ASX ANNOUNCEMENT **13 NOVEMBER 2024**

Q3 2024 Quarterly Activity Report and Form 10-Q submission

Key Highlights:

- EBR submitted the final module of its PMA application for its WiSE® CRT System to the U.S. FDA in August 2024
- The FDA formally accepted EBR's PMA application and commenced substantive review to assess the safety and effectiveness of EBR's WiSE CRT System, with an effective date of 29 August 2024
- EBR anticipates FDA regulatory approval in Q1 2025, with expected commercial launch later in 2025
- EBR launched a A$50m capital raising to support the manufacturing scale up and commercialisation of EBR's WiSE CRT System, to drive initial adoption in high volume US clinical sites and initial revenue in 2025
- EBR holds cash and short-term investments of US$74.2m / A$107.2m[1] as at 30 September 2024

Sunnyvale, California; 13 November 2024: EBR Systems, Inc. (ASX: **"EBR"**, **"EBR Systems"**, or the **"Company"**), developer of the world's only wireless cardiac pacing device for heart failure, is pleased to release its Quarterly Activity Report and Form 10-Q submission for the quarter ended 30 September 2024 ("**Q3 2024**").

John McCutcheon, EBR Systems' President & Chief Executive Officer said:

"We've had a significant milestone quarter, underpinned by our submission of the final PMA module and the FDA confirming that their substantive review is now underway. We are now in the final stages of our regulatory approval process and continue to maintain strong momentum towards anticipated approval in Q1 2025. We also successfully completed a A$50m capital raising, ensuring that we're well-funded to accelerate our commercialisation strategy and drive adoption in the US market in 2025. We wanted to take the opportunity to thank our securityholders for their ongoing support. We're excited about the upcoming quarter and look forward to updating shareholders on our continued progress and exciting developments."

Final module of PMA application submitted, and FDA confirms substantive review is underway

In August 2024, EBR Systems submitted the final Premarket Approval (PMA) module for its WiSE CRT (Cardiac Resynchronisation Therapy) System to the U.S. Food and Drug Administration (FDA). EBR's PMA application was subject to an initial review period to confirm that it is administratively complete and that technical elements of the application are adequate. EBR's PMA application includes extensive technical documentation and clinical data.

In September 2024, the FDA completed the initial review of the EBR PMA application and formally accepted the PMA application for substantive review. This phase will involve a comprehensive evaluation process of the PMA application, further feedback and information requests prior to a decision on approval. Key assessments include a Bioresearch Monitoring (BIMO) audit and a Pre-Approval Inspection (PAI). The Breakthrough Device designation for WiSE facilitates prioritised review and enhanced communication with the FDA. The Company anticipates FDA approval in Q1 2025.

The Company is gearing up for the commercial launch of WiSE in 2025, targeting the significant U.S. market opportunity of US$3.6bn initially. Preparation is currently underway to support key commercialisation activities such as manufacturing scale-up (including initial tooling). EBR will leverage established partnerships and presence in the US to drive initial sales, targeting US sites that participated in the SOLVE-CRT trial and other high-volume sites.

In August 2024, SOLVE-CRT study results were published in the *Journal of the American Medical Associate (JAMA) Cardiology*, which reinforces the trial's clinical significance. *JAMA Cardiology* is a leading international peer-reviewed

[1] Assumes an A$:US$ 0.69225 exchange rate

journal for clinical investigators, clinicians and trainees in cardiovascular medicine worldwide. The journal is highly selective, typically with ~10% of submissions accepted for publication.

Active media and investor engagement

In July 2024, EBR's management attended the 18th Bioshares Biotech Summit held in Fremantle, Western Australia. The Bioshares Biotech Summit is a high-profile investment conference for Australia's biotech sector.

In addition, EBR completed an Australian roadshow from 30 September to 2 October 2024, engaging with institutional and retail investors across Brisbane, Melbourne, and Sydney. The presentations focused on updates regarding the regulatory approval process, commercialisation pathway, recent *JAMA* publication, capital raising and outlook.

Corporate Update

In September 2024, EBR launched a A$50m capital raise composed of a fully underwritten institutional placement and fully underwritten 1-for-20 accelerated non-renounceable pro-rata entitlement offer – composed of an accelerated institutional entitlement offer and a retail entitlement offer. The funds raised will be used to primarily support commercialisation activities, manufacturing scale-up (including initial tooling) and ongoing research and development. The institutional placement and accelerated institutional entitlement offer raised A$45.8m and was successfully completed on 20 September 2024. Subsequent to quarter end, EBR successfully completed the A$4.2m retail entitlement offer on 10 October 2024

During the quarter, EBR had net operating cash outflows of US$9.9m / A$14.3m[2], mostly relating to staff costs, clinical and regulatory costs, general and administrative costs, and interest expense. In addition to its cash balance of US$36.4m / A$52.6m[2] on 30 September 2024, EBR held US$37.8m / A$54.6m[2] in investments which will become cash or cash equivalents in the future. Investments are made in fixed income instruments, have a weighted average maturity of 4.4 months, and have a minimum credit rating of A-2/P-2/F2 by at least 2 of 3 Nationally Recognised Statistical Rating Organisations, specifically Standard & Poor's, Moody's, or Fitch.

EBR filed a Form 10 Registration with the U.S. Securities and Exchange Commission (SEC) on 30 July 2024 for the Registration of Securities, pursuant to Section 12(b) or 12(g) of the U.S. Securities Exchange Act of 1934. EBR's Form 10 Registration was declared effective by the U.S. SEC on 30 September 2024. As such, EBR is now both a U.S. public reporting company and ASX-listed entity, subject to periodic reporting requirements of the U.S. Securities and Exchange Act of 1934 and Chapter 4 of the ASX Listing Rules, respectively. EBR has been granted a waiver from ASX Listing Rules 4.2A.3, 4.3A, 4.7B and 4.7C effective from 1 October 2024, which relieves the Company of the time and expense of the preparation and lodgement of two sets of periodic reports each relevant reporting period.

ENDS

This announcement has been authorised for release by the EBR Systems Finance Disclosure Committee, a committee of the Board of Directors

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[2] Assumes an A$:US$ 0.69225 exchange rate

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About EBR Systems

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 applications 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.

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For the transition period from _____to

Commission file number: 000-56671

EBR SYSTEMS, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

Not applicable.
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

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

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

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

As of November 12, 2024, the registrant had 370,776,200 shares of common stock, par value $0.0001 per share, including shares underlying all issued and outstanding Chess Depository Interests ("CDIs"), outstanding.

EBR SYSTEMS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2024

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ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 36,411,214	$ 14,578,752
Marketable securities	37,176,846	57,736,274
Non-trade receivables and unbilled reimbursements, net	53,564	230,734
Prepaid expenses	801,720	1,446,634
Other current assets	168,236	382,522
Total current assets	74,611,580	74,374,916
Property and equipment, net	924,276	1,088,771
Right of use operating lease asset	1,031,009	1,719,590
Marketable securities	593,906	1,125,554
Other assets	1,662,842	589,646
TOTAL ASSETS	**$ 78,823,613**	**$ 78,898,477**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,007,001	$ 1,856,134
Accrued expenses and other liabilities	3,924,714	4,095,347
Interest payable	223,333	224,309
Operating lease liability	510,121	250,876
Current portion of notes payable	59,657	21,496
Total current liabilities	6,724,826	6,448,162
Other liabilities	44,343	76,946
Operating lease liability	709,953	1,670,230
Notes payable, net	40,108,049	39,646,687
Total liabilities	47,587,171	47,842,025
Commitments and contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Common stock, $0.0001 par value; 600,000,000 shares authorized 364,044,810 and 307,020,758 shares issued and outstanding at September 30, 2024, and December 31, 2023, respectively	36,405	30,703
Common stock to be issued, net of issuance costs; $0.0001 par value, 5,075,733 and 0 shares to be issued as of September 30, 2024 and December 31, 2023, respectively	2,595,864	-
Common stock receivable, net of issuance costs	(2,595,864)	-
Additional paid-in capital	373,587,659	342,721,880
Accumulated deficit	(343,360,016)	(312,659,408)
Accumulated other comprehensive income	972,394	963,277
Total stockholders' equity	31,236,442	31,056,452
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 78,823,613**	**$ 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 6,298,423	$ 6,956,135	$ 20,171,306	$ 19,231,962
General and administrative	2,878,562	1,837,801	8,321,998	5,141,391
Total operating expenses	9,176,985	8,793,936	28,493,304	24,373,353
Loss from operations	(9,176,985)	(8,793,936)	(28,493,304)	(24,373,353)
Other (expense) income				
Interest expense	(1,525,746)	(1,515,155)	(4,559,890)	(2,979,471)
Interest income	651,314	1,079,528	2,350,238	2,230,510
Other income	1,618	41,386	10,461	390,426
(Loss) gain on foreign currency	(6,118)	55,712	(8,113)	3,153
Total other (expense) income	(878,932)	(338,529)	(2,207,304)	(355,382)
Loss before income taxes	(10,055,917)	(9,132,465)	(30,700,608)	(24,728,735)
Income tax expense	-	-	-	-
Net loss	$ (10,055,917)	$ (9,132,465)	$ (30,700,608)	$ (24,728,735)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.03)	$ (0.03)	$ (0.10)	$ (0.09)
Weighted-average number of common shares outstanding:				
Basic and diluted	311,192,703	305,692,267	308,914,435	282,766,448

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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Net loss	$ (10,055,917)	$ (9,132,465)	$ (30,700,608)	$ (24,728,735)
Other comprehensive income (loss)				
Change in unrealized gains on marketable securities	103,165	14,603	29,759	97,640
Foreign currency translation adjustments	1,184	(76,654)	(20,642)	(38,126)
Total other comprehensive income (loss)	104,349	(62,051)	9,117	59,514
Comprehensive loss	$ (9,951,568)	$ (9,194,516)	$ (30,691,491)	$ (24,669,221)

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)

	Nine Months Ended September 30, 2024								
	Common Stock		Common Stock To Be Issued		Common Stock Receivable	Additional Paid-in Capital	Accumulated Deficit	Total Other Comprehensive Income	Total Stockholders' Equity
	Shares	Par Value	Shares	Amount					
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
Exercise of stock options	75,102	8	-	-	-	18,575	-	-	18,583
Stock-based compensation	-	-	-	-	-	476,321	-	-	476,321
Issuance of common stock, net of issuance costs	55,856,325	5,585	-	-	-	29,478,237	-	-	29,483,822
Common stock receivable in connection with offering, net of issuance costs	-	-	5,075,733	2,595,864	(2,595,864)	-	-	-	-
Net loss	-	-	-	-	-	-	(10,055,917)	-	(10,055,917)
Other comprehensive income	-	-	-	-	-	-	-	104,349	104,349
Balance at September 30, 2024	364,044,810	$ 36,405	5,075,733	$ 2,595,864	$ (2,595,864)	$ 373,587,659	$ (343,360,016)	$ 972,394	$ 31,236,442

	Nine Months Ended September 30, 2023								
	Common Stock		Common Stock To Be Issued		Common Stock Receivable	Additional Paid-in Capital	Accumulated Deficit	Total Other Comprehensive Income	Total Stockholders' Equity
	Shares	Par Value	Shares	Amount					
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
Exercise of stock options	243,786	24	-	-	-	33,742	-	-	33,766
Stock-based compensation	-	-	-	-	-	351,426	-	-	351,426
Issuance of common stock, net of issuance costs	8,415,813	841	-	-	-	5,009,390	-	-	5,010,231
Net loss	-	-	-	-	-	-	(9,132,465)	-	(9,132,465)
Other comprehensive loss	-	-	-	-	-	-	-	(62,051)	(62,051)
Balance at September 30, 2023	306,970,758	$ 30,698	-	$ -	$ -	$ 342,280,258	$ (302,351,255)	$ 854,354	$ 40,814,055

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)

	Nine Months Ended September 30, 2024	2023
Cash flows from operating activities:		
Net loss	$ (30,700,608)	$ (24,728,735)
Adjustment to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	496,844	572,882
Amortization of deferred loan costs and discount on notes payable	461,362	321,349
Lease amortization	277,784	310,138
Stock-based compensation	1,256,026	873,597
Provision for doubtful accounts	4,520	40,485
Accretion of discount on marketable securities	(1,371,339)	(853,951)
Changes in operating assets and liabilities:		
Non-trade receivables and unbilled reimbursements	172,721	119,075
Prepaid expenses	645,011	1,139,478
Other assets	(1,019,739)	418,799
Accounts payable	28,912	(825,526)
Accrued expenses and other liabilities	(203,056)	(433,054)
Interest payable	(976)	131,611
Operating lease liability	(290,234)	(305,079)
Net cash used in operating activities	(30,242,772)	(23,218,931)
Cash flows from investing activities:		
Purchase of property and equipment	(207,898)	(245,620)
Purchase of marketable securities	(29,933,502)	(40,015,409)
Maturities of marketable securities	51,300,000	50,000,000
Sales of marketable securities	1,125,676	1,684,407
Net cash provided by investing activities	22,284,276	11,423,378
Cash flows from financing activities:		
Proceeds from notes payable	82,029	20,000,000
Repayment of notes payable	(22,371)	-
Payments of deferred loan costs	-	(200,000)
Proceeds from exercise of stock options	131,633	45,459
Proceeds from issuance of common stock	31,259,992	21,615,075
Payment of common stock issuance costs	(1,649,207)	(987,041)
Net cash provided by financing activities	29,802,076	40,473,493
Effect of exchange rate change on cash	(11,118)	(49,326)
Net change in cash and cash equivalents	21,832,462	28,628,614
Cash and cash equivalents, beginning of the period	14,578,752	15,456,338
Cash and cash equivalents, end of the period	$ 36,411,214	$ 44,084,952
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 4,099,504	$ 2,526,511
Cash paid for state income taxes	$ 1,625	$ 750
Supplemental disclosure of non-cash investing and financing activities:		
Remeasurement of lease liabilities	$ 410,797	$ -
Common stock to be issued	$ 2,761,558	$ -
Accrued issuance costs	$ 292,657	$ -
Purchases of property and equipment not yet paid	$ -	$ 3,841

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

Note 1 - Business and organization

Business overview

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

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

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

Note 2 - Summary of significant accounting policies

Basis of presentation

These unaudited condensed consolidated financial statements as of September 30, 2024, and for the three and nine months ended September 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, within the Company's Registration Statement on Form 10-12G, filed with the SEC on July 30, 2024.

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 September 30, 2024, unaudited condensed consolidated results of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023, and unaudited condensed consolidated cash flows for the nine months ended September 30, 2024 and 2023. The unaudited condensed consolidated results of operations for the three and nine months ended September 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 unaudited 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.

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 the 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 nine-month periods ended September 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 September 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 nine-month periods ended September 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.

Liquidity

For the three months and nine months ended September 30, 2024, the Company incurred a net loss of $10,055,917 and $30,700,608, respectively. During the nine months ended September 30, 2024, the Company had negative cash flows from operations of $30,242,772. 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 September 30, 2024, the Company had working capital of $67,886,754 and accumulated deficit of $343,360,016. The Company continues to face

risks similar to those of other companies of similar size in its industry, including, but not limited the need for successful commercialization of products, the need for additional capital, or financing, to fund operating losses, protection of proprietary technology, and dependence on key individuals. The Company has funded its operations through the issuance of common stock and debt instruments, as further discussed in Note 7, "Notes payable" and Note 9, "Common stock" below.

Concentration of credit risk

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

Non-trade receivables and unbilled reimbursements

Non-trade receivables are recorded for amounts due to the Company related to reimbursements of clinical trials expenses based upon contracted terms. 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.

Pre-launch inventory

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

As of September 30, 2024 and December 31, 2023, the Company capitalized $1,197,860 and $0 of pre-launch inventory costs, respectively, which is included in other assets in the unaudited condensed consolidated balance sheets. Pre-launch inventory, consisting of raw materials, is recorded at the lower of cost (determined using the first-in, first-out method) and net realizable value. The Company could be required to write down previously capitalized costs related to pre-launch inventories upon a change in facts and circumstances, including among other potential factors, a denial or significant delay of approval by regulatory bodies, a delay in commercialization, or other adverse factors.

Property and equipment

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

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

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

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

Other Income

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Clinical trial reimbursements	$ 1,618	$ 41,386	$ 10,461	$ 24,258
Research and development tax incentive	-	-	-	366,168
Total other income	$ 1,618	$ 41,386	$ 10,461	$ 390,426

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 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 unaudited 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 only impact our disclosures with no impact to our results of operations, cash flows and financial condition.

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 unaudited 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 unaudited 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 September 30, 2024, and December 31, 2023:

	September 30, 2024	December 31, 2023
Cash and cash equivalents:		
Cash	$ 415,594	$ 975,310
Money market funds	35,995,620	11,615,762
US Treasury securities	-	1,987,680
Total cash and cash equivalents	$ 36,411,214	$ 14,578,752
Marketable securities, short-term:		
US Treasury securities	$ 18,004,322	$ 18,991,771
Corporate bonds	16,179,825	14,836,424
Commercial paper	2,992,699	21,113,569
US Government Agency bonds	-	2,794,510
Total marketable securities, short-term	$ 37,176,846	$ 57,736,274
Marketable securities, long-term:		
Corporate bonds	$ 593,906	$ -
Asset backed securities	-	1,125,554
Total marketable securities, long-term	593,906	1,125,554
Total cash, cash equivalents, and marketable securities	$ 74,181,966	$ 73,440,580

During the nine-month period ended September 30, 2024, marketable securities were sold or matured for proceeds of $52,425,676 with no gain or loss realized. During the nine-month period ended September 30, 2023, marketable securities matured for proceeds of $51,684,407 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 September 30, 2024, and December 31, 2023:

	As of September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
US Treasury securities	$ 17,956,278	$ 48,328	$ (284)	$ 18,004,322
Corporate bonds	16,739,337	36,660	(2,266)	16,773,731
Commercial paper	2,992,460	455	(216)	2,992,699
Total marketable securities	$ 37,688,075	$ 85,443	$ (2,766)	$ 37,770,752

	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 September 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 September 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	$ 295,481	$ (284)	$ -	$ -	$ 295,481	$ (284)
Corporate bonds	3,345,323	(2,266)	-	-	3,345,323	(2,266)
Commercial paper	1,997,804	(216)	-	-	1,997,804	(216)
Total	$ 5,638,608	$ (2,766)	$ -	$ -	$ 5,638,608	$ (2,766)

	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)

The contractual maturities of the Company's marketable securities as of September 30, 2024 were as follows:

	Fair Value
One year or less	$ 37,176,846
One year to two years	593,906
Total minimum payments	$ 37,770,752

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 September 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 September 30, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 35,995,620	$ -	$ -	$ 35,995,620
Marketable securities				
US Treasury securities	-	18,004,322	-	18,004,322
Corporate bonds	-	16,773,731	-	16,773,731
Commercial paper	-	2,992,699	-	2,992,699
Total	$ 35,995,620	$ 37,770,752	$ -	$ 73,766,372

	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 unaudited 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 September 30, 2024, and December 31, 2023:

	September 30, 2024	December 31, 2023
Non-trade receivables	$ 45,528	$ 237,128
Unbilled reimbursements	8,036	135,772
Non-trade receivables and unbilled services	53,564	372,900
Less: allowance for doubtful accounts	-	(142,166)
Non-trade receivables and unbilled services, net	$ 53,564	$ 230,734

Bad debt expense for the three and nine-month periods ended September 30, 2024 and 2023 was $4,520 and $40,485, respectively.

Property and equipment, net

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

	September 30, 2024	December 31, 2023
Equipment	$ 3,478,673	$ 3,159,822
Computer software	574,780	574,780
Leasehold improvements	513,727	499,148
Total property and equipment	4,567,180	4,233,750
Less accumulated depreciation and amortization	(3,642,904)	(3,144,979)
Total property and equipment, net	$ 924,276	$ 1,088,771

Depreciation and amortization expense for the three-month period ended September 30, 2024 and 2023 was $101,316 and $191,876, respectively. Depreciation and amortization expense for the nine-month period ended September 30, 2024 and 2023 was $496,844 and $572,882, respectively. There were no impairments recorded during the three and nine-month periods ended September 30, 2024, and 2023.

Accrued expenses and other liabilities

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

	September 30, 2024	December 31, 2023
Accrued compensation and related liabilities	$ 2,622,471	$ 2,324,040
Accrued development expenses	564,259	875,501
Accrued warranty reserves	709,219	826,924
Accrued other expenses	28,765	68,882
Accrued expenses and other liabilities	$ 3,924,714	$ 4,095,347

See Note 14, "Commitments and contingencies" for additional disclosure on accrued warranty reserves.

Note 6 – Leases

The Company has an operating lease for its corporate headquarters and laboratory space, located in Sunnyvale, California. The initial lease expired June 30, 2024, with an option to extend the lease an additional sixty-months, which was used in the calculation of the right of use 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. The July 2024 lease remeasurement resulted in a $498,013 increase in the right of use asset and corresponding lease liability.

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

	September 30, 2024	December 31, 2023
Right of use asset	$ 1,031,009	$ 1,719,590
Lease liability, current	510,121	250,876
Lease liability, noncurrent	709,953	1,670,230
Remaining lease term	2.25 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 nine-month periods ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease costs	$ 128,993	$ 103,379	$ 344,963	$ 310,138
Variable lease costs	26,198	30,711	90,528	91,952
Total lease expense	$ 155,191	$ 134,090	$ 435,491	$ 402,090

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

Years Ended December 31,	
2024	$ 150,000
2025	600,000
2026	600,000
Total undiscounted lease payments	1,350,000
Less: effects of discounting	(129,926)
Total operating lease liabilities	$ 1,220,074

Note 7 - Notes payable

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

	September 30, 2024	December 31, 2023
Notes payable, current		
Current portion of notes payable	$ 59,657	$ 21,496
Notes payable, non-current		
Long-term portion of notes payable	41,800,000	41,800,000
Less: unamortized deferred loan costs	(576,504)	(734,579)
Less: unamortized discount	(1,115,447)	(1,418,734)
Notes payable, non-curent, net	$ 40,108,049	$ 39,646,687
Total notes payable, net	$ 40,167,706	$ 39,668,183

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

Years Ended December 31,		
2024	$	22,371
2025		37,286
2026		-
2027		41,800,000
Total minimum payments	$	41,859,657

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 September 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 $102,086 and $101,347 for the three-month period ended September 30, 2024 and 2023, respectively. Amortization of the discount was $303,287 and $189,970 for the nine-month period ended September 30, 2024 and 2023, respectively. This amount was recorded as additional interest expense in the accompanying unaudited condensed consolidated statements of operations. As of September 30, 2024 and December 31, 2023, the note has been shown net of unamortized discounts of $1,115,447 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 $53,144 and $53,017 for the three-month period ended September 30, 2024 and 2023, respectively. Amortization of loan costs was $158,075 and $131,379 for the nine-month period ended September 30, 2024 and 2023, respectively. As of September 30, 2024 and December 31, 2023, the note has been shown net of unamortized loan costs of $576,504 and $734,579, respectively.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of September 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 September 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 unaudited 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 September 30, 2024, the outstanding principal balance was $59,657 and was included in the current portion of notes payable in the unaudited condensed consolidated balance sheets.

Note 8 – Convertible preferred stock

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

As of September 30, 2024 and December 31, 2023, 600,000,000 shares were authorized, of which 364,044,810 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 issuance 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 issuance costs.

In September 2024, the Company completed a fully underwritten institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement issuance of 55,856,325 CDIs representing the same number of common stock at $0.82 Australian dollars per share, for proceeds of $29,483,822, net of $1,776,170 of related issuance costs.

In September 2024, the Company announced the retail component of the fully underwritten 1-for-20 pro-rata non-renounceable entitlement offer of 5,075,733 CDIs representing the same number of common stock at $0.82 Australian dollars per share. In connection with the entitlement offer, the Company received a binding commitment from the underwriter to purchase any entitlements not accepted by the Company's eligible securityholders. As a result, the Company recognized a common stock receivable of $2,595,864 which was presented as a reduction to equity in the Company's unaudited condensed consolidated balance sheets and unaudited condensed consolidated statement of changes in stockholders' equity as of September 30, 2024. The Company recorded a corresponding offset of $2,595,864 to common stock to be issued, a component of equity in the Company's unaudited condensed consolidated balance sheets and unaudited condensed consolidated statement of changes in stockholders' equity as of September 30, 2024. On October 16, 2024, the Company issued 5,075,733 CDIs and received proceeds of $2,595,864, net of $165,694 of related issuance costs.

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

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	20,825,312
2021 Equity Incentive Plan	37,733,732
Outside of 2021 Equity Incentive Plan	709,633
Total shares of Common stock reserved for issuance	79,058,056

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 September 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 September 30, 2024	19,789,379	$ 0.57	5.53

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, 37,733,732 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 September 30, 2024, options to purchase a total of 20,583,838 shares of common stock remained outstanding and 17,149,894 shares remain available for grant under the 2021 Plan and 709,633 remained outstanding outside of the 2021 Plan. As of September 30, 2024, options to purchase a total of 20,825,312 shares of common stock remained outstanding under the 2013 Plan. As of September 30, 2024, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the nine-month period ended September 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	7,750,948	0.64	
Cancelled	(2,679,020)	0.47	
Exercised	(1,167,727)	0.11	
Outstanding at September 30, 2024	42,118,783	$ 0.36	6.84
Vested and expected to vest at September 30, 2024	42,118,783	$ 0.36	6.84
Exercisable at September 30, 2024	27,548,666	$ 0.25	5.72

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 nine-month periods ended September 30, 2024 and 2023, was $0.43 per share and $0.38 per share, respectively.

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

	Nine Months Ended September 30,	
	2024	2023
Expected term (in years)	7.00	7.00
Expected volatility	65.17% - 67.34%	68.07% - 72.08%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	3.67% - 4.71%	3.38% - 4.44%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 255,428	$ 186,010	$ 583,452	$ 481,308
General and administrative	220,893	165,416	672,574	392,289
Total	$ 476,321	$ 351,426	$ 1,256,026	$ 873,597

At September 30, 2024, there was $5,506,039 of unamortized stock-based compensation cost, respectively, related to unvested stock options which is expected to be recognized over a weighted average period of 3.17 years.

Note 12 – Income taxes

During the three and nine-month periods ended September 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 nine-month periods ended September 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 nine-month period ended September 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 nine-month periods ended September 30, 2024, and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator – basic & diluted:				
Net loss attributable to common stockholders, basic and diluted	$ (10,055,917)	$ (9,132,465)	$ (30,700,608)	$ (24,728,735)
Denominator:				
Weighted-average number of shares outstanding, basic and diluted	311,192,703	305,692,267	308,914,435	282,766,448
Net loss per share attributable to common stockholders, basic and diluted	$ (0.03)	$ (0.03)	$ (0.10)	$ (0.09)

See Note 9, "Common stock" for common stock issued after September 30, 2024, but before these unaudited condensed consolidated financial statements were issued.

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 September 30, 2024 and 2023:

	September 30, 2024	September 30, 2023
Outstanding warrants	19,789,379	19,789,379
Outstanding stock options	42,118,783	33,892,919
Total dilutive shares	61,908,162	53,682,298

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 September 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 unaudited condensed consolidated financial statements.

Accrued warranty reserves

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

Changes in accrued warranty reserves were as follows for the three and nine-month periods ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Beginning of period	$ 749,575	$ 734,400	$ 826,924	$ 734,400
Warranty reserve accrued during the period	-	55,973	-	144,565
Settlement of warranty claims	(40,356)	(55,973)	(117,705)	(144,565)
End of period	$ 709,219	$ 734,400	$ 709,219	$ 734,400

Note 15 – Related party transactions

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

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes and other information included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2023 included in our registration statement on Form 10-12G, as amended, filed with the Securities and Exchange Commission July 30, 2024, as amended by Amendment No. 1 filed on September 18, 2024 and Amendment No. 2 filed on October 23, 2024, and effective as of September 30, 2024 ("Form 10"). In addition to historical data, this discussion contains forward-looking statements about our business, results of operations, cash flows, financial condition and prospects based on current expectations that involve risks, uncertainties, assumptions, and other important factors. Our actual results could differ materially from such forward-looking statements. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed in Part II, Item 1A. Risk Factors of the Form 10 and the section titled "Forward-Looking Statements" included therein. Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future. We use words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "seek," "should," "will," "would," and similar expressions to identify 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 resynchronization therapy ("CRT"), potentially offering endocardial heart tissue stimulation without the complications associated with traditional lead-based systems. 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.

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-CRT (Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy) 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 modules of our modular pre-market approval ("PMA") to the Food and Drug Administration ("FDA") 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 September 30, 2024, we had $74.2 million in cash, cash equivalents, and marketable securities and an accumulated deficit of $343.4 million.

On September 25, 2024, we issued 55,856,325 CDIs in connection with an institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement offer on the ASX. We raised approximately $29.5 million, net of issuance costs of approximately $1.8 million. On October 16, 2024, we issued

5,075,733 CDIs in connection with the retail component of a fully underwritten 1-for-20 pro-rata non-renounceable entitlement offer. We raised approximately $2.6 million, net of issuance costs of approximately $0.1 million.

Factors Affecting Our Business

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

- ***Regulatory approvals/clearances***. Our business strategy depends on the successful FDA submission and obtaining approval by the FDA of our WiSE CRT System on a timely basis.

- ***Market acceptance***. If approved, the growth of our business depends on our ability to gain wide acceptance of our WiSE CRT System by continuing to make physicians and other hospital staff aware of the benefits of WiSE CRT to generate increased demand and frequency of use, and thus increase sales to our hospital customers. Our ability to grow our business will also depend on our ability to expand our customer base in existing or new target markets.

- ***Sales force size and effectiveness***. If approved, the rate at which we grow our sales force and the speed at which newly hired salespeople become effective can impact our revenue growth or our costs incurred in anticipation of such growth. We intend to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts as well as broaden awareness of our products to new hospital accounts.

- ***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 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*" in the Form 10.

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

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

General and Administrative Expenses

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

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

- hire and retain additional general and administrative personnel to support the expected growth in our research and development activities and the preclinical and clinical development of our product candidates;
- continue to expand our commercial and administrative function to support the growth of our WiSE CRT commercialization;
- incur additional commercialization expenses prior to any regulatory approval of our product candidates;
- pursue payor coverage and reimbursement for our current and future product candidates;
- maintain, expand, and protect our intellectual property portfolio; and
- incur increased expenses associated with operating as a U.S. publicly reporting company, including increased costs of accounting, audit, legal, regulatory, and tax-related services, and director and officer insurance premiums.

Other Income (Expenses), net

Interest expense

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

Interest income

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

Other income

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

Gain/ (loss) on foreign currency

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

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles ("GAAP") in the United States. The preparation of unaudited condensed 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 unaudited condensed 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 unaudited condensed consolidated financial statements appearing elsewhere in this Form 10-Q, we believe the following accounting policies used in the preparation of our unaudited condensed 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 unaudited condensed consolidated financial statements by matching the appropriate expenses with the period in which services are provided. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. Our clinical trial accrual is dependent, in part, upon the receipt of timely and accurate reporting from the third parties. We estimate our liability using our judgment based upon the facts and circumstances known at the time. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates.

Stock-Based compensation

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

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

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

- *Fair Value of Our Common Stock*. Our stock is publicly traded on the ASX, and therefore we use the closing market price on the day before the option grant.
- *Expected Term*. The expected term represents the period that the stock-based awards are expected to be outstanding. As we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term, the expected term of stock options granted has been

determined using the simplified method, which is the average of the midpoints between the vesting date and the contractual term for all vesting tranches.

- *Risk-Free Interest Rate*. The risk-free interest rate is based on the rate of the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.
- *Expected Volatility*. The expected volatility was derived from the combination of the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business, and our stock price, as quoted on the ASX.
- *Dividend Rate*. The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

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

Income Taxes

We are subject to income taxes in the United States and multiple foreign jurisdictions. Our effective tax rates differ from the United States federal statutory rate, primarily due to changes in our valuation allowance, stock-based compensation expense, state and foreign tax benefit, federal research and development tax credits and other adjustments. Our effective tax rate was 0.00% and 0.00% for both the three-month and nine-month periods ended September 30, 2024 and 2023. The calculation of our provision for income taxes involves the use of estimates, assumptions and judgments while taking into account current tax laws, our interpretation of current tax laws and possible outcomes of future tax audits. We review our tax positions quarterly and adjust the balances as new information becomes available.

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

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

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

Recent Accounting Pronouncements

See the 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-Q.

Results of Operations

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

We recorded a net loss of $10.1 million in the three-month period ended September 30, 2024, an increase of $0.9 million, or 10.1%, from the three-month period ended September 30, 2023. The increased loss in 2024 was due to an increase in general and administrative expenses in 2024, which was offset partially by a decrease in research and development, as discussed below. Other (expense) income, net also increased in 2024 due to a decrease in interest income and increase in loss on foreign currency transactions, as discussed below.

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

	Three Months Ended September 30,		Change	
(in thousands)	2024	2023	Amount	%
Operating expenses:				
Research and development	$ 6,298	$ 6,956	$ (658)	(9.5%)
General and administrative	2,879	1,838	1,041	56.6 %
Total operating expenses	9,177	8,794	383	4.4%
Other (expense) income, net	(879)	(339)	(540)	159.3%
Loss before income tax	(10,056)	(9,133)	(923)	10.1%
Income tax expense	-	-	-	-
Net Loss	$ (10,056)	$ (9,133)	$ (923)	10.1%

Operating Expenses

Research and Development

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

	Three Months Ended September 30,		Change	
(in thousands)	2024	2023	Amount	%
Research and development expenses:				
R&D personnel expense	$ 4,491	$ 3,713	$ 778	21.0%
Clinical expenses	429	836	(407)	(48.7%)
Quality assurance	61	40	21	52.5%
Contract manufacturing, materials & components	935	1,938	(1,003)	(51.8%)
Facility allocation & depreciation	382	429	(47)	(11.0%)
Total research and development expense	$ 6,298	$ 6,956	$ (658)	(9.5%)

Research and development expenses decreased by $0.7 million, or 9.5%, during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. The decrease was primarily due to a $1.0 million decrease in contract manufacturing, materials and components, resulting from a decrease in professional services related to the development testing of WiSE CRT System, as well as capitalization of certain inventory purchases. Clinical trial expenses decreased by $0.4 million due to a decrease in clinical trial activities related to SOLVE-CRT Study. These decreases were offset by $0.8 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.

General and Administrative Expenses

General and administrative expenses increased by $1.0 million, or 56.6%, during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. Professional fees increased by $0.7 million, primarily resulting from higher accounting and legal related services in connection with preparation for the Form 10 filing. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits

increased by $0.2 million as a result of the expansion of our workforce to support our growth. Corporate expenses increased by $0.1 million, primarily resulting from the higher expenses related to investor relations.

Other (expense) income, net

Other (expense) income, net increased by $0.5 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. This increase primarily resulted from $0.4 million decrease in interest income that the company earned on its investments in marketable securities, including the accretion of discounts on marketable securities, as well as $0.1 million increase in loss on foreign currency transactions driven by the foreign currency exchange rates fluctuations for the period.

Comparison of the Nine Months Ended September 30, 2024, to the Nine Months Ended September 30, 2023

We recorded a net loss of $30.7 million in the nine-month period ended September 30, 2024, an increase of $6.0 million, or 24.2%, from the nine-month period ended September 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 nine months ended September 30, 2024, and 2023:

	Nine Months Ended September 30,		Change	
(in thousands)	2024	2023	Amount	%
Operating expenses:				
Research and development	$ 20,171	$ 19,232	$ 939	4.9%
General and administrative	8,322	5,141	3,181	61.9%
Total operating expenses	28,493	24,373	4,120	16.9%
Other (expense) income, net	(2,207)	(355)	(1,852)	521.7%
Loss before income tax	(30,700)	(24,728)	(5,972)	24.2%
Income tax expense	-	-	-	-
Net Loss	$ (30,700)	$ (24,728)	$ (5,972)	24.2%

Operating Expenses

Research and Development

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

	Nine Months Ended September 30,		Change	
(in thousands)	2024	2023	Amount	%
Research and development expenses:				
R&D personnel expense	$ 12,784	$ 10,706	$ 2,078	19.4%
Clinical expenses	1,266	2,348	(1,082)	(46.1%)
Quality assurance	185	67	118	176.1%
Contract manufacturing, materials & components	4,659	4,963	(304)	(6.1%)
Facility allocation & depreciation	1,277	1,148	129	11.2%
Total research and development expense	$ 20,171	$ 19,232	$ 939	4.9%

Research and development expenses increased by $0.9 million, or 4.9%, during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. The increase was primarily due to a $2.1 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. This increase was offset by a $1.1 million decrease in clinical trial expenses, primarily due to a decrease in clinical trial activities related to SOLVE-CRT Study.

General and Administrative Expenses

General and administrative expenses increased by $3.2 million, or 61.9%, during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. Professional fees increased by $1.8 million, primarily resulting from higher accounting and legal related services in connection with preparation for the Form 10 filing. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $1.1 million as a result of the expansion of our workforce to support our growth. Corporate expenses increased by $0.3 million, primarily resulting from the higher expenses related to investor relations.

Other (expense) income, net

Other (expense) income, net increased by $1.9 million during the nine months ended September 30, 2024, as compared to the nine months ended September 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. Additionally, other income has decreased by $0.4 million, primarily resulting from a decrease in refundable tax incentives. These changes were offset by a $0.1 million increase in interest income, including the accretion of discounts on marketable securities.

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 September 30, 2024, and December 31, 2023, we had approximately $74.2 million and $73.4 million, respectively, in cash, cash equivalents, and marketable securities. Subsequently, on October 16, 2024, we raised approximately $2.6 million, net of issuance costs of approximately $0.2 million, from the retail component of a fully underwritten 1-for-20 pro-rata non-renounceable entitlement offer. In the long-term, our ability to support our working capital and capital expenditure requirements will depend on many factors, including:

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

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

Loan and Security Agreements

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

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

As of September 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 September 30, 2024, and December 31, 2023, we were in compliance with all debt covenants.

Recent Financings

On September 25, 2024, we issued 55,856,325 CDIs in connection with an institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement offer on the ASX. We raised approximately $29.5 million, net of issuance costs of approximately $1.8 million. On October 16, 2024, we issued 5,075,733 CDIs in connection with the retail component of a fully underwritten 1-for-20 pro-rata non-renounceable entitlement offer. We raised approximately $2.6 million, net of issuance costs of approximately $0.1 million.

Contractual Obligations and Commitments

As of September 30, 2024, and December 31, 2023, we had $1.2 million and $1.9 million in operating lease obligations, respectively, for our corporate headquarters and laboratory space, located in Sunnyvale, California. As of September 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 September 30, 2024, and December 31, 2023, the outstanding principal balance was $59,657 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 September 30, 2024, and December 31, 2023, our obligations under such arrangements were approximately $12.5 million and $3.5 million, respectively.

Other than as described above, there have been no material changes to our contractual obligations and other commitments compared to those disclosed in our Form 10.

Working Capital

September 30, 2024, Compared to December 31, 2023

As of September 30, 2024, we had working capital of $67.9 million, comprised of current assets of $74.6 million and current liabilities of $6.7 million. Current assets, consisting of cash and cash equivalents, marketable securities, prepaid expenses, non-trade receivables and other current assets, increased by $0.2 million as of September 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 $0.3 million as of September 30, 2024, compared to December 31, 2023. The sale of common stock discussed above contributed to the overall increase in cash and cash equivalents, resulting in an increase in working capital as of September 30, 2024.

Cash Flows

September 30, 2024, Compared to September 30, 2023

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

	Nine Months Ended September 30,	
(in thousands)	2024	2023
Net cash used in operating activities	$ (30,243)	$ (23,219)
Net cash provided by investing activities	22,284	11,423
Net cash provided by financing activities	29,802	40,474
Effect of exchange rate change on cash	(11)	(49)
Cash and cash equivalents, beginning of the period	14,579	15,456
Cash and cash equivalents, end of the period	$ 36,411	$ 44,085

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2024, was $30.2 million, compared to $23.2 million during the nine months ended September 30, 2023, representing an increase in use of $7.0 million. This increase is primarily attributed to an increase in net loss of $6.0 million, a decrease in non-cash adjustments of $0.1 million, and a use of cash from changes in working capital of $0.9 million.

- The increase in net loss of $6.0 million resulted from increases in personnel costs due to the expansion of our workforce, increases in professional fees due to the preparation for the Form 10 filing, and increase other expense mainly driven by interest expense, as further described under “Results of Operations” above.

- Non-cash items primarily consisted of increases in share-based compensation of $0.4 million due to new options issuance to new hires and existing employees, offset by a decrease in accretion of discount on marketable securities of $0.5 million driven by fluctuating interest rates and maturity term.

- The increase in changes from working capital activities primarily consisted of a $0.9 million increase in accounts payable due to the timing of invoice payments, as well as $0.2 million increase in accrued expenses and other liabilities primarily driven by lower clinical trial expenses. This increase was partially offset by $1.4 million use of cash for other assets mainly due to capitalization of certain raw materials during the nine months ended September 30, 2024, a $0.5 million decrease in prepaids expenses due to decreased vendor prepayment

requirements for research and development materials and professional services, and a $0.1 million decrease in interest payable.

Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2024, was $22.3 million, compared to $11.4 million the nine months ended September 30, 2023, representing an increase in cash provided of $10.9 million. The increase was attributable to a $10.1 million decrease in the purchase of marketable securities, as well as a $0.8 million increase in cash from the maturities and sales of marketable securities during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2024, was $29.8 million, compared to $40.5 million during the nine months ended September 30, 2023, representing a decrease of $10.7 million. This decrease is primarily attributed to the $19.7 million borrowing, net of issuance cost, under tranche 2 of the loan and security during the nine months ended September 30, 2023. This decrease was partially offset by $8.9 million increase in proceeds from a capital raise, net of issuance cost, during the nine months ended September 30, 2024, as well as by a $0.1 million increase in proceeds from exercise of stock options.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4: CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15(d)-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2024.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating disclosure controls and procedures, our management recognizes that any system of controls, however well designed and operated, can provide only reasonable assurance, and not absolute assurance, that the desired control objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals in all future circumstances. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and our Chief Financial Officer

have concluded, based on their evaluation as of the end of the period covered by this quarterly report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors previously disclosed within Item 1A "Risk Factors" in the Form 10.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the three months ended September 30, 2024, we issued and sold the following unregistered securities:

a) On July 18, 2024, we granted stock option awards to eighty-two employees, to acquire up to 2,341,626 shares of common stock under the Company's 2021 Equity Incentive Plan. The option shares are exercisable at a price of $0.77 per share, which equaled the closing price of the common stock as of the date immediately prior to the grant date.

b) On July 31, 2024, we granted stock option awards to two employees, to acquire up to 148,000 shares of common stock under the Company's 2021 Equity Incentive Plan. The option shares are exercisable at a price of $0.74 per share, which equaled the closing price of the common stock as of the date immediately prior to the grant date.

c) On September 25, 2024, we issued 55,856,325 shares of common stock, in connection with an institutional placement and the institutional component of a 1-for-20 pro-rata accelerated non-renounceable entitlement offer ("Entitlement Offer") on the ASX, at a purchase price of $0.56 per share for aggregate gross proceeds of $31.3 million. Bell Potter Securities Limited, Morgans Corporate Limited, and E&P Capital Pty Limited were the joint lead managers and book runners for the Entitlement Offer. Wilsons Corporate finance Limited was also acting as a joint lead manager. The Entitlement Offer was fully underwritten by Bell Potter Securities Limited.

d) On September 30, 2024, we granted a stock option award to one employee, to acquire up to 125,000 shares of common stock under the Company's 2021 Equity Incentive Plan. The option shares are exercisable at a price of $0.60 per share, which equaled the closing price of the common stock as of the date immediately prior to the grant date.

The offers, sales and issuances of the securities described in paragraph 1(a), (b) and (d) 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 paragraph (c) 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 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are filed or furnished as part of this report:

		Incorporated by Reference		
Number	**Description**	**Schedule/Form**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of EBR Systems, Inc.	10-12G	3.1	9/18/2024
3.2	Amended and Restated Bylaws of EBR Systems, Inc.	10-12G	3.2	9/18/2024
4.2	Amended and Restated Investors' Rights Agreement dated October 13, 2021, between the EBR Systems, Inc. and the parties thereto.	10-12G	4.2	7/30/2024
10.1†	Addendum "D" to the Oakmead Lease, dated July 2024, between the Company and 480 Oakmead Properties, LLC†	10-12G/A	10.5	9/18/2024
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32.1#	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.			
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document			
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)			

*Filed herewith

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

† 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 the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EBR SYSTEMS, INC.

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

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

Date: November 12, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John McCutcheon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of EBR Systems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

/s/ John McCutcheon
John McCutcheon
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gary Doherty, certify that:

1. I have reviewed this quarterly report on Form 10-Q of EBR Systems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

/s/ Gary Doherty
Gary Doherty
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John McCutcheon, Chief Executive Officer of EBR Systems, Inc. (the "Company"), and Gary Doherty, Chief Financial Officer of the Company, each hereby certifies that, to the best of their knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 12, 2024

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 12th day of November 2024.

/s/ John McCutcheon	/s/ Gary Doherty
John McCutcheon	Gary Doherty
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial Officer)

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of EBR Systems, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."