the United States. Accordingly, to enable our shares of common stock to be cleared and settled electronically through CHESS, we have issued and will continue to issue depositary interests called CDIs.

CDIs confer the on the CDI holder the beneficial ownership in the shares of common stock, with one CDI representing an interest in one share. The legal title to such shares is held by CHESS Depositary Nominees Pty Limited (***CDN***), a subsidiary of ASX Limited, which acts as our Australian depositary nominee and issues the CDIs. CDI holders receive all direct economic and other benefits of the underlying shares of common stock.

A holder of CDIs who does not wish to have their trades settled in CDIs may request that their CDIs be converted into shares of common stock, in which case legal title to the shares of common stock will be transferred to the holder of CDIs.

There are a number of differences between holding CDIs and shares of common stock. The major differences are that:

- CDI holders do not have legal title in the underlying shares of common stock to which the CDIs relate (the legal title is held by CDN as summarized above); and
- CDI holders are not able to vote personally as shareholders at a meeting of EBR Systems. Instead, CDI holders are provided with a voting instruction form which enables them to instruct CDN in relation to the exercise of voting rights. Alternatively, CDI holders may instruct CDN to appoint themselves or another person as CDN's proxy with respect to the shares underlying their CDIs for the purpose of voting at shareholder meetings.

Warrants

As of June 30, 2024, we had the following warrants outstanding:

- warrants to purchase an aggregate of 309,278 shares of common stock at an exercise price of $0.82 per share and a term of 10 years expires on October 6, 2025;
- warrants to purchase an aggregate of 36,385 shares of common stock at an exercise price of $0.82 per share and a term of 10 years expires on June 30, 2026;
- warrants to purchase an aggregate of 1,950,607 shares of common stock at an exercise price of $0.41 per share and a term of 10 years expires on October 29, 2027;
- warrants to purchase an aggregate of 234,176 shares of common stock at an exercise price of $0.82 per share and a term of 10 years expires on February 28, 2028;

- warrants to purchase an aggregate of 4,438,347 shares of common stock at an exercise price of $0.59 per share and a term of 10 years expires on August 26, 2029;
- warrants to purchase an aggregate of 4,423,389 shares of common stock at an exercise price of $0.59 per share and a term of 10 years expires on March 13, 2030;
- warrants to purchase an aggregate of 441,500 shares of common stock at an exercise price of $0.14 per share and a term of 10 years expires on March 24, 2030;
- warrants to purchase an aggregate of 1,732,123 shares of common stock at an exercise price of $0.59 per share and a term of 10 years expires on February 12, 2031;
- warrants to purchase an aggregate of 3,111,787 shares of common stock at an exercise price of $0.59 per share and a term of 10 years expires on June 25, 2031; and
- warrants to purchase an aggregate of 3,111,787 shares of common stock at an exercise price of $0.59 per share and a term of 10 years expires on October 4, 2031.

Preferred Stock

Our board of directors is authorized, subject to limitations prescribed by Delaware law and the ASX Listing Rules, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences, and rights of the shares of each series and any of its qualifications, limitations, or restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by the company's stockholders unless required by the ASX Listing Rules. Our board of directors may, subject to the ASX Listing Rules, authorize the issuance of preferred stock with certain rights that could 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, have the effect of delaying, deferring, discouraging, or preventing 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.

Anti-Takeover Provisions

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as amended, include a number of provisions that may deter or impede hostile takeovers or changes of control or management. These provisions include:

Issuance of undesignated preferred stock. Our board of directors has the authority, without further action by the stockholders (unless required by the ASX Listing Rules), to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors (subject to such rights and preferences in accordance with the ASX Listing Rules.) The existence of authorized but unissued shares of preferred stock enables our board of directors to make it more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Board of directors vacancies. Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws authorize only our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors may be set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

Stockholder action; special meetings of stockholders. Our Amended and Restated Certificate of Incorporation provides that our stockholders may not take action by written consent but may only take action at annual or special meetings of our stockholders. Stockholders will not be permitted to cumulate their votes for the election of directors unless required by applicable law. Our Amended and Restated Certificate of Incorporation further provides that only the chairman of our board of directors, chief executive officer or a majority of our board of directors may call special meetings of our stockholders.

Advance notice requirements for stockholder proposals and director nominations. Our Amended and Restated Bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders. Our Amended and Restated Bylaws also specify certain requirements as to the form and content of a stockholder's notice. These provisions may make it more difficult for our stockholders to bring matters before our annual meeting of stockholders or to nominate directors at annual meetings of stockholders.

We designed these provisions to enhance the likelihood of continued stability in the composition of our board of directors and its policies, to discourage certain types of transactions that may involve an actual or threatened acquisition of us, and to reduce our vulnerability to an unsolicited acquisition proposal. We also designed these provisions to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they may also reduce fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law ("DGCL"), which prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the date the person became an interested stockholder, with the following exceptions:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.
- In general, Section 203 of the DGCL defines business combination to include the following:
- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits by or through the corporation.

In general, Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation. A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Choice of Forum

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action or proceeding asserting a claim of breach of a fiduciary duty by any of our stockholders, directors, officers, employees or agents to us or our stockholders; (3) any action or proceeding asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws or (4) any action or proceeding asserting a claim governed by the internal affairs doctrine. The exclusive forum provision does not apply to any actions brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

The provisions of Delaware law, our Amended and Restated Certificate of Incorporation, and our Amended and Restated Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our Board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Listing

Our common stock is currently listed on the Australian Securities Exchange, under the symbol "EBR".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Inc., Department CH 19228, Palatine, IL 60055-9228.

Item 12. Indemnification of Directors and Officers.

As permitted under Delaware law, EBR indemnifies certain officers and directors for certain events or occurrences that happen by reason of their relationship with, or position held at, EBR. The Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide for the indemnification of its directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law.

EBR has entered into indemnification agreements with its directors and certain officers to this effect, including advancement of expenses incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of EBR, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the Company's best interests.

Item 13. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders 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, 2023, and 2022, 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, 2023, 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, 2023, and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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

February 27, 2024 (July 29, 2024, as to the reclassification described in Note 2)

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

EBR SYSTEMS, INC.
Consolidated Balance Sheets

	December 31,	
	2023	**2022**
ASSETS		
Current assets		
Cash and cash equivalents	$ 14,578,752	$ 15,456,338
Marketable securities	57,736,274	48,073,019
Non-trade receivables and unbilled reimbursements, net	230,734	443,919
Prepaid expenses	1,446,634	2,004,441
Other current assets	382,522	607,543
Total current assets	74,374,916	66,585,260
Property and equipment, net	1,088,771	1,577,044
Right of use operating lease asset	1,719,590	1,941,138
Marketable securities	1,125,554	985,957
Other assets	589,646	589,624
TOTAL ASSETS	**$ 78,898,477**	**$ 71,679,023**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,856,134	$ 2,092,474
Accrued expenses and other liabilities	4,095,347	3,470,107
Interest payable	224,309	99,167
Operating lease liability	250,876	216,817
Current portion of notes payable, net	21,496	51,590
Total current liabilities	6,448,162	5,930,155
Other liabilities	76,946	482,448
Operating lease liability	1,670,230	1,921,106
Notes payable, net	39,646,687	19,396,221
Total liabilities	47,842,025	27,729,930
Commitments and contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Common stock, $0.0001 par value; 600,000,000 shares authorized, 307,020,758 and 270,752,201 shares issued and outstanding at December 31, 2023, and 2022, respectively	30,703	27,077
Additional paid-in capital	342,721,880	320,749,696
Accumulated deficit	(312,659,408)	(277,622,520)
Accumulated other comprehensive income	963,277	794,840
Total stockholders' equity	31,056,452	43,949,093
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 78,898,477**	**$ 71,679,023**

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,	
	2023	**2022**
Operating expenses		
Research and development	$ 27,146,026	$ 27,785,860
General and administrative	7,402,921	6,240,355
Total operating expenses	34,548,947	34,026,215
Loss from operations	(34,548,947)	(34,026,215)
Other (expense) income		
Interest expense	(4,483,731)	(1,525,795)
Interest income	3,281,440	1,118,163
Other income	718,959	1,346,759
(Loss) gain on foreign currency	(2,984)	483
Total other (expense) income	(486,316)	939,610
Loss before income tax	(35,035,263)	(33,086,605)
Income tax expense	(1,625)	(1,600)
Net loss	$ (35,036,888)	$ (33,088,205)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.12)	$ (0.12)
Weighted-average number of common shares outstanding:		
Basic and diluted	288,875,373	269,608,916

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,	
	2023	**2022**
Net loss	$ (35,036,888)	$ (33,088,205)
Other comprehensive income (loss)		
Change in unrealized gain (loss) on marketable securities	171,135	(118,218)
Foreign currency translation adjustments	(2,698)	(113,750)
Total other comprehensive income (loss)	168,437	(231,968)
Comprehensive loss	$ (34,868,451)	$ (33,320,173)

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, 2021	267,985,340	$ 26,800	$ 319,378,429	$ (244,534,315)	$ 1,026,808	$ 75,897,722
Exercise of stock options	2,766,861	277	421,317	-	-	421,594
Stock-based compensation	-	-	869,557	-	-	869,557
Adjustment to common stock issuance costs	-	-	80,393	-	-	80,393
Net loss	-	-	-	(33,088,205)	-	(33,088,205)
Other comprehensive loss	-	-	-	-	(231,968)	(231,968)
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

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

EBR SYSTEMS, INC.
Consolidated Statements of Cash Flows

	Twelve Months Ended December 31, 2023	2022
Cash flows from operating activities:		
Net loss	$ (35,036,888)	$ (33,088,205)
Adjustment to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	752,257	652,432
Amortization of deferred loan costs and discount on notes payable	476,037	210,137
Lease amortization	413,517	413,518
Stock-based compensation	1,305,811	869,557
Provision for doubtful accounts	40,485	(3,685)
Accretion of discount on marketable securities	(1,344,781)	(559,563)
Changes in operating assets and liabilities:		
Non-trade receivables and unbilled reimbursements	86,837	507,323
Prepaid expenses	556,143	(288,603)
Other assets	206,424	(452,964)
Accounts payable	(86,347)	726,456
Accrued expenses and other liabilities	215,483	1,237,650
Interest payable	126,294	(183,089)
Operating lease liability	(408,786)	(396,882)
Net cash used in operating activities	(32,697,514)	(30,355,918)
Cash flows from investing activities:		
Purchase of property and equipment	(354,054)	(730,179)
Purchase of marketable securities	(77,461,260)	(50,617,631)
Maturities and sales of marketable securities	69,174,324	2,000,000
Net cash used in investing activities	(8,640,990)	(49,347,810)
Cash flows from financing activities:		
Repayment of notes payable	-	(2,400,000)
Proceeds from notes payable	20,000,000	20,000,000
Payments of deferred loan costs	(204,075)	(794,317)
Proceeds from common stock offering	21,615,076	-
Payment of common stock offering costs	(999,949)	(213,326)
Proceeds from exercise of stock options	54,872	421,594
Net cash provided by financing activities	40,465,924	17,013,951
Effect of exchange rate change on cash	(5,006)	(96,225)
Net change in cash and cash equivalents	(877,586)	(62,786,002)
Cash and cash equivalents, beginning of the period	15,456,338	78,242,340
Cash and cash equivalents, end of the period	$ 14,578,752	$ 15,456,338
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 3,881,400	$ 1,498,747
Cash paid for income taxes	$ 775	$ 1,600

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

EBR SYSTEMS, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2023, AND 2022

Note 1 - Business and organization

Business overview

EBR Systems, Inc., and subsidiaries (collectively, "EBR", "we", "our" or the "Company") is a United States-based company dedicated to the superior treatment of cardiac rhythm disease by providing physiologically effective stimulation through leadless endocardial pacing. The Company is in the final phase of its U.S. pivotal trial and has already submitted several modules to the Food and Drug Administration ("FDA"). The Company targets final submission in 2024.

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 are 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, clinical trial accrual, and the valuation allowance on deferred taxes.

Reclassification

In 2024, the Company changed its presentation of the operating expenses in the consolidated statement of operations. Specifically, certain expenses, previously presented separately on the statement of operations, are now included either as a part of the research and development expenses, or as a part of the general and administrative expenses. As a result, the Company reclassified the prior year's balances in order to conform to the current year's presentation for the purpose of consistency of the financial statements, as shown below. These reclassifications had no impact on total operating expenses, net loss, net loss per share attributable to common stockholders, or total stockholders' equity.

	Amounts prior to reclassification	Reclassification of Sales, Clinical and Regulatory expenses into R&D	Reclassification of Marketing Expenses into G&A	Amounts post reclassification
	Year Ended December 31, 2023			
Operating expenses:				
Research and development	$ 15,822,355	$ 11,323,671	$ -	$ 27,146,026
Sales and marketing	6,894,312	(6,189,211)	(705,101)	-
Clinical and regulatory	5,134,460	(5,134,460)	-	-
General and administrative	6,697,820	-	705,101	7,402,921
Total operating expenses	$ 34,548,947	$ -	$ -	$ 34,548,947
	Year Ended December 31, 2022			
Operating expenses:				
Research and development	$ 13,228,782	$ 14,557,078	$ -	$ 27,785,860
Sales and marketing	8,107,645	(7,273,385)	(834,260)	-
Clinical and regulatory	7,283,693	(7,283,693)	-	-
General and administrative	5,406,095	-	834,260	6,240,355
Total operating expenses	$ 34,026,215	$ -	$ -	$ 34,026,215

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

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 "(Loss) gain 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 twelve-month periods ended December 31, 2023, and 2022, the Company did not make any contributions.

Segment information

Operating segments are defined as components 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 presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As such, management has determined that the Company operates as one operating segment that is focused exclusively on the advancement of the Company's leadless cardiac pacing system. Net assets outside of the U.S. were less than 10% of total net assets as of December 31, 2023, and 2022.

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 twelve-month periods ended December 31, 2023, and 2022, 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.

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. 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.

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 twelve-month periods ended December 31, 2023, and 2022, 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 12 months are recognized on the balance sheet date as right of use ("ROU") assets and current and non-current lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 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 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 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.

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 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 $3,281,440 and $1,118,163, for the twelve-month periods ended December 31, 2023, and 2022, 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. During the twelve-month periods ended December 31, 2023, and 2022, the Company recorded reimbursements of $57 and $842,552, respectively. During the twelve-month periods ended December 31, 2023, and 2022, the Company received refundable tax incentives from the Australian Taxation Office of $718,902 and $504,207, respectively, which are recorded as other income in the accompanying consolidated statements of operations.

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, FASB issued Accounting Standards Update ("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.

In November 2023, 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. This ASU is effective for fiscal years beginning after December 15, 2023. The Company believes that adoption of ASU 2023-07 will not have a material impact on the Company's consolidated financial statements.

In October 2023, the FASB issued ASU 2023-06, "*Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*" ("ASU 2023-06"). This ASU incorporates certain SEC disclosure requirements into the FASB Accounting Standards Codification ("Codification"). The amendments in the ASU are expected to clarify or improve disclosure and presentation requirements of a variety of Codification Topics, allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements, and align the requirements in the Codification with the SEC's regulations. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The adoption of this pronouncement is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In *August 2023*, the FASB issued ASU *2023-04*, "*Liabilities (Topic 405) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 121",* to amend and add various SEC paragraphs in the Accounting Standards Codification to reflect the issuance of SEC Staff Bulletin *No. 121*. The Company adopted this conforming guidance upon issuance and the adoption had *no* material impact on our consolidated financial statements and related disclosures.

In July 2023, the FASB issued ASU No. 2023-03 "*Presentation of Financial Statements (Topic 205), Income Statement – Reporting Comprehensive Income (Topic 22), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation – Stock Compensation (Topic 718): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 – General Revision of Regulation S-X: Income or Loss Applicable to Common Stock*". The ASU 2023-03 amends or supersedes various SEC paragraphs within the Codification to conform to past SEC announcements and guidance issued by the SEC. The Company adopted this conforming guidance upon issuance and the adoption had *no* material impact on our consolidated financial statements and related disclosures.

Note 3 – Cash, cash equivalents, and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following at December 31, 2023, and 2022:

	2023	2022
Cash and cash equivalents:		
Cash	$ 975,310	$ 332,255
Money market funds	11,615,762	15,124,083
US Treasury securities	1,987,680	-
Total cash and cash equivalents	$ 14,578,752	$ 15,456,338
Marketable securities, short-term:		
US Treasury securities	$ 18,991,771	$ 12,341,584
Corporate bonds	14,836,424	10,023,089
Commercial Paper	21,113,569	23,808,415
Asset backed securities	-	1,899,931
US Government Agency bonds	2,794,510	-
Total marketable securities, short-term	$ 57,736,274	$ 48,073,019
Marketable securities, long-term:		
Asset backed securities	$ 1,125,554	$ 985,957
Total marketable securities, long-term	$ 1,125,554	$ 985,957
Total cash, cash equivalents, and marketable securities	$ 73,440,580	$ 64,515,314

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. During the year ended December 31, 2022, marketable securities matured for proceeds of $2,000,000 with no gain or loss realized. 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, 2023, and 2022:

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

	As of December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
US Treasury securities	$ 12,382,149	$ -	$ (40,565)	$ 12,341,584
Corporate bonds	10,068,768	-	(45,679)	10,023,089
Commercial paper	23,808,415	-	-	23,808,415
Asset backed securities	2,917,862	-	(31,974)	2,885,888
Total marketable securities	$ 49,177,194	$ -	$ (118,218)	$ 49,058,976

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, 2023, and 2022, aggregated by major security type and the length of time the marketable securities have been in a continuous loss position:

	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
Corporate bonds	$ 2,285,253	$ (926)	$ -	$ -	$ 2,285,253	$ (926)
Commercial paper	9,439,882	(5,279)	-	-	9,439,882	(5,279)
Asset backed securities	-	-	1,125,554	(1,445)	1,125,554	(1,445)
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)

	As of December 31, 2022					
	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
US Treasury Securities	$ 12,341,584	$ (40,565)	$ -	$ -	$ 12,341,584	$ (40,565)
Corporate Bonds	10,023,089	(45,679)	-	-	10,023,089	(45,679)
Asset backed securities	2,885,888	(31,974)	-	-	2,885,888	(31,974)
Total	$ 25,250,561	$ (118,218)	$ -	$ -	$ 25,250,561	(118,218)

The contractual maturities of the Company's marketable securities as of December 31, 2023, were as follows:

	Fair Value
One year or less	$ 57,736,274
One year to two years	1,125,554
Total	$ 58,861,828

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, 2023, and 2022, the fair value measurement of the Company's financial assets measured on a recurring basis were as follows:

	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				
US Treasury securities	-	18,991,771	-	18,991,771
Corporate bonds	-	14,836,424	-	14,836,424
Commercial paper	-	21,113,569	-	21,113,569
Asset backed securities	-	1,125,554	-	1,125,554
US Government Agency bonds	-	2,794,510	-	2,794,510
Total	$ 13,603,442	$ 58,861,828	$ -	$ 72,465,270

	Fair Values as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 15,124,083	$ -	$ -	$ 15,124,083
Marketable securities				
US Treasury securities	-	12,341,584	-	12,341,584
Corporate bonds	-	10,023,089	-	10,023,089
Commercial paper	-	23,808,415	-	23,808,415
Asset backed securities	-	2,885,888	-	2,885,888
Total	$ 15,124,083	$ 49,058,976	$ -	$ 64,183,059

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. Non-trade receivables and unbilled reimbursements consisted of the following as of December 31, 2023, and 2022:

	2023	2022
Non-trade receivables	$ 237,128	$ 280,457
Unbilled reimbursements	135,772	265,143
Non-trade receivables and unbilled services	372,900	545,600
Less: allowance for doubtful accounts	(142,166)	(101,681)
Non-trade receivables and unbilled services, net	$ 230,734	$ 443,919

During the twelve-month period ended December 31, 2023, the provision for doubtful accounts totaled $40,485. During the twelve-month period ended December 31, 2022, the benefit from doubtful accounts totaled $3,685.

Property and equipment, net

Property and equipment consisted of the following as of December 31, 2023, and 2022:

	2023	2022
Equipment	$ 3,159,822	$ 2,981,787
Computer software	574,780	572,180
Leasehold improvements	499,148	415,590
Total property and equipment	4,233,750	3,969,557
Less accumulated depreciation and amortization	(3,144,979)	(2,392,513)
Total property and equipment, net	$ 1,088,771	$ 1,577,044

Depreciation and amortization expense on property and equipment was $752,257 and $652,432 for the twelve-month periods ended December 31, 2023, and 2022, respectively.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following at December 31, 2023 and 2022:

	2023	2022
Accrued compensation and related liabilities	$ 2,324,040	$ 1,980,453
Accrued development expenses	875,501	697,908
Accrued warranty reserve	826,924	734,400
Accrued other expenses	68,882	57,346
Accrued expenses and other liabilities	$ 4,095,347	$ 3,470,107

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 asset and lease liability. The Company held no other lease agreements at December 31, 2023. In January 2024, the Company signed an addendum to the operating lease, extending the expiration of the lease through June 30, 2025. Additionally, the addendum adjusted the monthly rent from $35,606 per month to $50,000 per month.

Amounts reported in the consolidated balance sheet for operating leases in which the Company is the lessee as of December 31, 2023, and 2022, were as follows:

	2023	2022
Right of use asset	$ 1,719,590	$ 1,941,138
Lease liability, current	250,876	216,817
Lease liability, noncurrent	1,670,230	1,921,106
Remaining lease term	5.50 years	6.50 years
Discount rate	10.00%	10.00%

The following table presents the components of lease costs in our statements of operations for the twelve-month periods ended December 31, 2023, and 2022:

	2023	2022
Operating lease costs	$ 413,517	$ 413,518
Variable lease costs	122,664	172,029
Short-term lease costs	-	570
Total lease expense	$ 536,181	$ 586,117

Future lease payments for non-cancellable operating leases as of December 31, 2023, were as follows:

Years Ended December 31,	
2024	$ 421,050
2025	433,682
2026	446,692
2027	460,093
2028	473,896
Thereafter	$ 240,450
Total undiscounted lease payments	2,475,863
Less: effects of discounting	(554,757)
Total operating lease liabilities	$ 1,921,106

Note 7 - Notes payable

At December 31, 2023, and 2022, notes payable consisted of the following:

	2023	2022
Current portion of notes payable	$ 21,496	$ 51,590
Long-term portion of notes payable	41,800,000	20,921,496
Less: unamortized deferred loan costs	(734,579)	(714,968)
Less: unamortized discount	(1,418,734)	(810,307)
Notes payable, net	$ 39,668,183	$ 19,447,811

The following table presents information regarding the Company's notes payable principal repayment obligations as of December 31, 2023:

Years Ended December 31,	
2024	$ 21,496
2025	-
2026	-
2027	41,800,000
Total minimum payments	$ 41,821,496

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, 2023, and 2022, the outstanding principal balance was $41,800,000 and $20,900,000, 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 ends on June 30, 2024. The Company will not receive FDA approval by June 30, 2024, and therefore will 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. 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% - 2% 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 $291,573 and $89,693 during the twelve-month period ended December 31, 2023, and 2022, respectively. This amount was recorded as additional interest expense in the accompanying consolidated statements of operations. As of December 31, 2023, and 2022, the note has been shown net of unamortized discounts of $1,418,734 and $810,307, 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 $184,464 and $79,350 for the twelve-month period ended December 31, 2023, and 2022. As of December 31, 2023, and 2022, the note has been shown net of unamortized loan costs of $734,579 and $714,968, respectively.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of December 31, 2023, and 2022, 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, 2023, and 2022, the outstanding principal balance was $21,496 and $73,086, respectively, of which $21,496 and $51,590 was included in the current portion of notes payable at December 31, 2023, and 2022, respectively.

Silicon Valley Bank – 2020

In March 2020, the Company entered into a loan and security agreement with Silicon Valley Bank and other lenders party thereto. The loan agreement provided for a term loan facility that included three tranches in a principal amount of $3,000,000, which if drawn would result in an aggregate outstanding principal amount of $9,000,000. As of December 31, 2022, the Company had repaid the outstanding principal balance under the loan agreement.

Interest on the term loan accrued on the principal amount outstanding at a floating per annum rate equal to the greater of 7.25% or 2.50% above the Prime Rate and is payable monthly in arrears. The Company was required to make interest only payments from April 2020 to June 2020. Thereafter, thirty monthly principal payments of $200,000 per month plus interest commencing July 2020 and continuing until the maturity of the note in December 2022.

During the twelve-month period ended December 31, 2022, the Company recorded interest expense of $61,424, which is included in the accompanying consolidated statements of operations. Additionally, the Company was required to make a final payment of $420,000 at the time the term loan was paid in full. This amount was recorded as additional interest expense over the life of the term loan. During the twelve-month period ended December 31, 2022, the Company recorded interest expense of $152,727, which is included in the accompanying consolidated statements of operations.

The Company incurred loan costs of $83,114, these costs were amortized over the life of the loan. Amortization of the loan costs was $30,245 during the twelve-month period ended December 31, 2022, which is included in interest expense in the accompanying consolidated statements of operations.

The note payable described above was issued with fully vested detachable warrants, which expire in March 2030. The note has been discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. Amortization of the discount was $10,848 in the twelve-month period ended December 31, 2022, which is included in interest expense in the accompanying consolidated statements of operation.

Note 8 – Convertible preferred stock

As of December 31, 2023, and 2022, 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, 2023, and 2022, no dividends have been declared.

As of December 31, 2023, and 2022, 600,000,000 shares were authorized, of which 307,020,758 shares and 270,752,201 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.

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.

Additionally, the Company has reserved the following shares of common stock for issuance as of December 31, 2023:

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	22,155,837
2021 Equity Incentive Plan	38,280,567
Total shares of Common stock reserved for issuance	80,225,783

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, 2023, and 2022. 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, 2022	19,811,028	$ 0.58	8.27
Issued	-	-	-
Expired	(21,649)	11.50	-
Balance at December 31, 2022	19,789,379	0.57	7.28
Issued	-	-	-
Expired/forfeited	-	-	-
Balance at December 31, 2023	19,789,379	$ 0.57	6.28

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, 38,280,567 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.

As of December 31, 2023, options to purchase a total of 16,058,745 shares of common stock remained outstanding and 22,221,822 shares remain available for grant under the 2021 Plan. As of December 31, 2023, options to purchase a total of 22,155,837 shares of common stock remained outstanding under the 2013 Plan. As of December 31, 2023, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the twelve-month period ended December 31, 2023, was as follows:

	Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding at January 1, 2023	32,217,927	$ 0.24	7.15
Granted	9,258,016	0.53	
Cancelled	(2,881,144)	0.28	
Exercised	(380,217)	0.14	
Outstanding at December 31, 2023	38,214,582	$ 0.31	7.09
Vested and expected to vest at December 31, 2023	38,214,582	$ 0.31	7.09
Exercisable at December 31, 2023	25,818,009	$ 0.22	6.21

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 twelve-month periods ended December 31, 2023, and 2022, was $0.37 per share and $0.29 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the twelve-month periods ended December 31, 2023, and 2022:

	2023	2022
Expected term (in years)	7.00	7.00
Expected volatility	68.03% - 72.08%	58.38% - 79.90%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	3.38% - 4.44%	1.94% - 3.49%

The following table presents classification of stock-based compensation expense within the accompanying consolidated statements of operations for the twelve-month periods ended December 31, 2023, and 2022:

	2023	2022
Research and development	$ 674,088	$ 495,433
General and administrative	631,723	374,124
Total	$ 1,305,811	$ 869,557

At December 31, 2023, there was $3,951,293 of unamortized stock-based compensation cost, respectively, related to unvested stock options which is expected to be recognized over a weighted average period of 3.15 years.

Note 12 – Income taxes

The Company recorded income tax expense of $1,625 and $1,600 for the twelve-month periods ended December 31, 2023, and 2022. The Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets.

The components of loss before income taxes are as follows:

	2023	2022
Domestic	$ (34,789,313)	$ (32,645,503)
Foreign	(245,950)	(442,702)
Total	$ (35,035,263)	$ (33,088,205)

The components of income tax expense are as follows:

	2023	2022
Current income tax expense:		
Federal	$ -	$ -
State	1,625	1,600
Foreign	-	-
Total current income tax expense	$ 1,625	$ 1,600
Deferred income tax expense:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total deferred tax expense	$ -	$ -
Net deferred tax assets	$ 1,625	$ 1,600

The Company's effective tax rate of 0.01% and 0.01% for the twelve-month periods ended December 31, 2023, and 2022, respectively, differs from the statutory U.S. federal rate as follows:

	2023	2022
Statutory tax rate	$ (7,321,441)	$ (6,973,527)
R&D credit generation	(344,374)	(370,183)
State and foreign tax benefit	(3,773,101)	(6,463,619)
Other non-deductible expenses	651,633	1,554,541
Change in valuation allowance	10,788,908	12,254,388
Effective tax rate	$ 1,625	$ 1,600

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

	2023	2022
Deferred tax assets:		
Net operating loss	$ 57,255,000	$ 48,332,000
Other accruals	870,000	829,000
Stock based compensation	457,000	249,000
Credit carryforwards	2,473,000	1,967,000
Intangible assets	12,343,000	13,409,000
Research & development capitalization	4,816,000	2,686,000
Fixed assets	39,000	-
Total deferred tax assets	78,253,000	67,472,000
Deferred tax liability		
Fixed assets	-	(9,000)
Total deferred tax liability	-	(9,000)
Net deferred tax asset before valuation allowance	78,253,000	67,463,000
Valuation allowance	(78,253,000)	(67,463,000)
Net deferred tax assets	$ -	$ -

As of December 31, 2023, the Company recorded the portion of its deferred tax assets that was 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, 2023, the Company's valuation allowance was $78,253,000, which increased by $10,788,908 for the twelve-month period ended December 31, 2023.

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 beginning in 2023. Beginning in fiscal 2024, 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 threshold, the Company is not an "Applicable Corporation". These provisions are not expected to impact the Company based on the current financial positions.

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.

As of December 31, 2023, the Company had federal NOL carryforwards of $191,303,120, available to reduce taxable income, of which $45,622,855 expire beginning 2027 and $145,680,265 do not expire. As of December 31, 2023, the Company had state NOL carryforwards of $173,133,821 available to reduce future state taxable income of which $170,893,173 expire beginning 2028 and $2,240,648 do not expire.

As of December 31, 2023, the Company had federal and state research and development credit carryforwards of $1,810,383 and $1,721,880, 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 twelve-month periods ended December 31, 2023, and 2022.

As of December 31, 2023, the Company's uncertain tax positions totaled $1,059,676, 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, but that decrease would be offset by a change in the valuation allowance given the full valuation allowance position of the Company.

The following is a roll-forward of the Company's liability related to uncertain tax positions at December 31, 2023, and 2022:

	2023	2022
Balance at January 1	$ 1,012,850	$ 656,159
Increase for current period tax positions	287,704	309,267
Decrease for release of FIN 48 reserves	(240,878)	-
Increase (decrease) for prior period tax positions	-	47,424
Balance as December 31	$ 1,059,676	$ 1,012,850

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, 2023, and 2022:

	2023	2022
Numerator – basic & diluted:		
Net loss attributable to common stockholders, basic and diluted	$ (35,036,888)	$ (33,088,205)
Denominator:		
Weighted-average number of shares outstanding, basic and diluted	288,875,373	269,608,916
Net loss per share attributable to common stockholders, basic and diluted	$ (0.12)	$ (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, 2023, and 2022:

	2023	2022
Outstanding warrants	19,789,379	19,789,379
Outstanding stock options	38,214,582	32,217,927
Total dilutive shares	58,003,961	52,007,306

Note 14 – 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, 2023, the Company's obligations under such arrangements were approximately $3,500,000.

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.

Note 15 – Subsequent Events

The Company has evaluated subsequent events that have occurred through February 27, 2024, which is the date that the consolidated financial statements were available to be issued. In January 2024, the Company signed an addendum to the operating lease, extending the expiration of the lease through June 30, 2025. Additionally, the addendum adjusted the monthly rent from $35,606 per month to $50,000 per month. No other subsequent events or transactions that required recognition or disclosure in the consolidated financial statements have been identified.

EBR SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 8,364,623	$ 14,578,752
Marketable securities	45,701,816	57,736,274
Non-trade receivables and unbilled reimbursements, net	410,774	230,734
Prepaid expenses	1,072,093	1,446,634
Other current assets	112,768	382,522
Total current assets	55,662,074	74,374,916
Property and equipment, net	842,448	1,088,771
Right of use operating lease asset	631,835	1,719,590
Marketable securities	-	1,125,554
Other assets	1,005,380	589,646
TOTAL ASSETS	**$ 58,141,737**	**$ 78,898,477**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,301,207	$ 1,856,134
Accrued expenses and other liabilities	3,474,017	4,095,347
Interest payable	223,333	224,309
Operating lease liability	547,814	250,876
Current portion of notes payable	82,029	21,496
Total current liabilities	6,628,400	6,448,162
Other liabilities	57,140	76,946
Operating lease liability	294,094	1,670,230
Notes payable, net	39,952,819	39,646,687
Total liabilities	46,932,453	47,842,025
Commitments and contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Common stock, $0.0001 par value; 600,000,000 shares authorized 308,113,383 and 307,020,758 shares issued and outstanding at June 30, 2024, and December 31, 2023, respectively	30,812	30,703
Additional paid-in capital	343,614,526	342,721,880
Accumulated deficit	(333,304,099)	(312,659,408)
Accumulated other comprehensive income	868,045	963,277
Total stockholders' equity	11,209,284	31,056,452
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 58,141,737**	**$ 78,898,477**

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

EBR SYSTEMS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 7,471,605	$ 6,663,036	$ 13,872,883	$ 12,275,827
General and administrative	3,270,321	1,614,722	5,443,436	3,303,590
Total operating expenses	10,741,925	8,277,758	19,316,319	15,579,417
Loss from operations	(10,741,925)	(8,277,758)	(19,316,319)	(15,579,417)
Other (expense) income				
Interest expense	(1,530,447)	(758,221)	(3,034,144)	(1,464,316)
Interest income	778,940	596,271	1,698,924	1,150,982
Other income (expense)	-	355,428	8,843	349,040
Loss on foreign currency	(1,256)	(53,443)	(1,995)	(52,559)
Total other (expense) income	(752,763)	140,035	(1,328,372)	(16,853)
Loss before income taxes	(11,494,688)	(8,137,723)	(20,644,691)	(15,596,270)
Income tax expense	-	-	-	-
Net loss	$ (11,494,688)	$ (8,137,723)	$ (20,644,691)	$ (15,596,270)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.04)	$ (0.03)	$ (0.07)	$ (0.06)
Weighted-average number of common shares outstanding:				
Basic and diluted	308,101,693	271,442,424	307,762,783	271,113,544

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

EBR SYSTEMS, INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net loss	$ (11,494,688)	$ (8,137,723)	$ (20,644,691)	$ (15,596,270)
Other comprehensive loss				
Change in unrealized (losses) gains on marketable securities	(23,979)	22,892	(73,406)	83,037
Foreign currency translation adjustments	7,106	48,515	(21,826)	38,528
Total other comprehensive (loss) income	(16,873)	71,407	(95,232)	121,565
Comprehensive loss	$ (11,511,561)	$ (8,066,316)	$ (20,739,923)	$ (15,474,705)

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

EBR SYSTEMS, INC.
Condensed Consolidated Statement of Changes in Stockholders' Equity
(Unaudited)

	Six Months Ended June 30, 2024					
	Common Stock		Additional	Accumulated	Total Other Comprehensive	Total Stockholders'
	Shares	Par Value	Paid-in Capital	Deficit	Income	Equity
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	1,069,500	107	110,630	-	-	110,737
Stock-based compensation	-	-	357,170	-	-	357,170
Net loss	-	-	-	(9,150,003)	-	(9,150,003)
Other comprehensive loss	-	-	-	-	(78,359)	(78,359)
Balance at March 31, 2024	308,090,258	$ 30,810	$ 343,189,680	$ (321,809,411)	$ 884,918	$ 22,295,997
Exercise of stock options	23,125	2	2,311	-	-	2,313
Stock-based compensation	-	-	422,535	-	-	422,535
Net loss	-	-	-	(11,494,688)	-	(11,494,688)
Other comprehensive loss	-	-	-	-	(16,873)	(16,873)
Balance at June 30, 2024	308,113,383	$ 30,812	$ 343,614,526	$ (333,304,099)	$ 868,045	$ 11,209,284

	Six Months Ended June 30, 2023					
	Common Stock		Additional	Accumulated	Total Other Comprehensive	Total Stockholders'
	Shares	Par Value	Paid-in Capital	Deficit	Income	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	86,431	9	11,684	-	-	11,693
Stock-based compensation	-	-	245,845	-	-	245,845
Net loss	-	-	-	(7,458,547)	-	(7,458,547)
Other comprehensive income	-	-	-	-	50,158	50,158
Balance at March 31, 2023	270,838,632	$ 27,086	$ 321,007,225	$ (285,081,067)	$ 844,998	$ 36,798,242
Stock-based compensation	-	-	276,326	-	-	276,326
Issuance of common stock, net of issuance costs	27,472,527	2,747	15,602,149	-	-	15,604,896
Net loss	-	-	-	(8,137,723)	-	(8,137,723)
Other comprehensive income	-	-	-	-	71,407	71,407
Balance at June 30, 2023	298,311,159	$ 29,833	$ 336,885,700	$ (293,218,790)	$ 916,405	$ 44,613,148

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

EBR SYSTEMS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30, 2024	2023
Cash flows from operating activities:		
Net loss	$ (20,644,691)	$ (15,596,270)
Adjustment to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	395,532	380,900
Amortization of deferred loan costs and discount on notes payable	306,132	166,986
Lease amortization	178,945	206,759
Stock-based compensation	779,705	522,171
Provision for doubtful accounts	-	40,485
Accretion of discount on marketable securities	(1,059,132)	(467,490)
Changes in operating assets and liabilities:		
Non-trade receivables and unbilled reimbursements	(180,302)	108,880
Prepaid expenses	374,226	864,430
Other assets	(158,778)	97,220
Accounts payable	430,902	(1,090,750)
Accrued expenses and other liabilities	(637,513)	(617,527)
Interest payable	(976)	14,069
Operating lease liability	(170,388)	(201,372)
Net cash used in operating activities	(20,386,338)	(15,571,509)
Cash flows from investing activities:		
Purchase of property and equipment	(156,526)	(176,799)
Purchase of marketable securities	(19,979,938)	(30,250,061)
Maturities of marketable securities	33,000,000	46,500,000
Sales of marketable securities	1,125,676	87,512
Net cash provided by investing activities	13,989,212	16,160,652
Cash flows from financing activities:		
Proceeds from notes payable	82,029	20,000,000
Payments of deferred loan costs	-	(200,000)
Proceeds from exercise of stock options	113,050	11,693
Proceeds from issuance of common stock	-	16,500,210
Payment of common stock issuance costs	-	(844,172)
Net cash provided by financing activities	195,079	35,467,731
Effect of exchange rate change on cash	(12,082)	43,880
Net change in cash and cash equivalents	(6,214,129)	36,100,754
Cash and cash equivalents, beginning of the period	14,578,752	15,456,338
Cash and cash equivalents, end of the period	$ 8,364,623	$ 51,557,092
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 2,728,988	$ 1,283,261
Cash paid for income taxes	$ 1,625	$ 750
Supplemental disclosure of non-cash investing activities:		
Remeasurement of lease liabilities	$ 908,810	$ -
Purchases of property and equipment not yet paid	$ 19,573	$ -
Accrued offering costs	$ -	$ 51,142

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

EBR SYSTEMS, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2024, AND 2023

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. The Company has completed its U.S. pivotal trial and has submitted all five modules to the Food and Drug Administration ("FDA") for the Pre-Market Approval.

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 condensed consolidated financial statements as of June 30, 2024, and for the three and six months ended June 30, 2024, and 2023 have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with our audited consolidated financial statements and the notes thereto for the year ended December 31, 2023, included in this filing.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the included disclosures are adequate, and the accompanying unaudited condensed consolidated financial statements contain all adjustments which are necessary for a fair presentation of our unaudited condensed consolidated financial position as of June 30, 2024, unaudited condensed consolidated results of operations and comprehensive loss for the three and six months ended June 30, 2024 and 2023, and unaudited condensed consolidated cash flows for the six months ended June 30, 2024 and 2023. The unaudited condensed consolidated results of operations for the three and six months ended June 30, 2024, are not necessarily indicative of the consolidated results of operations that may be expected for the year ending December 31, 2024.

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 condensed 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, clinical trial accrual, and the valuation allowance on deferred taxes.

Reclassification

In 2024, the Company changed its presentation of the operating expenses in the consolidated statement of operations. Specifically, certain expenses, previously presented separately on the statement of operations, are now included either as a part of the research and development expenses, or as a part of the general and administrative expenses. As a result, certain amounts within operating expenses for the six-month period ended June 30, 2023 have been reclassified to conform to the June 30, 2024 presentation, as shown below. These reclassifications had no impact on total operating expenses, net loss, net loss per share attributable to common stockholders, or total stockholders' equity.

	Six-month period ended June 30, 2023			
	Amounts prior to reclassification	Reclassification of Sales, Clinical and Regulatory expenses into R&D	Reclassification of Marketing Expenses into G&A	Amounts post reclassification
Operating expenses:				
Research and development	$ 6,666,983	$ 5,608,844	$ -	$ 12,275,827
Sales and marketing	3,583,928	(3,189,181)	(394,747)	-
Clinical and regulatory	2,419,663	(2,419,663)	-	-
General and administrative	2,908,843	-	394,747	3,303,590
Total operating expenses	$ 15,579,417	$ -	$ -	$ 15,579,417

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

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 "(Loss) gain 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 three and six-month periods ended June 30, 2024, and 2023, the Company did not make any contributions.

Segment information

Operating segments are defined as components 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 presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As such, management has determined that the Company operates as one operating segment that is focused exclusively on the advancement of the Company's leadless cardiac pacing system. Net assets outside of the U.S. were less than 15% of total net assets as of June 30, 2024, and December 31, 2023.

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 three and six-month periods ended June 30, 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.

EBR SYSTEMS, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2024, AND 2023

Liquidity

For the three months and six months ended June 30, 2024, the Company incurred a net loss of $11,494,688 and $20,644,691, respectively. During the six months ended June 30, 2024, the Company had negative cash flows from operations of $20,386,338. 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 June 30, 2024, the Company had working capital of $49,033,674 and accumulated deficit of $333,304,099. 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 and Note 9 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. Unbilled reimbursements represent amounts for services that have been rendered but for which reimbursements have not been billed. See Note 5, "Condensed consolidated balance sheet components" for additional information on non-trade receivables and unbilled reimbursements.

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 three and six-month periods ended June 30, 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 12 months are recognized on the balance sheet date as right of use ("ROU") assets and current and non-current lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 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 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 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.

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 FDA approval, and as such no revenue has been recorded from the sale of products. If 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 $778,940 and $596,271, for the three-month period ended June 30, 2024, and 2023, respectively, and $1,698,924 and $1,150,982, for the six-month period ended June 30, 2024, and 2023, respectively.

Other Income (Expense)

The Company periodically receives reimbursements of clinical trial expenses, which are recorded as other income in the accompanying condensed 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 three and six- month periods ended June 30, 2024, and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Clinical trial reimbursements	$ -	$ (10,740)	$ 8,843	$ (17,128)
Research and development tax incentive	-	366,168	-	366,168
Total other income (expense)	$ -	$ 355,428	$ 8,843	$ 349,040

Income taxes

The asset and liability approach is used for the financial reporting for income taxes. Deferred income balances reflect the effects of temporary differences between the financial reporting and income tax bases of the Company's assets and liabilities and are measured using enacted tax rates expected to apply when taxes are actually paid or recovered. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, or NOLs, and research and development credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse.

Income tax expense during interim periods is based on applying an estimated annual effective income tax rate to year-to-date income, plus any significant unusual or infrequently occurring items that are recorded in the interim period. The computation of the annual estimated effective tax rate at each interim period requires certain estimates and significant judgement including, but not limited to, the expected operating income for the year, projections of the proportion of income earned and taxed in various jurisdictions, permanent and temporary differences, and the likelihood of recovering deferred tax assets generated in the current year. The accounting estimates used to compute the provision for income taxes may change as new events occur, more experience is obtained, and additional information becomes known, or as the tax environment changes.

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 March 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-02, "*Codification Improvements-Amendments to Remove References to the Concepts Statements*". The amendments in this Update affect a variety of Topics in the Codification. The amendments apply to all reporting entities within the scope of the affected accounting guidance. This update contains amendments to the Codification that remove references to various Concepts Statements. This ASU is effective for public business entities for fiscal years beginning after December 15, 2024. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2025. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. The Company is currently evaluating the new guidance. The adoption of ASU 2024-02 is not expected to have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In March 2024, the FASB issued ASU 2024-01, "*Compensation—Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards*", which provides illustrative guidance to help entities determine whether profits interest and similar awards should be accounted for as share-based payment arrangements within the scope of ASC 718. ASU 2024-01 is effective for annual periods beginning after December 15, 2024, and interim periods within those annual periods. The Company is currently evaluating the new guidance. The adoption of ASU 2024-02 is not expected to have a material impact on the Company's condensed consolidated financial statements and related disclosures.

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 condensed 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. This ASU is effective for interim periods with fiscal years beginning after December 15, 2024. The Company believes that adoption of ASU 2023-07 will not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In October 2023, the FASB issued ASU 2023-06, "*Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*" ("ASU 2023-06"). This ASU incorporates certain SEC disclosure requirements into the FASB Accounting Standards Codification ("Codification"). The amendments in the ASU are expected to clarify or improve disclosure and presentation requirements of a variety of Codification Topics, allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements, and align the requirements in the Codification with the SEC's regulations. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The adoption of this pronouncement is not expected to have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In *August 2023*, the FASB issued ASU *2023-04*, "*Liabilities (Topic 405) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 121",* to amend and add various SEC paragraphs in the Accounting Standards Codification to reflect the issuance of SEC Staff Bulletin *No. 121*. The Company adopted this conforming guidance upon issuance and the adoption had *no* material impact on the Company's condensed consolidated financial statements and related disclosures.

In July 2023, the FASB issued ASU No. 2023-03 "*Presentation of Financial Statements (Topic 205), Income Statement – Reporting Comprehensive Income (Topic 22), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation – Stock Compensation (Topic 718): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 – General Revision of Regulation S-X: Income or Loss Applicable to Common Stock*". The ASU 2023-03 amends or supersedes various SEC paragraphs within the Codification to conform to past SEC announcements and guidance issued by the SEC. The Company adopted this conforming guidance upon issuance and the adoption had no material impact on the Company's condensed consolidated financial statements and related disclosures.

Note 3 – Cash, cash equivalents, and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following at June 30, 2024, and December 31, 2023:

	June 30, 2024	December 31, 2023
Cash and cash equivalents:		
Cash	$ 594,821	$ 975,310
Money market funds	7,769,802	11,615,762
US Treasury securities	-	1,987,680
Total cash and cash equivalents	$ 8,364,623	$ 14,578,752
Marketable securities, short-term:		
US Treasury securities	$ 17,572,070	$ 18,991,771
Corporate bonds	19,925,503	14,836,424
Commercial Paper	8,204,243	21,113,569
US Government Agency bonds	-	2,794,510
Total marketable securities, short-term	$ 45,701,816	$ 57,736,274
Marketable securities, long-term:		
Asset backed securities	$ -	$ 1,125,554
Total marketable securities, long-term	$ -	$ 1,125,554
Total cash, cash equivalents, and marketable securities	$ 54,066,439	$ 73,440,580

During the six-month period ended June 30, 2024, marketable securities were sold or matured for proceeds of $34,125,676 with no gain or loss realized. During the six-month period ended June 30, 2023, marketable securities matured for proceeds of $46,587,512 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 June 30, 2024, and December 31, 2023:

	As of June 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
US Treasury securities	$ 17,583,327	$ 342	$ (11,599)	$ 17,572,070
Corporate bonds	19,929,413	2,233	(6,143)	19,925,503
Commercial paper	8,209,565	-	(5,322)	8,204,243
Total marketable securities	$ 45,722,305	$ 2,575	$ (23,064)	$ 45,701,816

	As of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
US Treasury securities	$ 18,972,928	$ 18,843	$ -	$ 18,991,771
Corporate bonds	14,811,749	25,601	(926)	14,836,424
Commercial paper	21,101,403	17,445	(5,279)	21,113,569
Asset backed securities	1,126,999	-	(1,445)	1,125,554
US Government Agency bonds	2,796,078	1,297	(2,865)	2,794,510
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 June 30, 2024, and December 31, 2023, aggregated by major security type and the length of time the marketable securities have been in a continuous loss position:

	As of June 30, 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
US Treasury Securities	$ 14,440,436	$ (11,599)	$ -	$ -	$ 14,440,436	$ (11,599)
Corporate bonds	14,040,466	(6,143)	-	-	14,040,466	(6,143)
Commercial paper	8,204,243	(5,322)	-	-	8,204,243	(5,322)
Total	$ 36,685,145	$ (23,064)	$ -	$ -	$ 36,685,145	$ (23,064)

	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
Corporate bonds	$ 2,285,253	$ (926)	$ -	$ -	$ 2,285,253	$ (926)
Commercial paper	9,439,882	(5,279)	-	-	9,439,882	(5,279)
Asset backed securities	-	-	1,125,554	(1,445)	1,125,554	(1,445)
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)

All of the Company's marketable securities totaling $45,701,816 as of June 30, 2024, mature in less than one year.

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 June 30, 2024, and December 31, 2023, the fair value measurement of the Company's financial assets measured on a recurring basis were as follows:

	Fair Values as of June 30, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 7,769,802	$ -	$ -	$ 7,769,802
Marketable securities				
US Treasury securities	-	17,572,070	-	17,572,070
Corporate bonds	-	19,925,503	-	19,925,503
Commercial paper	-	8,204,243	-	8,204,243
Total	$ 7,769,802	$ 45,701,816	$ -	$ 53,471,618

	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				
US Treasury securities	-	18,991,771	-	18,991,771
Corporate bonds	-	14,836,424	-	14,836,424
Commercial paper	-	21,113,569	-	21,113,569
Asset backed securities	-	1,125,554	-	1,125,554
US Government Agency bonds	-	2,794,510	-	2,794,510
Total	$ 13,603,442	$ 58,861,828	$ -	$ 72,465,270

In the Company's condensed 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 – Condensed Consolidated balance sheet components

Non-trade receivables and unbilled reimbursements, net

Non-trade receivables and unbilled reimbursements include the 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 June 30, 2024, and December 31, 2023:

	June 30, 2024	December 31, 2023
Non-trade receivables	$ 417,168	$ 237,128
Unbilled reimbursements	135,772	135,772
Non-trade receivables and unbilled services	552,940	372,900
Less: allowance for doubtful accounts	(142,166)	(142,166)
Non-trade receivables and unbilled services, net	$ 410,774	$ 230,734

Bad debt expense for the three and six-month periods ended June 30, 2024 and 2023 was $0 and $40,485, respectively.

Property and equipment, net

Property and equipment consisted of the following as of June 30, 2024 and December 31, 2023:

	June 30, 2024	December 31, 2023
Equipment	$ 3,293,373	$ 3,159,822
Computer software	574,780	574,780
Leasehold improvements	513,727	499,148
Total property and equipment	4,381,880	4,233,750
Less accumulated depreciation and amortization	(3,539,432)	(3,144,979)
Total property and equipment, net	$ 842,448	$ 1,088,771

Depreciation and amortization expense for the three-month period ended June 30, 2024 and 2023 was $182,441 and $190,199, respectively. Depreciation and amortization expense for the six-month period ended June 30, 2024 and 2023 was $395,532 and $380,900, respectively. There were no impairments recorded during the three and six-month periods ended June 30, 2024 and 2023.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following at June 30, 2024 and December 31, 2023:

	June 30, 2024	December 31, 2023
Accrued compensation and related liabilities	$ 2,116,099	$ 2,324,040
Accrued development expenses	602,420	875,501
Accrued warranty reserve	749,575	826,924
Accrued other expenses	5,923	68,882
Accrued expenses and other liabilities	$ 3,474,017	$ 4,095,347

EBR SYSTEMS, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2024, AND 2023

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 asset and lease liability. The Company held no other lease agreements at December 31, 2023. 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 asset and corresponding 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 asset and corresponding 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.

Amounts reported in the condensed consolidated balance sheets for operating leases in which the Company is the lessee as of June 30, 2024, and December 31, 2023, were as follows:

	June 30, 2024	December 31, 2023
Right of use asset	$ 631,835	$ 1,719,590
Lease liability, current	547,814	250,876
Lease liability, noncurrent	294,094	1,670,230
Remaining lease term	1.50 years	5.50 years
Discount rate	10.00%	10.00%

The following table presents the components of lease costs in our statements of operations for three and six-month periods ended June 30, 2024, and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease costs	$ 114,988	$ 103,380	$ 215,971	$ 206,759
Variable lease costs	33,619	30,620	64,330	61,241
Total lease expense	$ 148,607	$ 134,000	$ 280,301	$ 268,000

Future lease payments for non-cancellable operating leases as of June 30, 2024, were as follows:

Years Ended December 31,	
2024	$ 300,000
2025	600,000
Total undiscounted lease payments	900,000
Less: effects of discounting	(58,092)
Total operating lease liabilities	$ 841,908

Note 7 - Notes payable

At June 30, 2024 and December 31, 2023, notes payable consisted of the following:

	June 30, 2024	December 31, 2023
Current portion of notes payable	$ 82,029	$ 21,496
Long-term portion of notes payable	41,800,000	41,800,000
Less: unamortized deferred loan costs	(629,648)	(734,579)
Less: unamortized discount	(1,217,533)	(1,418,734)
Notes payable, net	$ 40,034,848	$ 39,668,183

The following table presents information regarding the Company's notes payable principal repayment obligations as of June 30, 2024:

Years Ended December 31,	
2024	$ 44,743
2025	37,286
2026	-
2027	41,800,000
Total minimum payments	$ 41,882,029

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 June 30, 2024, and December 31, 2023, the outstanding principal balance was $41,800,000. 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 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.

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 $100,725 and $44,605 for the three-month period ended June 30, 2024 and 2023, respectively. Amortization of the discount was $201,201 and $88,624 for the six-month period ended June 30, 2024 and 2023, respectively. This amount was recorded as additional interest expense in the accompanying condensed consolidated statements of operations. As of June 30, 2024 and December 31, 2023, the note has been shown net of unamortized discounts of $1,217,533 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 $52,499 and $39,435 for the three-month period ended June 30, 2024 and 2023, respectively. Amortization of loan costs was $104,931 and $78,362 for the six-month period ended June 30, 2024 and 2023, respectively. As of June 30, 2024 and December 31, 2023, the note has been shown net of unamortized loan costs of $629,648 and $734,579, respectively.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of June 30, 2024, and December 31, 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 June 30, 2024, and December 31, 2023, the outstanding principal balance was $0 and $21,496, respectively, and was included in the current portion of notes payable in the condensed 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 June 30, 2024, the outstanding principal balance was $82,029 and was included in the current portion of notes payable in the condensed consolidated balance sheets.

Note 8 – Convertible preferred stock

As of June 30, 2024, and December 31, 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 June 30, 2024, and December 31, 2023, no dividends have been declared.

As of June 30, 2024 and December 31, 2023, 600,000,000 shares were authorized, of which 308,113,383 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.

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.

Additionally, the Company has reserved the following shares of common stock for issuance as of June 30, 2024:

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	20,865,312
2021 Equity Incentive Plan	37,768,834
Outside of 2021 Equity Incentive Plan	709,633
Total shares of Common stock reserved for issuance	79,133,158

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 June 30, 2024, and December 31, 2023. These warrants are exercisable any time at the option of the holder until their expiration date.

	Number of Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Balance at December 31, 2023	19,789,379	$ 0.57	6.28
Issued	-	-	-
Expired/forfeited	-	-	-
Balance at June 30, 2024	19,789,379	$ 0.57	5.78

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, 37,768,834 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.

As of June 30, 2024, options to purchase a total of 18,378,209 shares of common stock remained outstanding and 19,390,625 shares remain available for grant under the 2021 Plan and 709,633 remained outstanding outside of the 2021 Plan. As of June 30, 2024, options to purchase a total of 20,865,312 shares of common stock remained outstanding under the 2013 Plan. As of June 30, 2024, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the six-month period ended June 30, 2024, was as follows:

	Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2023	38,214,582	$ 0.31	7.09
Granted	5,136,322	0.58	
Cancelled	(2,305,125)	0.46	
Exercised	(1,092,625)	0.10	
Outstanding at June 30, 2024	39,953,154	$ 0.34	6.92
Vested and expected to vest at June 30, 2024	39,953,154	$ 0.34	6.92
Exercisable at June 30, 2024	25,562,473	$ 0.23	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 six-month periods ended June 30, 2024 and 2023, was $0.39 per share and $0.39 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the six-month periods ended June 30, 2024 and 2023:

	Six Months Ended June 30,	
	2024	2023
Expected term (in years)	7.00	7.00
Expected volatility	66.49% - 67.34%	71.34% - 72.08%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	4.28% -4.71%	3.38%-3.74%

The following table presents classification of stock-based compensation expense within the accompanying condensed consolidated statements of operations for the three and six-month periods ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 189,089	$ 152,928	$ 328,024	$ 295,299
General and administrative	233,447	123,398	451,681	226,872
Total	$ 422,536	$ 276,326	$ 779,705	$ 522,171

At June 30, 2024, there was $4,740,714 of unamortized stock-based compensation cost, respectively, related to unvested stock options which is expected to be recognized over a weighted average period of 3.19 years.

Note 12 – Income taxes

During the three and six-month periods ended June 30, 2024, and 2023, the Company does not have an income tax benefit or expense. The Company has historically incurred net operating losses and maintains a full valuation allowance against its net deferred tax assets. Valuation allowances are recorded when the expected realization of the deferred tax assets does not meet a "more likely than not" criterion. Realization of the Company's deferred tax assets are dependent upon the generation of future taxable income, the amount and timing of which are uncertain.

The Company's effective tax rate was 0% for the three and six-month periods ended June 30, 2024 and 2023. The difference between the effective tax rate and the federal statutory rate of 21% was primarily due to the full valuation allowance recorded on the Company's net deferred tax assets, state and foreign tax benefit, research and development tax credit, and other non-deductible expenses.

During the six-month period ended June 30, 2024, there were no material changes to the Company's uncertain tax positions.

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 for the three and six-month periods ended June 30, 2024, and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator – basic & diluted:				
Net loss attributable to common stockholders, basic and diluted	$(11,494,688)	$ (8,137,723)	$(20,644,691)	$(15,596,270)
Denominator:				
Weighted-average number of shares outstanding, basic and diluted	308,101,693	271,442,424	307,762,783	271,113,544
Net loss per share attributable to common stockholders, basic and diluted	$ (0.04)	$ (0.03)	$ (0.07)	$ (0.06)

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 June 30, 2024 and 2023:

	June 30, 2024	June 30, 2023
Outstanding warrants	19,789,379	19,789,379
Outstanding stock options	39,953,154	35,379,828
Total dilutive shares	59,742,533	55,169,207

Note 14 – 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 June 30, 2024, the Company's obligations under such arrangements were approximately $12,500,000.

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 condensed consolidated financial statements.

Note 15 – Subsequent Events

The Company has evaluated subsequent events that have occurred through September 17, 2024, which is the date that the condensed consolidated financial statements were available to be issued and determined that there were no subsequent events or transactions that required recognition or disclosure in the condensed consolidated financial statements, except as discussed in Note 6 above.

Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 15. Financial Statements and Exhibits.

Exhibit Number	Exhibit Description	
3.1	Amended and Restated Certificate of Incorporation	
3.2*	Amended and Restated Bylaws	
4.1*	Reference is made to Exhibits 3.1 and 3.2	
4.2	Amended and Restated Investors' Rights Agreement, dated October 13, 2021, between the Company and the parties thereto.	
4.3	Form of Warrant to Purchase Stock issued on March 25, 2020	
4.4	Warrant to Purchase Stock, dated October 30, 2017, between the Company and M.H. Carnegie Co. Pty Ltd	
4.5*	Form of Warrant to Purchase Stock issued between August 26, 2019, and October 4, 2021	
4.6*	Form of Warrant to Purchase Stock issued between October 6, 2015, and February 28, 2018	
10.1*	Loan and Security Agreement, dated June 28 2022, between the Company and Runway Growth Finance Corp†	
10.2*	Standard Industrial/Commercial Multi—Tenant Lease, dated March 30, 2017, between the Company and 480 Oakmead Properties, LLC (the "Oakmead Lease")†	
10.3	Addendum "B" to the Oakmead Lease, dated January 2024, between the Company and 480 Oakmead Properties, LLC†	
10.4	Addendum "C" to the Oakmead Lease, dated March 2024, between the Company and 480 Oakmead Properties, LLC†	
10.5	Addendum "D" to the Oakmead Lease, dated July 2024, between the Company and 480 Oakmead Properties, LLC†	
10.6	Offer Letter entered into between the Company and John McCutcheon, dated May 29, 2019#	
10.7	Offer Letter entered into between the Company and Allan Will, dated August 21, 2019#	
10.8	Offer Letter entered into between the Company and Gary Doherty, dated August 29, 2023#	
10.9	Offer Letter entered into between the Company and Michael Hendricksen, dated October 27, 2021#	
10.10	Offer Letter entered into between the Company and Frank Hettmann, dated April 8, 2021#	
10.11*	Form of Severance and Change of Control Agreement entered into between the Company and each of its executive officers#	
10.12*	2021 Equity Incentive Plan, as amended#	
10.13*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Equity Incentive Plan (Australian Grants)#	
10.14*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Equity Incentive Plan (United Kingdom Grants)#	
10.15*	Australian Sub-Plan under the 2021 Equity Incentive Plan#	
10.16*	United Kingdom Sub-Plan under the 2021 Equity Incentive Plan#	
10.17*	2013 Equity Incentive Plan, as amended#	
10.18*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2013 Equity Incentive Plan#	
10.19	Form of Indemnification Agreement entered into between the Company and each of its directors and executive officers#	
21.1*	List of Subsidiaries	

*Previously filed

#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.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this amendment no. 1 to the registration statement 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

Date: September 17, 2024