ASX ANNOUNCEMENT **14 May 2025**

Q1 2025 Form 10-Q submission and Quarterly Activity Report

Key Highlights:

- EBR secured FDA approval for the WiSE CRT System on April 11, 2025, the world's first and only leadless solution for left ventricular endocardial pacing, subsequent to quarter end
- Successful FDA Pre-Approval Inspection (PAI) completed in January 2025 with no Form FDA 483 observations, paving the way for our subsequent FDA approval
- WiSE CRT System accepted into CMS' Transitional Coverage for Emerging Technologies (TCET) pathway and subsequently proposed for maximum New Technology Add-On Payment (NTAP) reimbursement
- Signed a new 11-year lease agreement for a 51,000 sq. ft. manufacturing facility, significantly enhancing manufacturing capabilities and operational flexibility ahead of full-scale commercialisation
- EBR holds cash, marketable securities and restricted cash of US$52.8m/ A$84.5m[1] as at 31 March 2025

Sunnyvale, California; 14 May 2025: 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 March quarter ("Q1 2025").

EBR secures FDA approval for the WiSE CRT System

Subsequent to quarter end, EBR achieved a major milestone by securing FDA approval for the Company's WiSE CRT System, marking a critical advancement in cardiac pacing technology. The FDA approval followed a comprehensive review process, including the submission of five detailed Premarket Approval (PMA) modules, the completion of a Pre-Approval Inspection (PAI) of EBR's manufacturing facilities in January 2025 with no FDA form 483 observations, and the resolution of any queries that arose from the FDA's review of the submitted modules.

The WiSE CRT System represents the world's first leadless pacing technology specifically for left ventricular endocardial pacing, addressing a significant unmet clinical need for heart failure patients unable to benefit from traditional lead-based systems. EBR plans to launch the WiSE CRT System in phases. A limited market release is planned for 2025, with sales expected during the second half of the year, ramping towards full commercial distribution during 2026. The initial phase of the rollout will concentrate on high-volume centres, specifically those involved in previous clinical trials, aimed at gathering early user experience and facilitating wider adoption.

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

"2025 has already seen numerous landmark achievements for EBR, highlighted by the FDA approval of our transformative WiSE CRT System in April. In addition to FDA approval, EBR was also accepted into the TCET reimbursement pathway and expanded our manufacturing capabilities through a newly leased facility. We remain focused on executing our strategic commercialisation strategy, and we look forward to bringing this groundbreaking technology to patients who urgently need it. On behalf of EBR, I extend our deepest gratitude to our shareholders, partners, and dedicated team for their continued support and commitment."

Progress across reimbursement pathways

During the quarter, the WiSE CRT System was successfully accepted into Centers for Medicare & Medicaid Services' (CMS) newly enacted Transitional Coverage for Emerging Technologies (TCET) reimbursement pathway. The

[1] Assumes an A$:US$0.625 exchange rate

TCET pathway is intended to expedite Medicare coverage for innovative FDA-designated Breakthrough Devices, enhancing patient access to significant medical advancements. Acceptance into the TCET pathway allows EBR to engage early with CMS through an Evidence Preview process, aligning closely with Medicare expectations and potentially streamlining coverage approval. The pathway will also enable Medicare coverage for the WiSE system, including transitional coverage of up to five years. Acceptance is highly selective, with CMS indicating that only five new technologies per year will qualify, highlighting the clinical importance and transformative potential of the WiSE CRT System.

Subsequent to quarter end, CMS announced that it is proposing to approve EBR's WiSE CRT System for the New Technology Add-On Payment (NTAP) reimbursement beginning 1 October 2025. CMS has recommended the maximum add-on payment of 65% of the device cost in addition to the normal MS-DRG payment, which would effectively cover the full cost of the WiSE System. The NTAP, once finalized and awarded, will significantly enhance the commercial appeal of the WiSE System by reducing financial barriers and accelerating market adoption. The NTAP reimbursement program will remain in effect for three years once approved.

Also subsequent to quarter end, EBR successfully submitted its application to CMS for the Transitional Pass-Through (TPT) reimbursement program for EBR's WiSE System as announced on 5 May, 2025. The TPT reimbursement program is designed to facilitate hospital adoption of breakthrough medical technologies that demonstrate substantial clinical improvement for patients, but whose costs are not yet fully incorporated into standard Medicare payment rates. When granted, the TPT reimbursement program will support hospital adoption for outpatients and allow EBR's sales team to present a clear reimbursement pathway to hospitals. Once approved, the program is expected to be effective 1 October 2025, allowing hospitals adopting the WiSE CRT System to receive enhanced Medicare payments for up to 2-3 years, providing further significant support to the commercial rollout in the US.

Expansion of manufacturing capabilities

During the quarter, EBR secured an 11-year lease for a state-of-the-art, 51,000 sq ft facility in Santa Clara, California. The new facility expands EBR's corporate, R&D, and manufacturing space, ensuring that there is sufficient room to accommodate future growth and demand for WiSE. This significant expansion positions EBR to scale up its manufacturing capacity and meet anticipated future demand.

The phased occupancy terms and landlord-funded tenant improvements totalling approximately US$4m, alongside an EBR-allocated budget of US$1.3m for equipment and furnishings, provide optimal financial flexibility and operational scalability. EBR will upgrade and qualify the new facility over the next year and intends to move staff and equipment progressively, expecting to complete its transition into the new facility during H1 2026. Following completion of the required build out and installation of key equipment, the FDA will perform a manufacturing Post-Approval Inspection (PAI) akin to the effort recently concluded for the current facility.

Active media and investor engagement

During the quarter, EBR has maintained an active presence in the media and investment community. EBR's management presented at leading investor conferences, such as the 2025 Emergence Conference in Sydney, the Bell Potter Healthcare Horizons Summit, and the ASX Small and Mid-Cap conference. Management also hosted investor roadshows across multiple cities in Australia, providing an opportunity for shareholders to directly engage with the Company. These engagements facilitated broad dissemination of EBR's pivotal research outcomes, strategic initiatives, and commercialisation strategy.

Corporate update

In March 2024, EBR achieved the significant milestone of admission into the S&P/ASX All Ordinaries Index. The inclusion in the index increases the Company's visibility amongst investors, validates the company's strong market performance, and effectively paves the way for increased liquidity and broader investment opportunities.

In addition to its cash balance of US$8.9m/ A$14.2m[2] on 31 March 2025, EBR held US$41.3m/ A$66.1m[3] in marketable securities which will become cash or cash equivalents in the future and had restricted cash of

[2] Assumes an A$:US$0.625 exchange rate

US$2.6m/ A$4.2m[3], relating to a security deposit on the new facility lease signed during the quarter. Investments are made in fixed income instruments, have a weighted average maturity of 5.1 months, and have an average credit rating of A+, A1, AA- by Standard & Poor's, Moody's, and Fitch, respectively.

Quarterly activity report

Key Highlights:

- During the quarter, EBR had net operating cash outflows of US$13.6m/ A$21.7m[3]
- Payments for research and development increased from the prior quarter, driven by project spend and related validation costs.
- Labor costs trended higher as the Company began the expansion of its field clinical team and manufacturing support in anticipation of our FDA approval, and the payment of 2024 bonuses in January 2025.

(Unaudited)

(Dollars in U.S. $)	Quarter ended 31 Mar 2025
Cash flows from operating activities	
Receipts from customers	$ -
Payments for	
research and development	(1,626,562)
product manufacturing and operating costs	(2,252,573)
advertising and marketing	(377,140)
leased assets	(158,972)
staff costs	(6,530,262)
administration and corporate costs	(1,789,364)
Interest received	-
Interest and other costs of finance paid	419,790
Income taxes paid	(1,248,612)
Government grants and tax incentives	-
Net cash from / (used in) operating activities	(13,563,695)
Cash flows from investing activities	
Payments to acquire property plant and equipment	(60,472)
Proceeds from maturities and disposal of marketable securities	17,966,613
Net cash from / (used in) investing activities	17,906,141
Cash flows from financing activities	
Proceeds from exercise of options	263,984
Repayment of borrowings	(22,371)
Net cash from / (used in) financing activities	241,613
Cash, cash equivalents, and restricted cash at beginning of period	6,917,546
Net cash from / (used in) operating activities	(13,563,695)
Net cash from / (used in) in investing activities	17,906,141
Net cash from / (used in) financing activities	241,613
Effect of movement in exchange rates on cash held	981
Cash and cash equivalents at end of period	$ 11,502,586

ENDS

[3] Assumes an A$:US$0.625 exchange rate

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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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, conduction system pacing 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 has been approved by the FDA and is 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 March 31, 2025

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 (State or Other Jurisdiction of Incorporation or Organization)	**57-1164669** (I.R.S. Employer Identification No.)
480 Oakmead Parkway **Sunnyvale, CA** (Address of Principal Executive Offices)	**94085** (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 May 12, 2025, the registrant had 373,076,861 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 MARCH 31, 2025

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PART I — FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	March 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 8,899,018	$ 6,917,546
Marketable securities	38, 968,404	53,746,411
Non-trade receivables and unbilled reimbursements, net	778,971	441,439
Pre-launch inventory	3,232,330	1,391,008
Prepaid expenses	1,459,766	1,693,560
Other current assets	139,374	276,419
Total current assets	53,477,863	64,466,383
Restricted cash, noncurrent	2,603,568	-
Property and equipment, net	1,243,737	794,959
Right of use operating lease asset	13,470,082	929,243
Marketable securities	2,318,822	5,303,950
Pre-launch inventory, noncurrent	1,486,086	1,451,532
Other assets	900,717	613,427
TOTAL ASSETS	**$ 75,500,875**	**$ 73,559,494**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,748,691	$ 3,247,453
Accrued expenses and other liabilities	3,059,665	4,295,841
Interest payable	220,444	224,889
Operating lease liability	683,106	522,525
Current portion of notes payable	14,914	37,286
Total current liabilities	6,726,820	8,327,994
Other liabilities	235,829	37,617
Operating lease liability	13,562,952	574,777
Notes payable, net	40,416,514	40,263,605
Total liabilities	60,942,115	49,203,993
Commitments and contingencies (Note 16)		
STOCKHOLDERS' EQUITY		
Common stock, $0.0001 par value; 600,000,000 shares authorized, 372,896,324 and 371,076,200 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	37,290	37,108
Additional paid-in capital	377,671,092	376,902,576
Accumulated deficit	(364,011,951)	(353,457,680)
Accumulated other comprehensive income	862,329	873,497
Total stockholders' equity	14,558,760	24,355,501
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 75,500,875**	**$ 73,559,494**

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 March 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 5,418,682	$ 6,401,279
General and administrative	4,363,004	2,173,115
Total operating expenses	9,781,686	8,574,394
Loss from operations	(9,781,686)	(8,574,394)
Other (expense) income		
Interest expense	(1,397,076)	(1,503,697)
Interest income	633,093	919,984
Other income	-	8,843
Loss on foreign currency	(8,602)	(739)
Total other (expense), net	(772,585)	(575,609)
Loss before income tax	(10,554,271)	(9,150,003)
Income tax benefit (expense)	-	-
Net loss	$ (10,554,271)	$ (9,150,003)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.03)	$ (0.03)
Weighted-average number of common shares outstanding:		
Basic and diluted	372,541,173	307,423,873

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 March 31,	
	2025	**2024**
Net loss	$ (10,554,271)	$ (9,150,003)
Other comprehensive loss		
Change in unrealized loss on marketable securities	(10,662)	(49,427)
Foreign currency translation adjustments	(506)	(28,932)
Total other comprehensive loss income	(11,168)	(78,359)
Comprehensive loss	$ (10,565,439)	$ (9,228,362)

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)

	Common Stock		Additional	Accumulated	Total Other	Total
	Shares	Par Value	Paid-in Capital	Deficit	Comprehensive Income	Stockholders' Equity
Balance at December 31, 2023	307,020,758	$ 30,703	$ 342,721,880	$ (312,659,408)	$ 963,277	$ 31,056,452
Exercise of stock options	1,069,500	107	110,630	-	-	110,737
Stock-based compensation	-	-	357,170	-	-	357,170
Net loss	-	-	-	(9,150,003)	-	(9,150,003)
Other comprehensive loss	-	-	-	-	(78,359)	(78,359)
Balance at March 31, 2024	308,090,258	$ 30,810	$ 343,189,680	$ (321,809,411)	$ 884,918	$ 22,295,997

	Common Stock		Additional	Accumulated	Total Other	Total
	Shares	Par Value	Paid-in Capital	Deficit	Comprehensive Income	Stockholders' Equity
Balance at December 31, 2024	371,076,200	$ 37,108	$ 376,902,576	$ (353,457,680)	$ 873,497	$ 24,355,501
Exercise of stock options	1,820,124	182	263,802	-	-	263,984
Stock-based compensation	-	-	504,714	-	-	504,714
Net loss	-	-	-	(10,554,271)	-	(10,554,271)
Other comprehensive loss	-	-	-	-	(11,168)	(11,168)
Balance at March 31, 2025	372,896,324	$ 37,290	$ 377,671,092	$ (364,011,951)	$ 862,329	$ 14,558,760

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)

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (10,554,271)	$ (9,150,003)
Adjustment to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	78,863	213,091
Amortization of deferred loan costs and discount on notes payable	152,909	152,906
Lease amortization	296,696	84,767
Stock-based compensation	504,714	357,170
Accretion of discount on marketable securities	(214,140)	(681,032)
Changes in operating assets and liabilities:		
Non-trade receivables and unbilled reimbursements	(337,532)	84,317
Pre-launch inventory	(2,160,790)	-
Prepaid expenses	233,851	242,933
Other assets	135,883	81,731
Accounts payable	(686,046)	(212,620)
Accrued expenses and other liabilities	(1,320,608)	(1,134,995)
Interest payable	(4,445)	(10,547)
Operating lease liability	311,221	(87,490)
Net cash used in operating activities	(13,563,695)	(10,059,772)
Cash flows from investing activities:		
Purchase of property and equipment	(60,472)	(73,893)
Purchase of marketable securities	-	(8,877,691)
Maturities of marketable securities	13,655,000	10,900,000
Sales of marketable securities	4,311,613	1,085,474
Net cash provided by investing activities	17,906,141	3,033,890
Cash flows from financing activities:		
Repayment of notes payable	(22,371)	-
Proceeds from notes payable	-	82,029
Proceeds from exercise of stock options	263,984	110,737
Net cash provided by financing activities	241,613	192,766
Effect of exchange rate change on cash	981	(19,573)
Net change in cash, cash equivalents, and restricted cash	4,585,040	(6,852,689)
Cash, cash equivalents, and restricted cash, beginning of the period	6,917,546	14,578,752
Cash, cash equivalents, and restricted cash, end of the period	$ 11,502,586	$ 7,726,063
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 1,248,611	$ 1,360,362
Supplemental disclosure of non-cash investing and financing activities:		
Remeasurement of lease liabilities	$ -	$ 908,810
Purchases of property and equipment not yet paid	$ 517,229	$ 38,859
Initial recognition of right of use asset and operating lease liability	$ 12,837,535	$ -

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 device able to provide stimulation to endocardial heart tissue for the correction of heart rhythm conditions without requiring the use of leads. This implantable device delivers left-ventricle endocardial pacing for cardiac resynchronization therapy ("CRT"), without the use of wires or leads going into the heart. On April 11, 2025, the Company received notification that the Food and Drug Administration ("FDA") has completed its review of the premarket approval application ("PMA") and approved the WiSE CRT System for commercial distribution in the United States.

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 - Going concern

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. At each reporting period, the Company evaluates whether there are conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that the financial statements are issued. The Company's evaluation entails analyzing prospective operating budgets and forecasts for expectations of its cash needs and comparing those needs to the current cash, cash equivalents and marketable securities balances. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by its plans or when its plans alleviate substantial doubt about its ability to continue as a going concern.

For the three months ended March 31, 2025 and 2024, the Company incurred a net loss of $10,554,271 and $9,150,003, respectively. During the three months ended March 31, 2025 and 2024, the Company had negative cash flows from operations of $13,563,695 and $10,059,772, respectively. As of March 31, 2025, the Company had working capital of $46,751,043 and accumulated deficit of $364,011,951.

Based on the Company's cash, cash equivalents, and marketable securities as of March 31, 2025, and its expectation to generate operating losses and negative operating cash flows in the foreseeable future, as well as potential liquidity to become less than the $2.5 million required under its existing debt covenants during the next twelve months, there exists substantial doubt regarding the Company's ability to continue as a going concern for a period of at least twelve months from the date of issuance of these condensed consolidated financial statements. The Company was in compliance with its debt covenant as of March 31, 2025. Upon the occurrence of a breach of debt covenants, Runway Growth Finance Corp may, at its option, declare all obligations immediately due and payable. In an effort to alleviate these conditions, the Company will need to raise capital through the issuance of additional common stock or borrowings from financial institutions. The Company's ability to obtain additional capital in the equity capital markets is subject to several factors, including market and economic conditions, the Company's performance, and investor sentiment with respect to the Company and its industry. The condensed consolidated financial statements of the Company do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

Note 3 - Summary of significant accounting policies

Basis of presentation

These unaudited condensed consolidated financial statements as of March 31, 2025, and for the three months ended March 31, 2025 and 2024 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, 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 March 31, 2025, unaudited condensed consolidated results of operations and comprehensive loss for the three months ended March 31, 2025 and 2024, and unaudited condensed consolidated cash flows for the three months ended March 31, 2025 and 2024. The unaudited condensed consolidated results of operations for the three months ended March 31, 2025, are not necessarily indicative of the consolidated results of operations that may be expected for the year ending December 31, 2025.

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, capitalized pre-launch inventory, 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 on foreign currency" in the period in which they occur.

Employee benefits

Employees that satisfy certain eligibility requirements, including requirements related to age and length of service, are eligible to participate in the EBR Systems, Inc. 401(k) Plan ("Plan"). The Plan is intended to qualify as a tax-qualified 401(k) plan so that contributions to the Plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the Plan. Under the Plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee as directed by participants. Effective January 1, 2025, the Company began a matching contribution under the Plan. The Company matches 100% of employee contributions to the Plan up to 3% of eligible compensation, with a maximum annual match of $5,000 per employee. Matching contributions vest 25% after one year of service and are fully vested after two years of service. For the three months ended March 31, 2025 and 2024, the Company match expense was $138,330 and $0, respectively.

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.

Restricted cash

The restricted cash, noncurrent balance of $2,603,568 as of March 31, 2025, relates to cash deposits restricted under letters of credit issued on behalf of the Company in support of indebtedness to creditors incurred in the ordinary course of business. There was no restricted cash as of December 31, 2024.

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.

On a quarterly basis, the Company reviews its available-for-sale debt securities for credit-related impairment. An investment security is deemed impaired if the fair value of the investment is less than its amortized cost. For available-for-sale debt securities in an unrealized loss position, the Company evaluates at the individual security level whether the decline in fair value has resulted from credit losses or other factors. In making this assessment the Company considers the issuer of the securities and their creditworthiness, any changes to the rating of the security and any adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, an allowance for credit losses is recorded with an offsetting entry to earnings. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive income.

The Company typically invests in highly-rated securities and generally limits the amount of credit exposure to any one issuer. Additionally, the Company does not intend to sell the impaired securities, and it is not more likely than not that the Company will be required to sell the investments before recovery of the amortized cost bases. Unrealized losses during the three months ended March 31, 2025 and 2024, were primarily the result of market conditions, such as increasing interest rate movements, unusual market volatility, or industry-related events. Since the fluctuation in fair value is due to changes in market conditions and not credit quality, and because the Company does not intend to sell the investments and it is more likely than not that the Company will not be required to sell the investments before recovery of their amortized cost bases, the Company concluded that an allowance for credit losses was not required as of March 31, 2025.

Interest and dividends on available-for-sale securities are included in other income and expense. See Note 4, "Cash, cash equivalents, restricted cash, and marketable securities" for additional disclosure on marketable securities.

Concentration of credit risk

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

Non-trade receivables and unbilled reimbursements

Non-trade receivables are recorded for amounts due to the Company related to reimbursements of clinical trials expenses based upon contracted terms, and the sale of materials to contract manufacturers. Unbilled reimbursements represent amounts for services that have been rendered but for which reimbursements have not been billed. See Note 6, "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 pre-launch inventory begins when the Company determines that (i) positive clinical trial results have been obtained in order to support regulatory approval is probable; (ii) uncertainties regarding regulatory approval have been significantly reduced; and (iii) it is probable that these capitalized costs will provide future economic benefit, in excess of capitalized costs. On April 11, 2025, the Company received notification that the FDA has approved the WiSE CRT System for commercial distribution. At that time, the Company reclassified pre-launch inventory as inventory.

As of March 31, 2025 and December 31, 2024, the Company capitalized $4,718,416 and $2,842,540 of pre-launch inventory costs, respectively. At March 31, 2025, the Company had $3,232,330 and $1,486,086 of capitalized pre-launch inventory recorded in current and noncurrent assets, respectively. At December 31, 2024, the Company had $1,391,008 and $1,451,532 of capitalized pre-launch inventory recorded in current and noncurrent assets, respectively. The Company based the classification of pre-launch inventory on the Company's forecasted utilization within one year from the balance sheet date. Pre-launch inventory, consisting of raw materials, work-in-progress and finished goods, is recorded at the lower of cost (determined using the first-in, first-out method) or net realizable value. Net realizable value is determined as the estimated selling price in the ordinary course of business.

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 months ended March 31, 2025 and 2024, 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 noncurrent 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 7, "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.

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, commercialization, 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 12, "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. During the three months ended March 31, 2025 and 2024, the Company recorded reimbursements of $0 and $8,843, respectively.

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 adoption of ASU 2023-09 will be reflected in the Company's annual financial statements for the year ending December 31, 2025 and is not expected to have a material impact on the Company's consolidated financial statements and related disclosures

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures.* This ASU improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, the ASU enhances interim disclosure requirements, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, provides new segment disclosure requirements for entities with a single reportable segment, and other disclosure requirements. The Company adopted ASU 2023-07 in the year ended December 31, 2024. Refer to Note 15 for enhanced disclosures associated with the adoption of this ASU.

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

Note 4 - Cash, cash equivalents, and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following at March 31, 2025 and December 31, 2024:

	March 31, 2025	December 31, 2024
Cash and cash equivalents:		
Cash	$ 375,222	$ 3,210,556
Money market funds	8,523,796	3,706,990
Total cash and cash equivalents	$ 8,899,018	$ 6,917,546
Marketable securities, short-term:		
Asset backed securities	$ 2,002,677	$ 2,002,957
Commercial paper	1,172,838	1,156,709
Corporate bonds	17,405,461	23,951,700
US Treasury securities	18,387,428	26,635,045
Total marketable securities, short-term	$ 38,968,404	$ 53,746,411
Marketable securities, long-term:		
Asset backed securities	$ 2,318,822	$ 2,305,317
Corporate bonds	-	2,386,774
US Treasury securities	-	611,859
Total marketable securities, long-term	$ 2,318,822	$ 5,303,950
Total cash, cash equivalents, and marketable securities	$ 50,186,244	$ 65,967,907

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within our condensed consolidated balance sheets as of March 31, 2025 and March 31, 2024, to the total of such amounts as presented in the condensed consolidated statements of cash flows:

	March 31, 2025	March 31, 2024
Cash and cash equivalents	$ 8,899,018	$ 7,726,063
Restricted cash, noncurrent	2,603,568	-
Total cash, cash equivalents, and restricted cash	$ 11,502,586	$ 7,726,063

During the three-month period ended March 31, 2025, marketable securities were sold or matured for proceeds of $17,966,613 with a realized gain of $8,265. During the three-month period ended March 31, 2024, marketable securities were sold or matured for proceeds of $11,985,474 with no gain or loss realized. See Note 5, "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 March 31, 2025 and December 31, 2024:

	As of March 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
Asset backed securities	$ 4,321,067	$ 474	$ (42)	$ 4,321,499
Commercial paper	1,174,057	-	(1,219)	1,172,838
Corporate bonds	17,407,124	3,953	(5,616)	17,405,461
US Treasury securities	18,388,034	8,771	(9,377)	18,387,428
Total marketable securities	$ 41,290,282	$ 13,198	$ (16,254)	$ 41,287,226

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

The following table shows the unrealized losses and fair values for those marketable securities that were in an unrealized loss position as of March 31, 2025 and December 31, 2024, aggregated by major security type and the length of time the marketable securities have been in a continuous loss position:

	As of March 31, 2025					
	In Loss Position for Less Than 12 Months		In Loss Position for 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Asset backed securities	$ 998,362	$ (42)	$ -	$ -	$ 998,362	$ (42)
Commercial paper	1,172,838	(1,219)	-	-	1,172,838	(1,219)
Corporate bonds	8,479,628	(5,616)	-	-	8,479,628	(5,616)
US Treasury Securities	11,085,747	(9,377)	-	-	11,085,747	(9,377)
Total	$ 21,736,575	$ (16,254)	$ -	$ -	$ 21,736,575	$ (16,254)

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

The contractual maturities of the Company's marketable securities as of March 31, 2025, were as follows:

	Fair Value
One year or less	$ 38,968,404
Two years to three years	2,318,822
Total minimum payments	$ 41,287,226

Note 5 - 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 3, "Summary of significant accounting policies". At March 31, 2025 and December 31, 2024, the fair value measurement of the Company's financial assets measured on a recurring basis were as follows:

	Fair Values as of March 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 8,523,796	$ -	$ -	$ 8,523,796
Marketable securities				
Asset backed securities	-	4,321,499	-	4,321,499
Commercial paper	-	1,172,838	-	1,172,838
Corporate bonds	-	17,405,461	-	17,405,461
US Treasury securities	-	18,387,428	-	18,387,428
Total	$ 8,523,796	$ 41,287,226	$ -	$ 49,811,022

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

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 6 - Condensed consolidated balance sheet components

Non-trade receivables and unbilled reimbursements, net

Non-trade receivables and unbilled reimbursements include sales of materials to contract manufacturers, reimbursements of clinical trial expenses incurred, and various other reimbursements. Non-trade receivables and unbilled reimbursements were as follows as of March 31, 2025 and December 31, 2024:

	March 31, 2025	December 31, 2024
Non-trade receivables	$ 564,004	$ 433,051
Unbilled reimbursements	-	8,388
Reimbursement for leasehold improvements	185,691	-
Related party reimbursement	29,276	-
Non-trade receivables and unbilled services	778,971	441,439
Less: provision for credit losses	-	-
Non-trade receivables and unbilled services, net	$ 778,971	$ 441,439

As of March 31, 2025, the Company had an outstanding receivable of $29,276 from Host-Plus, a beneficial owner of more than 5% of our common stock, which consisted of certain legal fees that were paid on behalf of Host-Plus by the Company. No related party receivable was outstanding as of December 31, 2024. During the three months ended March 31, 2025 and 2024, there was no change in the provision for credit losses.

Pre-launch inventory

Pre-launch inventory consisted of the following as of March 31, 2025 and December 31, 2024:

	March 31, 2025	December 31, 2024
Raw materials	$ 1,496,493	$ 2,842,540
Work in process	2,456,887	-
Finished goods	765,036	-
Pre-launch inventory	$ 4,718,416	$ 2,842,540
Pre-launch inventory – current	$ 3,232,330	$ 1,391,008
Pre-launch inventory – noncurrent	$ 1,486,086	$ 1,451,532

Property and equipment, net

Property and equipment consisted of the following as of March 31, 2025 and December 31, 2024:

	March 31, 2025	December 31, 2024
Equipment	$ 3,443,097	$ 3,433,881
Computer software	888,706	574,780
Leasehold improvements	513,727	513,727
Construction in progress	204,822	-
Total property and equipment	5,050,352	4,522,388
Less accumulated depreciation and amortization	(3,806,615)	(3,727,429)
Total property and equipment, net	$ 1,243,737	$ 794,959

Depreciation and amortization expense for the three months ended March 31, 2025 and 2024, was $78,863 and $213,091, respectively. There were no impairments recorded during the three months ended March 31, 2025 and 2024.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following at March 31, 2025 and December 31, 2024:

	March 31, 2025	December 31, 2024
Accrued compensation and related liabilities	$ 2,029,422	$ 3,116,301
Accrued development expenses	405,423	482,417
Accrued warranty reserves	525,901	692,404
Accrued other expenses	98,919	4,719
Accrued expenses and other liabilities	$ 3,059,665	$ 4,295,841

See Note 16, “Commitments and contingencies” for additional disclosure on accrued warranty reserves.

Note 7 – Leases

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

In January 2025, the Company executed an operating lease for its new corporate headquarters, laboratory and manufacturing facility in Santa Clara, California. The term of the lease commenced on January 17, 2025, the date on which the landlord made the property available to the Company for the purpose of constructing leasehold improvements that will remain the property of the Company during lease term. As a result of entering into this lease agreement, the Company recorded a right-of-use asset and corresponding lease liability of $12,837,535, net of the tenant improvement allowance of $4,090,880 on the commencement date. The lease payments begin on the later of: (i) June 1, 2025; or (ii) the date the tenant improvements are deemed complete, which is expected to be January 2026. The monthly base rent payment is $52,000 in year one; $80,340 in year two; $110,334 in year three; $145,282 in year four; and increasing 3% annually thereafter. The lease provides for a term of 132 months and includes an option to extend the lease for an additional five years, which was used in the calculation of the right of use asset and lease liability, as the Company is reasonably certain that the option will be exercised. The Company determined the probability of the exercise of a lease extension option based on its long-term strategic business outlook, significant leasehold improvements that are expected to have significant economic value to the Company, and costs relating to signing a new lease, among other factors.

Amounts reported in the unaudited condensed consolidated balance sheets for operating leases in which the Company is the lessee as of March 31, 2025 and December 31, 2024, were as follows:

	March 31, 2025	December 31, 2024
Right of use asset	$ 13,470,082	$ 929,243
Lease liability, current	683,106	522,525
Lease liability, noncurrent	13,562,952	574,777
Weighted-average remaining lease term	15.52 years	2.00 years
Weighted-average discount rate	6.48%	10.00%

The following table presents the components of lease costs in our statements of operations for three months ended March 31, 2025 and 2024:

	Three Months Ended March 31, 2025	2024
Operating lease costs	$ 572,226	$ 100,983
Variable lease costs	33,000	30,711
Short-term lease costs	8,972	-
Total lease expense	$ 614,198	$ 131,694

Future lease payments for non-cancellable operating leases, net of the tenant improvement allowance as of March 31, 2025, were as follows:

Years Ended December 31,	
2025	$ 450,000
2026	1,224,000
2027	964,080
2028	1,324,003
2029	1,743,384
Thereafter	25,484,420
Total undiscounted lease payments	31,189,887
Less: effects of discounting	(12,852,949)
Less: tenant improvement allowance	(4,090,880)
Total operating lease liabilities	$ 14,246,058

Note 8 - Notes payable

At March 31, 2025 and December 31, 2024, notes payable consisted of the following:

	March 31, 2025	December 31, 2024
Notes payable, current		
Current portion of notes payable	$ 14,914	$ 37,286
Notes payable, noncurrent		
Long-term portion of notes payable	41,800,000	41,800,000
Less: unamortized deferred loan costs	(471,026)	(523,291)
Less: unamortized discount	(912,460)	(1,013,104)
Notes payable, noncurrent, net	$ 40,416,514	$ 40,263,605
Total notes payable, net	$ 40,431,428	$ 40,300,891

The following table presents information regarding the Company's notes payable principal repayment obligations as of March 31, 2025:

Years Ended December 31,	
2025	$ 14,914
2026	-
2027	41,800,000
Total minimum payments	$ 41,814,914

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. The final tranche provided $10,000,000 and the draw period was scheduled to commence on the date the Company 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. As of March 31, 2025 and December 31, 2024, the outstanding principal balance was $41,800,000.

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

The Company has accounted for the final payment of $1,800,000 as a discount of the note that will be amortized over the life of the loan using the effective interest method. Amortization of the discount was $100,644 and $100,475 for the three-month period ended March 31, 2025 and 2024, respectively. This amount was recorded as additional interest expense in the accompanying unaudited condensed consolidated statements of operations. As of March 31, 2025 and December 31, 2024, the note has been shown net of unamortized discounts of $912,460 and $1,013,104, respectively.

The Company incurred loan costs of $998,393, which are being amortized over the life of the loan using the effective interest method. Amortization of loan costs was $52,265 and $52,431 for the three-month period ended March 31, 2025 and 2024, respectively. As of March 31, 2025 and December 31, 2024, the note has been shown net of unamortized loan costs of $471,026 and $523,291, respectively.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of March 31, 2025 and December 31, 2024, the Company was in compliance with all debt covenants.

Bank of America Leasing & Capital, LLC

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 March 31, 2025 and December 31, 2024, the outstanding principal balance was $14,914 and $37,286, respectively, and was included in the current portion of notes payable in the unaudited condensed consolidated balance sheets.

Note 9 - Convertible preferred stock

As of March 31, 2025 and December 31, 2024, 10,000,000 shares of convertible preferred stock were authorized, of which no shares were issued or outstanding.

Note 10 - 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 March 31, 2025 and December 31, 2024, no dividends have been declared.

As of March 31, 2025 and December 31, 2024, 600,000,000 shares were authorized, of which 372,896,324 shares and 371,076,200 shares, respectively, were outstanding including shares underlying all CDIs.

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.

Additionally, the Company has reserved the following shares of common stock for issuance as of March 31, 2025:

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	17,278,905
2021 Equity Incentive Plan	37,504,358
Outside of 2021 Equity Incentive Plan	709,633
Total shares of Common stock reserved for issuance	75,282,275

Note 11 - Warrants

Equity classified common stock warrants

The Company has issued warrants to purchase shares of its common stock, which are exercisable any time at the option of the holder until their expiration date. As of March 31, 2025, the weighted-average exercise price of outstanding warrants was $0.57 with a weighted-average remaining contractual life of 5.03 years.

The following warrants were outstanding as of March 31, 2025 and December 31, 2024:

Warrant Issuance	Shares of Common Stock Issuable for Outstanding Warrants as of March 31, 2025	Shares of Common Stock Issuable for Outstanding Warrants as of December 31, 2024	Exercise Price	Expiration Date
October 6, 2015	309,278	309,278	$ 0.82	October 6, 2025
June 30, 2016	36,385	36,385	$ 0.82	June 30, 2026
October 30, 2017	1,950,607	1,950,607	$ 0.41	October 29, 2027
February 28, 2018	234,176	234,176	$ 0.82	February 28, 2028
August 26, 2019	4,438,347	4,438,347	$ 0.59	August 26, 2029
March 13, 2020	4,423,389	4,423,389	$ 0.59	March 13, 2030
March 25, 2020	441,500	441,500	$ 0.14	March 24, 2030
February 12, 2021	1,732,123	1,732,123	$ 0.59	February 12, 2031
June 25, 2021	2,887,518	2,887,518	$ 0.59	June 25, 2031
August 16, 2021	224,269	224,269	$ 0.59	June 25, 2031
October 4, 2021	3,111,787	3,111,787	$ 0.59	October 4, 2031
Total	19,789,379	19,789,379		

Note 12 - 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 in connection with its initial public offering. Under the 2021 Plan, 37,504,358 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 March 31, 2025, options to purchase a total of 22,377,618 shares of common stock remained outstanding and 15,126,740 shares remain available for grant under the 2021 Plan and 709,633 remained outstanding outside of the 2021 Plan. As of March 31, 2025, options to purchase a total of 17,278,905 shares of common stock remained outstanding under the 2013 Plan. As of March 31, 2025, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the three-month period ended March 31, 2025, was as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2024	41,918,671	$ 0.38	6.88
Granted	828,800	1.02	
Cancelled	(561,191)	0.62	
Exercised	(1,820,124)	0.15	
Outstanding at March 31, 2025	40,366,156	$ 0.40	6.76
Vested and expected to vest at March 31, 2025	40,366,156	$ 0.40	6.76
Exercisable at March 31, 2025	26,252,255	$ 0.29	5.68

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 three months ended March 31, 2025 and 2024, was $0.64 per share and $0.37 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Expected term (in years)	5.53 – 6.08	7.00
Expected volatility	65.27% - 65.73%	66.96% - 67.34%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	4.09% - 4.47%	4.20% - 4.28%

The following table presents classification of stock-based compensation expense within the accompanying unaudited condensed consolidated statements of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 243,612	$ 138,936
General and administrative	261,102	218,234
Total	$ 504,714	$ 357,170

At March 31, 2025, there was $5,573,573 of unamortized stock-based compensation cost, related to unvested stock options which is expected to be recognized over a weighted-average period of 2.94 years.

Note 13 - Income taxes

During the three months ended March 31, 2025 and 2024, 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 months ended March 31, 2025 and 2024. 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 benefits, research and development tax credits, and other non-deductible expenses.

During the three-month period ended March 31, 2025, there were no material changes to the Company's uncertain tax positions.

Note 14 - 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 months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Numerator – basic & diluted:		
Net loss attributable to common stockholders, basic and diluted	$ (10,554,271)	$ (9,150,003)
Denominator:		
Weighted-average number of shares outstanding, basic and diluted	372,541,173	307,423,873
Net loss per share attributable to common stockholders, basic and diluted	$ (0.03)	$ (0.03)

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 March 31, 2025 and 2024:

	March 31, 2025	March 31, 2024
Outstanding warrants	19,789,379	19,789,379
Outstanding stock options	40,366,156	39,217,071
Total dilutive shares	60,155,535	59,006,450

Note 15 - Segment information

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

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

The table below reports information about the segment loss for the three months ended March 31, 2025 and 2024.

	Three Months Ended March 31, 2025	2024
Research and development expenses		
Personnel-related expenses	$ 4,182,905	$ 3,860,827
Clinical expenses	392,604	291,658
Quality assurance and regulatory approval expense	86,755	60,967
Contract manufacturing, materials and components	730,619	1,731,338
Facility-related and other expenses	25,799	456,489
Total research and development expenses	5,418,682	6,401,279
General and administrative expenses		
Personnel-related expenses	2,299,835	1,080,022
Professional services expenses	1,084,399	502,235
Corporate expense	578,093	513,233
Facility-related and other expenses	400,677	77,625
Total general and administrative expense	4,363,004	2,173,115
Loss from operations	(9,781,686)	(8,574,394)
Other (expense) income		
Interest expense	(1,397,076)	(1,503,697)
Interest income	633,093	919,984
Other Income, net [(a)]	(8,602)	8,104
Total other (expense), net	(772,585)	(575,609)
Income tax (expense)	-	-
Consolidated net loss	$ (10,554,271)	$ (9,150,003)

[(a)] Other Income (Expense) includes gain/ (loss) on foreign currency, and reimbursements of clinical trial expenses.

Note 16 - 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 March 31, 2025, the Company's obligations under such arrangements were approximately $16,200,000.

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 months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
Beginning of period	$ 692,404	$ 826,924
Warranty reserve accrued during the period	-	-
Settlement of warranty claims	(166,503)	(36,993)
End of period	$ 525,901	$ 789,931

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, 2024. In addition to historical data, this discussion contains forward-looking statements about our business, ability to continue as a going concern, ability to successfully commercialize our WiSE CRT System, 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 I, Item 1A. Risk Factors of our Annual Report on Form 10-K. 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 developed the WiSE CRT System ("WiSE'), 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 device is part of a cardiac resynchronization therapy ("CRT"), 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.

On April 11, 2025, we received notification that the Center for Devices and Radiological Health ("CDRH") of the Food and Drug Administration ("FDA") had completed its review of our premarket approval application ("PMA") for the WiSE CRT System and approved the WiSE CRT System for commercial distribution in the U.S. for adult patients who are at least 22 years of age, are indicated for CRT, have an existing or are eligible for an implanted right ventricular pacing system, and are in one of the following two categories: patients in whom previous coronary sinus ("CS") lead implantation was unsuccessful, or where an implanted lead has been turned off, referred to as "previously untreatable"; or patients with previously implanted pacemakers or Implantable Cardioverter-Defibrillators ("ICDs") in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation, referred to as "high risk upgrades".

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

a) U.S. Strategy

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

LMR Phase 1: Initial Target Accounts

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

LMR Phase 2: Expansion and Optimization

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

LMR Phase 3: Increase Implants Per Site

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

Full Market Release

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

b) OUS Strategy

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

As a result of its breakthrough device designation ("BDD"), our WiSE CRT technology is expected to be eligible for incremental payment coverage in the U.S. for up to three years following FDA approval. The Centers for Medicare & Medicaid Services ("CMS") has proposed approval of the New Technology Add-On Payment ("NTAP") for our WiSE CRT System for fiscal year 2026, subject to final approval before October 1, 2025. CMS has recommended WiSE receive the maximum add on payment of 65% of the device cost, which is in additional to the normal Medicare Severity Diagnosis Related Group ("MS-DRG") payment. In combination, if approved, these reimbursements are intended to fully cover the cost of the WiSE CRT System.

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 March 31, 2025, we had $50.2 million in cash, cash equivalents, and marketable securities and an accumulated deficit of $364.0 million.

Our WiSE CRT System has been approved by the FDA for commercial distribution in April 2025, and we will begin commercializing WiSE during the second quarter of 2025. The commercial potential of and our ability to successfully commercialize WiSE is unproven and will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, as well as compliance with applicable laws and regulations. Based on our current operating plans and assumptions we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenue from U.S. sales of WiSE will be sufficient to fund our projected operating requirements into the first quarter of 2026.

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 clearances/post-approval study ("PAS")***. Our business strategy depends on the successful FDA submission of our PAS and ongoing annual reporting of our WiSE CRT System to the FDA.

- ***Market acceptance***. The growth of our business depends on our ability to successfully commercialize our WiSE CRT System and 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***. 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 CMS and payors, and to capitalize on recent CMS proposals to approve our WiSE CRT System for the NTAP beginning October 1, 2025.
- ***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 provided 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 our Form 10-K.

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

- hire and retain additional personnel, including research, clinical, development, 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 commercial launch of our WiSE CRT System;
- 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 critical accounting estimates are more fully described in our Annual Report on Form 10-K for the year ended December 31, 2024. There have been no significant changes to our critical accounting estimates since December 31, 2024.

Recent Accounting Pronouncements

See the sections titled "Summary of Significant Accounting Policies—Recently issued accounting pronouncements" in Note 3 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Non- GAAP Financial Measures

Adjusted earnings before interest, income taxes, depreciation and amortization ("Adjusted EBITDA"), a non-GAAP measure used by management to assess operating performance, is defined as net loss, excluding interest expense, net, depreciation and amortization, and stock-based compensation. Adjusted EBITDA is intended as a supplemental measure of our performance and provides useful information to management and investors regarding our operating results.

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

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

A reconciliation between net loss and adjusted EBITDA is presented below:

	Three Months Ended March 31,	
(in thousands)	2025	2024
Reconciliation of net loss to non-GAAP Adjusted EBITDA		
Net loss	$ (10,554)	$ (9,150)
Interest expense, net	(764)	(584)
Depreciation and amortization	79	213
Stock-based compensation [(a)]	505	357
Adjusted EBITDA	$ (10,734)	$ (9,164)

[(a)] Represents non-cash expense associated with our share-based payments.

Results of Operations

Comparison of the Three Months Ended March 31, 2025, to the Three Months Ended March 31, 2024

We recorded a net loss of $10.6 million in the three-month period ended March 31, 2025, an increase of $1.4 million, or 15.4%, from the three-month period ended March 31, 2024. The increased loss in 2025 was due to an increase in general and administrative expenses, which was partially offset by a decrease in research and development expenses, as discussed below. Other (expense), net also increased in 2025, primarily due to a decrease in interest income, as discussed below. The following table summarizes our operating results for the three months ended March 31, 2025 and 2024:

(in thousands)	Three Months Ended March 31, 2025	2024	Change Amount	%
Operating expenses:				
Research and development	$ 5,419	$ 6,401	$ (982)	(15.3%)
General and administrative	4,363	2,173	2,190	100.8%
Total operating expenses	9,782	8,574	1,208	14.1%
Other (expense), net	(773)	(576)	(197)	34.2%
Loss before income tax	(10,555)	(9,150)	(1,405)	15.4%
Income tax expense	-	-	-	0.0%
Net Loss	$ (10,555)	$ (9,150)	$ (1,405)	15.4%

Operating Expenses

Research and Development

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

(in thousands)	Three Months Ended March 31, 2025	2024	Change Amount	%
Research and development expenses:				
R&D personnel expense	$ 4,183	$ 3,861	$ 322	8.3%
Clinical expenses	393	292	101	34.6%
Quality assurance	86	61	25	41.0%
Contract manufacturing, materials & components	731	1,731	(1,000)	(57.8%)
Facility related and other expense	26	456	(430)	(94.3%)
Total research and development expense	$ 5,419	$ 6,401	$ (982)	(15.3%)

Research and development expenses decreased by $1.0 million, or 15.3% during the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. 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 pre-launch inventory. Facility-related expenses decreased by $0.4 million, as we began to capitalize certain overhead costs during the three months ended March 31, 2025. These decreases were partially offset by a $0.3 million increase in personnel-related expenses, including salaries, bonuses, and certain fringe benefits, resulting from an expansion in our workforce to support the ongoing development efforts of the WiSE CRT System; and a $0.1 million increase in clinical expenses, primarily resulting from higher travel expenses, including lodging, air travel and ground transportation due to patient follow-up visits for the SOLVE-CRT Study.

General and Administrative Expenses

General and administrative expenses increased by $2.2 million, or 100.8%, during the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $1.2 million as a result of the expansion of our workforce to support our commercialization effort in anticipation of FDA approval of the WiSE CRT System. Professional fees increased by $0.6 million, primarily resulting from higher accounting and legal related services associated with being a public filer in the US. Travel expenses increased by $0.3 million, which included higher lodging, air travel and ground transportation expenses resulting from travel required for training of the commercial team. Corporate expenses increased by $0.1 million, primarily resulting from the higher expenses related to insurance premiums.

Other (expense) income, net

Other (expense) income, net increased by $0.2 million during the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. This increase primarily resulted from a $0.3 million decrease in interest income earned on investments in marketable securities, including the accretion of discounts on marketable securities, which was partially offset by a $0.1 million decrease in interest expense.

Liquidity and Capital Resources

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 March 31, 2025 and December 31, 2024, we had approximately $50.2 million and $66.0 million, respectively, in cash, cash equivalents, and marketable securities. Based on our cash, cash equivalents, and marketable securities as of March 31, 2025, and our expectation to generate operating losses and negative operating cash flows in the foreseeable future, there exists substantial doubt regarding our ability to continue as a going concern for a period of at least twelve months from the date of this Form 10-Q.

Going concern consideration

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. For the three months ended March 31, 2025 and 2024, we incurred a net loss of $10,554,271 and $9,150,003, respectively. During the three months ended March 31, 2025 and 2024, we had negative cash flows from operations of $13,563,695 and $10,059,772, respectively. As of March 31, 2025, we had working capital of $46,751,043 and accumulated deficit of $364,011,951. These factors raise substantial doubt about our ability to continue as a going concern. Until we are able to generate consistent and sufficient revenue from sales of our WiSE CRT System, our ability to continue as a going concern is dependent on our ability to raise additional capital through the issuance of additional common stock or borrowings from financial institutions. Our ability to obtain additional capital in the equity capital markets is subject to several factors, including market and economic conditions, our performance, and investor sentiment with respect to our company and our industry.

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 March 31, 2025 and December 31, 2024, 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 March 31, 2025 and December 31, 2024, we were in compliance with all debt covenants.

Future Funding Requirements

Despite recent FDA approval of WiSE CRT System, the outcome of any clinical activities and/or regulatory approval process is highly uncertain, we cannot reasonably estimate whether our future development activities may succeed; or whether we will be able to effectively commercialize WiSE CRT System in the U.S., if at all. We may never recoup our investment in any WiSE CRT System development which would adversely affect our financial condition and our business and business prospects. In addition, our plans and timing expectations could be further delayed or interrupted by the effects of macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues.

To date, we have not generated any commercial product revenue. We will continue to require additional capital to successfully commercialize WiSE CRT System and fund operations for the foreseeable future. Our primary uses of cash are to fund our operations, which consist primarily of research and development expenses, manufacturing automation and scaleup, and general and administrative expenses. We expect our expenses to continue to increase in connection with our ongoing activities as we continue to commercialize WiSE CRT System.

We may seek to raise capital through equity offerings or debt financings, collaboration agreements, or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our consolidated financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the cost and timing of establishing sales, marketing a distribution capabilities;
- the cost, timing and results of our post-marketing trial and regulatory reviews;
- the cost of our research and development activities for new and modified products;
- 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 WiSE CRT System;
- 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.

If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us. If we raise funds through collaborations, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or delay investments in our manufacturing scale-up and automation. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets. Furthermore, this Quarterly Report on Form 10-Q contains statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

Contractual Obligations and Commitments

As of March 31, 2025, we had $1.0 million in operating lease obligations for our corporate headquarters and laboratory space located in Sunnyvale, California. Additionally, in January 2025, we entered into a new lease agreement for our new corporate headquarters, laboratory and manufacturing facility in Santa Clara, California, for which we had recorded $13.3 million in operating lease obligations as of March 31, 2025.

As of March 31, 2025, 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 March 31, 2025, the outstanding principal balance was $14,914. 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 March 31, 2025, our obligations under such arrangements were approximately $16.2 million.

Working Capital

March 31, 2025, Compared to December 31, 2024

As of March 31, 2025, we had working capital of $46.8 million, comprised of current assets of $53.5 million and current liabilities of $6.7 million. Current assets, consisting of cash and cash equivalents, marketable securities, pre-launch inventory, prepaid expenses, non-trade receivables and other current assets, decreased by $11.2 million as of March 31, 2025, compared to December 31, 2024. The decrease was primarily caused by a decrease in cash, cash equivalents and marketable securities as a result of cash used in operating activities for the three months ended March 31, 2025. Refer to the cash flows discussion below for further details. Current liabilities, consisting primarily of accounts payable, accrued liabilities, lease obligations, the current portion of notes payable and interest payable, decreased by approximately $1.8 million as of March 31, 2025, compared to December 31, 2024. The decrease primarily resulted from the payout of annual bonuses in January 2025, and a reduction in accounts payable from December 31, 2024 to March 31, 2025.

Cash Flows

March 31, 2025, Compared to March 31, 2024

The following table summarizes our cash flows for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
(in thousands)	2025	2024
Net cash used in operating activities	$ (13,564)	$ (10,060)
Net cash provided by investing activities	17,906	3,034
Net cash provided by financing activities	242	193
Effect of exchange rate change on cash	1	(20)
Net change in cash and cash equivalents	$ 4,585	$ (6,853)

Operating Activities

Net cash used in operating activities during the three months ended March 31, 2025, was $13.6 million, compared to $10.1 million during the three months ended March 31, 2024, representing an increase in use of $3.5 million. This increase is primarily attributed to an increase in net loss of $1.4 million, a decrease in cash from changes in working capital of $2.8 million, which were partially offset by an increase in non-cash adjustments of $0.7 million.

- The increase in net loss of $1.4 million primarily resulted from increases in personnel costs, increases in professional fees, and decrease in interest income, as further described under “Results of Operations” above.

- Non-cash items primarily consisted of increases in accretion of discount on marketable securities of $0.5 million driven by fluctuating interest rates and maturity term, and a $0.2 million increase in the adjustment to lease amortization due to the company entering into a new lease agreement in 2025.
- The decrease in changes from working capital activities primarily consisted of $2.1 million use of cash for pre-launch inventory purchases during the three months ended March 31, 2025, a $0.7 million decrease in accounts payable and accrued expenses due to the timing of invoice payments, and a $0.4 million decrease in non-trade receivables due to the timing of collections. These decreases were partially offset by a $0.4 million increase in operating lease liability due to the company entering into a new lease agreement in 2025.

Investing Activities

Net cash provided by investing activities during the three months ended March 31, 2025, was $17.9 million, compared to $3.0 million during the three months ended March 31, 2024, representing an increase in cash provided of $14.9 million. The increase was attributable to a $8.9 million decrease in the purchase of marketable securities, as well as a $6.0 million increase in cash from the maturities and sales of marketable securities during the three months ended March 31, 2025, as compared to the three months ended March 31, 2024.

Financing Activities

Net cash provided by financing activities during both three months ended March 31, 2025 and 2024, was $0.2 million. The cash provided by financing activities during the three months ended March 31, 2025, was primarily attributable to the proceeds from exercise of stock options. Cash provided by financing activities during the three months ended March 31, 2024, was comprised from $0.1 million in proceeds from exercise of stock options and $0.1 million in proceeds from note payable related to the software purchase agreement.

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 judgement 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 March 31, 2025.

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 March 31, 2025, 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

In addition to other information set forth in this report, readers should carefully consider the factors discussed in Part I, Item 1A. "Risk Factors" of our 2024 Annual Report on Form 10-K, as updated and supplemented below. Any of the risk factors disclosed in our reports could materially affect our business, financial condition or future results. The risks described here and in our 2024 Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition and/or operating results. The discussion of the risk factor below updates the corresponding disclosure under the same heading in the 2024 Annual Report on Form 10-K and may contain material changes to the corresponding risk factor discussion in our 2024 Annual Report on Form 10-K.

There is substantial doubt regarding our ability to continue as a going concern. If we are unable to raise additional capital when needed, we may be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

In April 2025, we received FDA approval to commercialize WiSE CRT System in the U.S., and we plan to initiate a commercial launch of WiSE in the U.S. during the second quarter of 2025. WiSE is our only product approved for marketing by the FDA and our ability to generate revenue from product sales and achieve profitability is wholly dependent on our ability to successfully commercialize WiSE in the U.S. Our operations have consumed substantial amounts of cash since our inception.

As of March 31, 2025, we had working capital of $46,751,043 and accumulated deficit of $364,011,951. These factors raise substantial doubt about our ability to continue as a going concern. Until we are able to generate consistent and sufficient revenue from the sales of our WiSE CRT System, our ability to continue as a going concern is dependent on our ability to raise additional capital through the issuance of additional common stock or borrowings from financial institutions. Our ability to obtain additional capital in the equity capital markets is subject to several factors, including market and economic conditions, our performance, and investor sentiment with respect to our company and our industry.

We may not be able to obtain additional funding on acceptable terms, or at all. As a result of geopolitical events, including the conflicts in Ukraine and Gaza, inflation, rising interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants and other operating restrictions that could adversely impact our ability to conduct our business. Our current lender already has a security interest in substantially all of our assets, including proceeds from the sale of our intellectual property, which may prevent or limit our ability to incur additional indebtedness.

Our funding requirements and the timing of our need for additional capital are subject to change based on a number of factors, including:

- the degree of success we experience in commercializing our WiSE CRT System;
- the cost, timing and results of our post-marketing trial 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 any 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 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.

We may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Changes in economic conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business, operations, and financial condition.

Our operations and performance are impacted by global, regional and U.S. economic and geopolitical conditions. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the medical device industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to attract non-U.S. investment, employees, customers, and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition, and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to other risk factors described in our 2024 Annual Report on Form 10-K.

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

None.

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-K	3.1	3/24/2025
3.2	Amended and Restated Bylaws of EBR Systems, Inc.	10-K	3.2	3/24/2025
4.2	Amended and Restated Investors' Rights Agreement dated October 13, 2021, between EBR Systems, Inc., and the parties thereto.	10-K	4.2	3/24/2025
10.1	Lease Agreement, dated January 17, 2025, between the Company and Drawbridge 4600 Patrick Henry, LLC	10-K	10.7	3/24/2025
10.2	First Amendment to Loan and Security Agreement, dated March 21, 2025, between the Company and Runway Growth Finance Corp.	10-K	10.2	3/24/2025
10.3	Addendum "E" to the Oakmead Lease, dated April 2025, between the Company and 480 Oakmead Properties, LLC.			
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.

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: May 13, 2025