ASX ANNOUNCEMENT **13 August 2025**

Q2 2025 Quarterly Activity Report and Form 10-Q submission

Key Highlights:

- EBR secured FDA approval for the novel WiSE® CRT System, the world's first and only leadless solution for left ventricular endocardial pacing
- Successfully completed first commercial implants of the WiSE CRT System in leading U.S. medical centers ahead of anticipated reimbursement add-ons
- Subsequent to quarter end, the U.S. Centers for Medicare & Medicaid Services' ("CMS") confirmed approval of the New Technology Add-On Payment ("NTAP") reimbursement for inpatients at the maximum rate
- Preliminary approval secured from CMS for Transitional Pass-Through ("TPT") reimbursement to support outpatient adoption
- EBR successfully completed a A$75.9m capital raising to advance the commercialisation strategy for EBR's novel WiSE® system
- EBR holds cash, cash equivalents, restricted cash and marketable securities of US$87.2m / A$133.6m[1] as at 30 June 2025

Sunnyvale, California; 13 August 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 June quarter ("**Q2 2025**").

EBR secures FDA approval for the WiSE® CRT System

EBR secured FDA approval for the Company's WiSE cardiac resynchronization therapy ("CRT") System in April 2025, marking a critical advancement in cardiac pacing technology. 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 intends to roll out the WiSE CRT System strategically in phases. An initial limited market release will commence in late 2025, timed to coincide with the expected initiation of reimbursement add-on payments for both inpatient (NTAP) and outpatient (TPT) settings from October 2025. The initial phase of the rollout will concentrate on high-volume centres and is aimed at gathering early user experience and facilitating wider adoption, ramping towards full commercial distribution during 2026.

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

"Securing FDA approval and completing the WiSE System's first commercial implants are key milestones for EBR. Supported by significant advancements in reimbursement and our recent capital raising, EBR is ideally positioned to execute our commercial strategy. Our team is eager to launch our limited market release in October, coinciding with the initiation of NTAP and TPT Medicare payments."

First commercial WiSE® implants completed

Building on the momentum of FDA approval, EBR successfully completed its first commercial implants of the WiSE system during the quarter. The procedures took place at St. David's Medical Centre and the Cleveland Clinic, two

[1] Assumes an A$:US$0.65249 exchange rate as at 30 June 2025

of several leading U.S. institutions participating in this pilot release of the WiSE system. These cases are representative of two of the main indications for WiSE – Previously Untreatable (CRT patient with non-functional CS lead) and High-Risk Upgrade (Micra® leadless pacemaker patient with pacing induced heart failure). This further supports EBR's US$3.6bn Total Available Market estimate as these are key elements of that projected market. These implants occurring ahead of anticipated reimbursement add-ons is testament to the clinical importance of the WiSE System to both patients and treating physicians. The limited market release is expected to begin in Q4 2025.

NTAP and TPT reimbursement pathways

During Q2 2025, CMS proposed approval for the NTAP reimbursement for FY2026 at the maximum reimbursement rate of up to US$41,145 based on an average WiSE selling price of US$63,300, This is in addition to the normal MS-DRG payment, which is intended to cover the procedure and remaining device costs. The NTAP reimbursement will enable customer reimbursement for inpatient procedures in the Medicare patient population from October 2025. NTAP reimbursement significantly reduces financial barriers for patients and supports EBR's overall commercialisation strategy by improving patient access to this innovative technology and accelerating market adoption in the US. Subsequent to quarter end, CMS confirmed final approval for the NTAP reimbursement.

EBR also secured preliminary approval from CMS for the TPT reimbursement. Final approval, which is expected to become effective October 2025, will provide hospitals with Medicare reimbursement when treating patients in an outpatient setting with the WiSE CRT System for a period of three years. 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 in standard Medicare payment rates. Preliminary approval is a significant commercial milestone, as access to the TPT reimbursement scheme will support hospital adoption for outpatients and allow EBR's commercial team to present a clear reimbursement pathway to hospitals. Following preliminary approval, EBR will continue to engage with CMS through the upcoming annual rulemaking and public comment process, with a final determination to follow.

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 Emergence Dubai, Barrenjoey Healthcare Conference, and Morgans Emerging Leaders Conference. Management also hosted investor roadshows during the quarter as part of the capital raising transaction, providing an opportunity for new investors and shareholders to directly engage with the Company. These engagements focused on EBRs achievement of FDA approval, strategic initiatives, and commercialisation strategy.

Corporate update

EBR successfully completed a A$75.9m capital raising in Q2 2025, composed of a A$55.9m institutional placement and a A$20.0m Security Purchase Plan ("SPP") which was heavily oversubscribed. The funds raised will be used to primarily support the commercialisation strategy for EBR's novel WiSE CRT System.

In addition to the cash or cash equivalent balance of US$45.0m / A$69.0m[2] on 30 June 2025, EBR held US$2.6m / A$4.0m[2] in restricted cash, and US$39.6m / A$60.6m[2] in marketable securities, which will become cash or cash equivalents in the future. Investments are made in fixed income instruments, have a weighted average maturity of 2.0 months, and have a minimum credit rating of A-2/P-2/F2 by at least 2 of 3 Nationally Recognised Statistical Rating Organisations, specifically Standard & Poor's, Moody's or Fitch.

Quarterly activity report

Key Highlights

- During the quarter, EBR had net operating cash outflows of US$11.5m / A$17.6m[2].

[2] Assumes an A$:US$0.65249 exchange rate as at 30 June 2025

- Gross margin for the quarter was favourably impacted by the use of inventory that was previously expensed during our clinical trial. Margins will continue to reflect favourable impacts in the near term as the supply of previously expensed inventory is utilised.
- Payments for research and development, and product manufacturing and operating costs trended lower during the second quarter resulting from project spending and the timing of payments made to vendors.
- Payments for sales and marketing and staff costs increased trended higher during the second quarter resulting from our commercialisation efforts after we received FDA approval in April 2025.

(Unaudited)

(U.S. Dollars in thousands)	Quarter ended 30 Jun 2025	31 Mar 2025
Cash flows from operating activities		
Receipts from customers	$ 12	$ -
Payments for		
research and development	(371)	(1,628)
product manufacturing and operating costs	(1,380)	(2,253)
advertising and marketing	(519)	(377)
leased assets	(161)	(159)
staff costs	(6,742)	(6,530)
administration and corporate costs	(1,525)	(1,788)
Interest received	499	420
Interest and other costs of finance paid	(1,289)	(1,249)
Income taxes paid	(1)	-
Net cash from / (used in) operating activities	(11,477)	(13,564)
Cash flows from investing activities		
Payments to acquire property, plant, and equipment	(889)	(60)
Payments to acquire investments	(9,370)	-
Proceeds from disposal of investments	11,154	17,967
Net cash from / (used in) investing activities	895	17,907
Cash flows from financing activities		
Proceeds from issues of shares	48,828	-
Proceeds from exercise of share options	168	264
Transaction costs related to issues of shares	(2,313)	-
Repayment of borrowings	(15)	(22)
Net cash from / (used in) financing activities	46,668	242
Cash, cash equivalents, and restricted cash at beginning of period	11,504	6,918
Net cash from / (used in) operating activities	(11,477)	(13,564)
Net cash from / (used in) in investing activities	895	17,907
Net cash from / (used in) financing activities	46,668	242
Effect of movement in exchange rates on cash held	7	1
Cash and cash equivalents at end of period	$ 47,597	$ 11,504

ENDS

This announcement has been authorised for release by the EBR Systems General 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 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 U.S.

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 June 30, 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	**57-1164669**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
480 Oakmead Parkway Sunnyvale, CA	**94085**
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

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

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

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

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

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

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

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

As of August 12, 2025, the registrant had 449,552,201 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 JUNE 30, 2025

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PART I — FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,993,424	$ 6,917,546
Marketable securities	36,704,864	53,746,411
Accounts and other receivables, net	2,097,882	441,439
Inventory	5,133,867	1,391,008
Prepaid expenses	1,262,537	1,693,560
Other current assets	152,454	276,419
Total current assets	90,345,028	64,466,383
Restricted cash, noncurrent	2,603,568	-
Property and equipment, net	3,008,747	794,959
Right of use operating lease asset	13,183,580	929,243
Marketable securities	2,900,071	5,303,950
Inventory, noncurrent	2,311,820	1,451,532
Other assets	577,504	613,427
TOTAL ASSETS	**$ 114,930,318**	**$ 73,559,494**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,766,785	$ 3,247,453
Accrued expenses and other liabilities	3,867,600	4,295,841
Interest payable	206,667	224,889
Operating lease liability	846,721	522,525
Current portion of notes payable	-	37,286
Total current liabilities	9,687,773	8,327,994
Other liabilities	208,349	37,617
Operating lease liability	14,766,626	574,777
Notes payable, net	40,571,441	40,263,605
Total liabilities	65,234,189	49,203,993
Commitments and contingencies (Note 15)		
STOCKHOLDERS' EQUITY		
Common stock, $0.0001 par value; 600,000,000 shares authorized, 449,552,201 and 371,076,200 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	44,956	37,108
Additional paid-in capital	424,765,056	376,902,576
Accumulated deficit	(375,979,392)	(353,457,680)
Accumulated other comprehensive income	865,509	873,497
Total stockholders' equity	49,696,129	24,355,501
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 114,930,318**	**$ 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 June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenue	$ 169,704	$ -	$ 169,704	$ -
Cost of goods sold	85,275	-	85,275	-
Gross profit	84,429	-	84,429	-
Operating expenses:				
Research and development	5,951,558	7,471,604	11,370,240	13,872,883
Selling, general and administrative	5,264,805	3,270,321	9,627,809	5,443,436
Total operating expenses	11,216,363	10,741,925	20,998,049	19,316,319
Loss from operations	(11,131,934)	(10,741,925)	(20,913,620)	(19,316,319)
Other (expense) income:				
Interest expense	(1,430,947)	(1,530,447)	(2,828,022)	(3,034,144)
Interest income	613,990	778,940	1,247,083	1,698,924
Other income	-	-	-	8,843
(Loss) on foreign currency	(18,550)	(1,256)	(27,152)	(1,995)
Total other (expense), net	(835,507)	(752,763)	(1,608,091)	(1,328,372)
Loss before income taxes	(11,967,441)	(11,494,688)	(22,521,711)	(20,644,691)
Income tax benefit (expense)	-	-	-	-
Net loss	$ (11,967,441)	$ (11,494,688)	$ (22,521,711)	$ (20,644,691)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.03)	$ (0.04)	$ (0.06)	$ (0.07)
Weighted-average number of common shares outstanding:				
Basic and diluted	395,862,055	308,101,693	384,266,036	307,762,783

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Net loss	$ (11,967,441)	$ (11,494,688)	$ (22,521,711)	$ (20,644,691)
Other comprehensive income (loss):				
Change in unrealized gains on marketable securities	(8,058)	(23,979)	(18,721)	(73,406)
Foreign currency translation adjustments	11,238	7,106	10,732	(21,826)
Total other comprehensive income (loss)	3,180	(16,873)	(7,989)	(95,232)
Comprehensive loss	$ (11,964,261)	$ (11,511,561)	$ (22,529,700)	$ (20,739,923)

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

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

	Six Months Ended June 30, 2025					
	Common Stock		Additional	Accumulated	Accumulated 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
Exercise of stock options	755,877	76	168,020	-	-	168,096
Stock-based compensation	-	-	704,119	-	-	704,119
Issuance of common stock, net of issuance costs	75,900,000	7,590	46,221,825	-	-	46,229,415
Net loss	-	-	-	(11,967,441)	-	(11,967,441)
Other comprehensive income	-	-	-	-	3,180	3,180
Balance at June 30, 2025	449,552,201	$ 44,956	$ 424,765,056	$ (375,979,392)	$ 865,509	$ 49,696,129

	Six Months Ended June 30, 2024					
	Common Stock		Additional	Accumulated	Accumulated 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
Exercise of stock options	23,125	2	2,311	-	-	2,313
Stock-based compensation	-	-	422,535	-	-	422,535
Net loss	-	-	-	(11,494,688)	-	(11,494,688)
Other comprehensive loss	-	-	-	-	(16,873)	(16,873)
Balance at June 30, 2024	308,113,383	$ 30,812	$ 343,614,526	$ (333,304,099)	$ 868,045	$ 11,209,284

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

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

	Six Months Ended June 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (22,521,711)	$ (20,644,691)
Adjustment to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	197,329	395,532
Amortization of deferred loan costs and discount on notes payable	307,836	306,132
Lease amortization	583,198	178,945
Stock-based compensation	1,208,833	779,705
Loss on disposal of fixed assets	35,153	-
Accretion of discount on marketable securities	(324,469)	(1,059,132)
Changes in operating assets and liabilities:		
Accounts and other receivables	(1,656,640)	(180,302)
Inventory	(4,603,147)	-
Prepaid expenses	431,590	374,226
Other assets	146,578	(158,778)
Accounts payable	23,009	430,902
Accrued expenses and other liabilities	(528,081)	(637,513)
Interest payable	(18,222)	(976)
Operating lease liability	1,678,511	(170,388)
Net cash used in operating activities	(25,040,233)	(20,386,338)
Cash flows from investing activities:		
Purchase of property and equipment	(948,793)	(156,526)
Purchase of marketable securities	(9,369,440)	(19,979,938)
Maturities of marketable securities	24,809,000	33,000,000
Sales of marketable securities	4,311,614	1,125,676
Net cash provided by investing activities	18,802,381	13,989,212
Cash flows from financing activities:		
Proceeds from notes payable	-	82,029
Repayment of notes payable	(37,286)	-
Proceeds from exercise of stock options	432,080	113,050
Proceeds from issuance of common stock	48,828,060	-
Payment of common stock issuance costs	(2,313,143)	-
Net cash provided by financing activities	46,909,711	195,079
Effect of exchange rate change on cash	7,587	(12,082)
Net change in cash, cash equivalents, and restricted cash	40,679,446	(6,214,129)
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	$ 47,596,992	$ 8,364,623
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 2,538,409	$ 2,728,988
Cash paid for income taxes	$ 1,380	$ 1,625
Supplemental disclosure of non-cash investing and financing activities		
Remeasurement of lease liabilities	$ -	$ 908,810
Purchases of property and equipment not yet paid	$ 1,523,512	$ 19,573
Initial recognition of right of use asset and operating lease liability	$ 12,837,535	$ -
Accrued common stock issuance costs	$ 285,502	$ -

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 developed the WiSE CRT System ("WiSE"), 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 U.S. Food and Drug Administration ("FDA") has completed its review of the premarket approval application ("PMA") and approved WiSE 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 - Summary of significant accounting policies

Basis of presentation

These unaudited condensed consolidated financial statements as of June 30, 2025, and for the three and six months ended June 30, 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 June 30, 2025, unaudited condensed consolidated results of operations and comprehensive loss for the three and six months ended June 30, 2025 and 2024, and unaudited condensed consolidated cash flows for the six months ended June 30, 2025 and 2024. The unaudited condensed consolidated results of operations for the three and six months ended June 30, 2025, are not necessarily indicative of the consolidated results of operations that may be expected for the year ending December 31, 2025.

Liquidity

The accompanying unaudited condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. For the six months ended June 30, 2025 and 2024, the Company incurred a net loss of $22,521,711 and $20,644,691, respectively. During the six months ended June 30, 2025 and 2024, the Company had negative cash flows from operations of $25,040,233 and $20,386,338, respectively. The Company has incurred operating losses and negative cash flows from operations since inception and anticipates such conditions to continue in the foreseeable future. As of June 30, 2025, the Company had working capital of $80,657,255 and accumulated deficit of $375,979,392. The Company continues to face risks similar to those of other companies of similar size in its industry, including, but not limited the need for successful commercialization of products, the need for additional capital, or financing, to fund operating losses, protection of proprietary technology, and dependence on key individuals. The Company has funded its operations through the issuance of common stock and debt instruments, as further discussed in Note 7, "Notes payable" and Note 9, "Common stock" below.

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 June 30, 2025 and 2024, the Company match expense was $104,040 and $0, respectively. For the six months ended June 30, 2025 and 2024, the Company match expense was $242,370 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 June 30, 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 and six months ended June 30, 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 June 30, 2025.

Interest and dividends on available-for-sale securities are included in other income and expense. See Note 3, “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.

Accounts and other receivables and allowance for credit losses

Trade receivables represent amounts due from customers for the sale of our product. Non-trade receivables are recorded from amounts due to the Company from contract manufacturers. Unbilled reimbursements represent reimbursement of clinical trial expenses for which reimbursements have not been billed. Reimbursement for leasehold improvements represent allowable costs and fees that will be reimbursed by the landlord in according to the lease agreement. See Note 5, “Condensed consolidated balance sheet components” for additional information on accounts and other receivables.

Trade accounts receivable are recorded at the invoiced amount, net of allowances for credit losses for any potential uncollectible amounts. The allowance for credit losses is based on our assessment of the collectability of accounts. Management regularly reviews the adequacy of the allowance for credit losses on a collective basis by considering the age of each outstanding invoice, each customer’s expected ability to pay and collection history, current market conditions, and reasonable and supportable forecasts of future economic conditions to determine whether the allowance is appropriate. Accounts and other receivables are written-off and charged against an allowance for credit losses when the Company has exhausted collection efforts without success. During the three and six months ended June 30, 2025 and 2024, the Company recorded no provision for credit losses. As of June 30, 2025 and December 31, 2024, the outstanding trade accounts receivable balance was $259,199.

Inventory

Inventory is comprised of raw materials, work-in-progress and finished goods. Inventory is stated 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.

Pre-launch inventory costs associated with products that have not yet received regulatory approval are capitalized if there is probable future commercial use and future economic benefit. If future commercial use and future economic benefit are not considered probable, then costs associated with pre-launch inventory that has not yet received regulatory approval are expensed as research and development expense during the period the costs are incurred. The determination to capitalize 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. Pre-launch inventory was recorded at the lower of cost (determined using the first-in, first-out method) and net realizable value.

On April 11, 2025, the Company received notification from the FDA that WiSE had been approved for commercial distribution in the United States. At that time, the Company began presenting pre-launch inventory as inventory in the unaudited condensed consolidated financial statements and accompanying notes.

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

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for potential impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that carrying value exceeds fair value. Fair value is determined using various valuation techniques, including discounted cash flow models, quoted market values, and third-party independent appraisals, depending on the nature of the asset. For the three and six months ended June 30, 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 6, “Leases” for additional disclosure on leases.

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

Revenue recognition

In accordance with Accounting Standards Codification 606 *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when control is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for the goods or services. To recognize revenue, the Company applied the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied.

The Company recognizes all of its revenue from contracts with customers at a point in time. As the majority of revenue consists of sales of WiSE and battery replacements, where the Company's sales representative provides assistance at the point of implantation at hospitals or medical facilities, the Company recognizes revenue upon completion of the procedure. The Company also generates a small portion of its revenue from the sale of surgical tool kits that are ordered in advance of a procedure. As the performance obligation is the delivery of the product, the Company recognizes revenue for the surgical tool kits upon shipment to the customers. For all performance obligations, the standalone selling price is directly observable as these goods are sold separately by the Company. Sales prices are specified in the executed customer contract and purchase order prior to the transfer of control to the customer. The Company's standard payment terms are generally net 30 days.

The following table summarizes revenue from contracts with customers disaggregated by product for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue:				
WiSE CRT System	$ 146,070	$ -	$ 146,070	$ -
Surgical tool kits	3,424	-	3,424	-
Battery replacements	20,210	-	20,210	-
Total revenue	$ 169,704	$ -	$ 169,704	$ -

Cost of goods sold

The Company purchases components and materials from third-party suppliers and manufacturers. Cost of goods sold consists primarily of costs related to materials, manufacturing overhead costs, reserves for excess, and obsolete and non-sellable inventories. Manufacturing overhead costs includes the cost of material procurement and operations and quality supervision and management personnel, including employee compensation, stock-based compensation, supplies, and travel. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs, such as shipping and handling costs.

Warranty

The Company has a warranty program that offers a warranty on the battery, electrode and transmitter ("Warranty Parts") of the WiSE for a period of three years commencing on the date of implant. In the event the Warranty Parts function in a manner inconsistent with their intended operation and performance due to the quality of materials or workmanship, and should such an event occur with the three-year period commencing on the implantation date, the Company will provide the customer a replacement at no additional cost. The warranty is not priced or sold separately. It is intended to safeguard the customer against defects, and it does not provide incremental service to the customer. As such, it is considered an assurance type warranty and is not accounted as a service type warranty, which could represent a separate performance obligation. The warranty is accounted for as an accrued warranty reserve. The current portion is included within "Accrued expenses and other liabilities", and the long-term portion is included within "Other liabilities" in our unaudited condensed consolidated balance sheets. See Note 5, "Condensed consolidated balance sheet components" for additional disclosure on accrued warranty reserves.

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.

Selling, general and administrative

Selling, general and administrative includes operating expenses incurred in our executive, finance, legal, sales, marketing, and other administrative functions, as well as losses on the disposal of property and equipment.

Stock-based compensation

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

Other income

The Company periodically receives reimbursements of clinical trial expenses, which are recorded as other income in the accompanying unaudited condensed consolidated statements of operations. During the three months ended June 30, 2025 and 2024, the Company recorded no other income. During the six months ended June 30, 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 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. In January 2025, the FASB issued an update 2025-01 "*Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date",* which revises the effective date of ASU 2024-03 to clarify that all public business entities are required to adopt the guidance in annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact of this standard on its disclosures.

Note 3 – Cash, cash equivalents, and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following at June 30, 2025 and December 31, 2024:

	June 30, 2025	December 31, 2024
Cash and cash equivalents:		
Cash	$ 993,266	$ 3,210,556
Money market funds	44,000,158	3,706,990
Total cash and cash equivalents	$ 44,993,424	$ 6,917,546
Marketable securities, short-term:		
Asset backed securities	$ 2,004,057	$ 2,002,957
Commercial paper	7,118,290	1,156,709
Corporate bonds	12,313,213	23,951,700
US Treasury securities	15,269,304	26,635,045
Total marketable securities, short-term	$ 36,704,864	$ 53,746,411
Marketable securities, long-term:		
Asset backed securities	$ 2,308,013	$ 2,305,317
Corporate bonds	592,058	2,386,774
US Treasury securities	-	611,859
Total marketable securities, long-term	$ 2,900,071	$ 5,303,950
Total cash, cash equivalents, and marketable securities	$ 84,598,359	$ 65,967,907

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within our unaudited condensed consolidated balance sheets as of June 30, 2025 and June 30, 2024, to the total of such amounts as presented in the unaudited condensed consolidated statements of cash flows:

	June 30, 2025	June 30, 2024
Cash and cash equivalents	$ 44,993,424	$ 8,364,623
Restricted cash, noncurrent	2,603,568	-
Total cash, cash equivalents, and restricted cash	$ 47,596,992	$ 8,364,623

During the six months ended June 30, 2025, marketable securities were sold or matured for proceeds of $29,120,614 with a realized gain of $8,265. During the six months ended June 30, 2024, marketable securities were sold or matured for proceeds of $34,125,676 with no gain or loss realized. See Note 4, "Fair value measurements" for additional information regarding the fair value of cash equivalents and marketable securities.

The following tables summarizes the unrealized gains and losses related to the Company's available-for-sale marketable securities, by major security type, as of June 30, 2025 and December 31, 2024:

	As of June 30, 2025			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities:				
Asset backed securities	$ 4,311,329	$ 741	$ -	$ 4,312,070
Commercial paper	7,120,934	164	(2,808)	7,118,290
Corporate bonds	12,906,299	3,658	(4,686)	12,905,271
US Treasury securities	15,277,487	268	(8,451)	15,269,304
Total marketable securities	$ 39,616,049	$ 4,831	$ (15,945)	$ 39,604,935

	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 June 30, 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 June 30, 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
Commercial paper	$ 5,371,323	$ (2,808)	$ -	$ -	$ 5,371,323	$ (2,808)
Corporate bonds	8,239,843	(4,686)	-	-	8,239,843	(4,686)
US Treasury Securities	14,255,994	(8,451)	-	-	14,255,994	(8,451)
Total	$ 27,867,160	$ (15,945)	$ -	$ -	$ 27,867,160	$ (15,945)

	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 June 30, 2025, were as follows:

	Fair Value
One year or less	$ 36,704,864
One year to two years	592,058
Two years to three years	2,308,013
Total minimum payments	$ 39,604,935

Note 4 – Fair value measurement

Management's assessment of the significance of a particular input to the fair value measurement requires judgement and may affect the valuation of financial assets and liabilities and their placement within the fair value hierarchy, as discussed in Note 2, "Summary of significant accounting policies". At June 30, 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 June 30, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 44,000,158	$ -	$ -	$ 44,000,158
Marketable securities:				
Asset backed securities	-	4,312,070	-	4,312,070
Commercial paper	-	7,118,290	-	7,118,290
Corporate bonds	-	12,905,271	-	12,905,271
US Treasury securities	-	15,269,304	-	15,269,304
Total	$ 44,000,158	$ 39,604,935	$ -	$ 83,605,093

	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 accounts and other receivables, other assets, accounts payable and accrued expenses approximated their fair values due to the nature and relatively short maturities. The fair value of debt approximates its carrying value as it is variable rate debt or has relatively short maturities.

Note 5 – Condensed consolidated balance sheet components

Accounts and other receivables, net

Accounts and other receivables includes amounts due from sales of Company's product to customers, sales of materials to contract manufacturers, reimbursements of clinical trial expenses incurred, and reimbursements for leasehold improvements. Accounts and other receivables, net were as follows as of June 30, 2025 and December 31, 2024:

	June 30, 2025	December 31, 2024
Trade receivables	$ 259,199	$ -
Non-trade receivables	421,428	433,051
Unbilled reimbursements	-	8,388
Reimbursement for leasehold improvements	1,417,255	-
Accounts and other receivables	2,097,882	441,439
Less: provision for credit losses	-	-
Accounts and other receivables, net	$ 2,097,882	$ 441,439

During the three and six months ended June 30, 2025 and 2024, the Company recorded no provision for credit losses.

Inventory

Inventory consisted of the following as of June 30, 2025, and pre-launch inventory consisted of the following at December 31, 2024:

	June 30, 2025	December 31, 2024
Raw materials	$ 1,152,705	$ 2,842,540
Work in process	4,585,803	-
Finished goods	1,707,179	-
Inventory	$ 7,445,687	$ 2,842,540
Inventory – current	$ 5,133,867	$ 1,391,008
Inventory – noncurrent	$ 2,311,820	$ 1,451,532

Property and equipment, net

Property and equipment consisted of the following as of June 30, 2025 and December 31, 2024:

	June 30, 2025	December 31, 2024
Equipment	$ 3,642,868	$ 3,433,881
Computer software	913,120	574,780
Leasehold improvements	547,259	513,727
Construction in progress	1,746,607	-
Total property and equipment	6,849,854	4,522,388
Less: accumulated depreciation and amortization	(3,841,107)	(3,727,429)
Total property and equipment, net	$ 3,008,747	$ 794,959

As of June 30, 2025, construction in progress pertains to tenant improvements for the Company's new corporate headquarters, laboratory, and manufacturing facility in Santa Clara, California. Depreciation and amortization expense for the three months ended June 30, 2025 and 2024 was $118,466 and $182,441, respectively. Depreciation and amortization expense for the six months ended June 30, 2025 and 2024 was $197,261 and $395,532, respectively.

In June 2025, the Company retired certain programmer equipment and recorded loss on disposal of fixed assets of $35,153 for the three and six months ended June 30, 2025. The loss on disposal of fixed assets is included as a part of selling, general and administrative expenses in the unaudited condensed consolidated statement of operations.

There were no impairments recorded during the three and six months ended June 30, 2025 and 2024.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following at June 30, 2025 and December 31, 2024:

	June 30, 2025	December 31, 2024
Accrued compensation and related liabilities	$ 2,715,202	$ 3,116,301
Accrued development expenses	392,747	482,417
Accrued warranty reserves	425,616	692,404
Accrued other expenses	334,035	4,719
Accrued expenses and other liabilities	$ 3,867,600	$ 4,295,841

Changes in accrued warranty reserves were as follows for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Beginning of period	$ 525,901	$ 789,931	$ 692,404	$ 826,924
Warranty reserve accrued during the period	17,109	-	17,109	-
Settlement of warranty claims	(107,208)	(40,356)	(273,711)	(77,349)
End of period	$ 435,802	$ 749,575	$ 435,802	$ 749,575
Warranty reserve - current	$ 425,616	$ 749,575	$ 425,616	$ 749,575
Warranty reserve - noncurrent	$ 10,186	$ -	$ 10,186	$ -

Note 6 – Leases

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

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 June 30, 2025 and December 31, 2024, were as follows:

	June 30, 2025	December 31, 2024
Right of use operating lease asset	$ 13,183,580	$ 929,243
Lease liability, current	846,721	522,525
Lease liability, noncurrent	14,766,626	574,777
Weighted-average remaining lease term	15.58 years	2.00 years
Weighted-average discount rate	6.45%	10.00%

The following table presents the components of lease costs in our unaudited statements of operations for three and six month ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating lease costs	$ 579,610	$ 114,988	$ 1,151,836	$ 215,971
Variable lease costs	33,000	33,619	66,000	64,330
Short-term lease costs	3,560	-	12,532	-
Total lease expense	$ 616,170	$ 148,607	$ 1,230,368	$ 280,301

Future lease payments for non-cancellable operating leases, net of the tenant improvement allowance as of June 30, 2025, were as follows:

Years Ending December 31,	
2025 (remaining six months)	$ 300,000
2026	1,224,000
2027	964,080
2028	1,324,003
2029	1,743,384
Thereafter	25,484,420
Total undiscounted lease payments	31,039,887
Less: effects of discounting	(11,335,660)
Less: tenant improvement allowance	(4,090,880)
Total operating lease liabilities	$ 15,613,347

Note 7 - Notes payable

At June 30, 2025 and December 31, 2024, notes payable consisted of the following:

	June 30, 2025	December 31, 2024
Notes payable, current		
Current portion of notes payable	$ -	$ 37,286
Notes payable, noncurrent		
Long-term portion of notes payable	41,800,000	41,800,000
Less: unamortized deferred loan costs	(418,112)	(523,291)
Less: unamortized discount	(810,447)	(1,013,104)
Notes payable, noncurrent, net	$ 40,571,441	$ 40,263,605
Total notes payable, net	$ 40,571,441	$ 40,300,891

The following table presents information regarding the Company's notes payable principal repayment obligations as of June 30, 2025:

Years Ending December 31,	
2025 (remaining six months)	$ -
2026	-
2027	41,800,000
Total minimum payments	$ 41,800,000

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. As of June 30, 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 $102,014 and $100,725 for the three months ended June 30, 2025 and 2024, respectively. Amortization of the discount was $202,657 and $201,201 for the six months ended June 30, 2025 and 2024, respectively. This amount was recorded as additional interest expense in the accompanying unaudited condensed consolidated statements of operations. As of June 30, 2025 and December 31, 2024, the note has been shown net of unamortized discounts of $810,447 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 $52,913 and $52,499 for the three months ended June 30, 2025 and 2024, respectively. Amortization of loan costs was $105,179 and $104,931 for the six months ended June 30, 2025 and 2024, respectively. As of June 30, 2025 and December 31, 2024, the note has been shown net of unamortized loan costs of $418,112 and $523,291, respectively.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of June 30, 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 June 30, 2025 and December 31, 2024, the outstanding principal balance was $0 and $37,286, respectively, and was included in the current portion of notes payable in the unaudited condensed consolidated balance sheets.

Note 8 – Convertible preferred stock

As of June 30, 2025 and December 31, 2024, 10,000,000 shares of convertible preferred stock were authorized, of which no shares were issued or outstanding.

Note 9 – Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors. As of June 30, 2025 and December 31, 2024, no dividends have been declared.

As of June 30, 2025 and December 31, 2024, 600,000,000 shares were authorized, of which 449,552,201 shares and 371,076,200 shares, respectively, were outstanding.

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

In May 2025, the Company completed an institutional placement of 55,900,000 CDIs representing the same number of common stock at $0.64 per share, for proceeds of $33,468,468, net of $2,497,592 of related issuance costs. In June 2025, the Company completed a non-underwritten rights offering to existing stockholders, or Securities Purchase Plan, and issued an additional 20,000,000 CDIs representing the same number of common stock at $0.64 per share, for proceeds of $12,760,947, net of $101,053 of related issuance costs.

Additionally, the Company has reserved the following shares of common stock for issuance as of June 30, 2025:

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	16,571,305
Amended 2021 Equity Incentive Plan	37,104,519
Outside of Amended 2021 Equity Incentive Plan	1,061,195
Total shares of Common stock reserved for issuance	74,526,398

Note 10 – 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 June 30, 2025, the weighted-average exercise price of outstanding warrants was $0.57 with a weighted-average remaining contractual life of 4.78 years.

The following warrants were outstanding as of June 30, 2025 and December 31, 2024:

Warrant Issuance	Shares of Common Stock Issuable for Outstanding Warrants as of June 30, 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 11 – Stock-based compensation

The Company and its stockholders adopted an equity incentive plan (the "2013 Plan") in 2013, which reserved shares of the Company's common stock for the granting of incentive and nonqualified stock options to employees, directors, and consultants. On October 14, 2021, the Company replaced the 2013 Plan with the 2021 Equity Incentive Plan ("2021 Plan") in connection with its initial public offering, which was then amended by the Board of Directors and approved by the stockholders on March 18, 2025 and May 21, 2025, respectively. Under the amended 2021 Plan, 37,104,519 shares of common stock are reserved. The Company may grant options to purchase common stock, stock appreciation rights, restricted stock awards and other forms of stock-based compensation. Stock options generally vest over four years and expire no later than 10 years from the date of grant. The Board of Directors has the authority to select the employees to whom options are granted and determine the terms of each option, including: i) the number of shares of common stock subject to the option; ii) when the option becomes exercisable; iii) the option exercise price, which must be at least 100% of the fair market value of the common stock as of the date of grant; and iv) the duration of the option, which may not exceed 10 years.

As of June 30, 2025, options to purchase a total of 29,210,639 shares of common stock remained outstanding and 7,893,880 shares remain available for grant under the amended 2021 Plan and 1,061,195 remained outstanding outside of the amended 2021 Plan. As of June 30, 2025, options to purchase a total of 16,571,305 shares of common stock remained outstanding under the 2013 Plan. As of June 30, 2025, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the six months ended June 30, 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	8,434,851	0.88	
Cancelled	(934,382)	0.54	
Exercised	(2,576,001)	0.17	
Outstanding at June 30, 2025	46,843,139	$ 0.48	7.10
Vested and expected to vest at June 30, 2025	46,843,139	$ 0.48	7.10
Exercisable at June 30, 2025	27,030,350	$ 0.32	5.67

The fair value of the options granted to employees is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the volatility of the Company's common stock, an assumed risk-free interest rate and expected dividends. The Company uses the simplified calculation of expected life and volatility is based on an average of the historical volatilities of the common stock of several publicly traded entities with characteristics similar to those of the Company. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The Company uses the straight-line method for expense attribution. The weighted-average grant-date fair values of stock options granted during the six months ended June 30, 2025 and 2024, was $0.56 per share and $0.39 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,	
	2025	2024
Expected term (in years)	5.53 - 6.08	7.00
Expected volatility	65.27% - 67.80%	66.49% - 67.34%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	3.93% - 4.47%	4.28% - 4.71%

The following table presents classification of stock-based compensation expense within the accompanying unaudited condensed consolidated statements of operations for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 263,599	$ 189,089	$ 507,211	$ 328,024
Selling, general and administrative	440,520	233,447	701,622	451,681
Total	$ 704,119	$ 422,536	$ 1,208,833	$ 779,705

At June 30, 2025, there was $8,970,897 of unamortized stock-based compensation cost, related to unvested stock options which is expected to be recognized over a weighted-average period of 3.03 years.

Note 12 – Income taxes

During the three and six months ended June 30, 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 and six months ended June 30, 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 benefit, research and development tax credit, and other non-deductible expenses.

During the six months ended June 30, 2025, there were no material changes to the Company's uncertain tax positions.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. We are currently assessing its impact on our consolidated financial statements.

Note 13 – Net loss per share

The following tables sets forth the computation of basic and diluted net loss per share attributable to common stockholders for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Numerator – basic & diluted:				
Net loss attributable to common stockholders, basic and diluted	$ (11,967,441)	$(11,494,688)	$ (22,521,711)	$ (20,644,691)
Denominator:				
Weighted-average number of shares outstanding, basic and diluted	395,862,055	308,101,693	384,266,036	307,762,783
Net loss per share attributable to common stockholders, basic and diluted	$ (0.03)	$ (0.04)	$ (0.06)	$ (0.07)

The following potentially dilutive shares have been excluded from the computation of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to the Company's net loss:

	June 30,	
	2025	2024
Outstanding warrants	19,789,379	19,789,379
Outstanding stock options	46,843,139	39,953,154
Total dilutive shares	66,632,518	59,742,533

Note 14 - Segment information

An operating segment is defined as a component of an entity for which discrete financial information is available that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's Chief Executive Officer is the CODM. The CODM reviews financial information on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. The Company's only product is its WiSE CRT System. Thus, the total Company's consolidated results represent only the results of the WiSE CRT System 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 is 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 sales and marketing activities of the Company's WiSE CRT System.

The Company's CODM uses revenue and net loss at the consolidated level as the primary measures of the segment's performance. Segment revenue derived from sales to customers in the United States was $149,494 for the three and six months ended June 30, 2025. The UK revenue was $20,210 for the three and six months ended June 30, 2025. There was no segment revenue recorded during the three and six months ended June 30, 2024. Significant expenses within net loss include costs of goods sold, research and development, and selling general and administrative expenses. Other segment items within net loss include interest income, interest expense, and other (expense) income. In addition to the segment's expenses that are presented on the unaudited condensed 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 unaudited condensed consolidated statement of operations, as included below.

The table below reports information about the segment loss for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	$ 169,704	$ -	$ 169,704	$ -
Cost of goods sold	85,275	-	85,275	-
Gross profit	84,429	-	84,429	-
Operating expenses:				
Research and development:				
Personnel-related expenses	4,665,325	4,431,832	8,848,230	8,292,659
Clinical expenses	568,117	546,066	960,721	837,724
Quality assurance and regulatory approval expense	83,496	63,281	170,251	124,248
Contract manufacturing, materials and components	529,781	1,992,211	1,260,400	3,723,549
Facility-related and other expenses	104,839	438,214	130,638	894,703
Total research and development expenses	5,951,558	7,471,604	11,370,240	13,872,883
Selling, general and administrative expenses:				
Personnel-related expenses	2,814,974	1,203,531	5,114,809	2,283,553
Professional services expenses	1,032,420	1,452,965	2,116,819	1,955,199
Corporate expense	638,688	447,000	1,216,781	960,232
Facility-related and other expenses	778,723	166,825	1,179,400	244,452
Total selling, general and administrative expense	5,264,805	3,270,321	9,627,809	5,443,436
Total operating expenses	11,216,363	10,741,925	20,998,049	19,316,319
Loss from operations	(11,131,934)	(10,741,925)	(20,913,620)	(19,316,319)
Other (expense) income:				
Interest expense	(1,430,947)	(1,530,447)	(2,828,022)	(3,034,144)
Interest income	613,990	778,940	1,247,083	1,698,924
Other (expense) income, net [(a)]	(18,550)	(1,256)	(27,152)	6,848
Total other (expense) income	(835,507)	(752,763)	(1,608,091)	(1,328,372)
Loss before income taxes	(11,967,441)	(11,494,688)	(22,521,711)	(20,644,691)
Income tax expense	-	-	-	-
Net loss	$ (11,967,441)	$ (11,494,688)	$ (22,521,711)	$ (20,644,691)

(a) Other (expense) income includes loss on foreign currency and reimbursements of clinical trial expenses.

Note 15 – Commitments and contingencies

Purchase commitments

The Company purchases raw materials, manufacturing equipment, and various services from a variety of vendors. During the normal course of business, in order to manage manufacturing lead times and help ensure an adequate supply of certain items, we enter into agreements with suppliers that either allow us to procure goods and services when we choose or that establish purchase requirements over the term of the agreement. In certain instances, our purchase agreements allow us to cancel, reschedule, or adjust our purchase requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our purchase commitments are firm and noncancelable. As of June 30, 2025, the Company's obligations under such arrangements were approximately $13,500,000.

Contingencies

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

Note 16 – Related party transactions

In June 2025, we issued 20,000,000 shares of common stock at $0.64 per share in connection with a non-underwritten rights offering to existing stockholders, or Securities Purchase Plan. Dr. Bronwyn Evans, a member of our Board of Directors, participated in the Securities Purchase Plan and purchased 30,000 CDIs for the aggregate purchase price of $19,293.

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 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 WiSE 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 WiSE and approved WiSE 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: 1) 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 2) 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 have launched WiSE with the focus on driving adoption of WiSE at key, high-volume, 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 have implemented a Limited Market Release ("LMR"), with the following objectives:

LMR objective 1: Initial Target Accounts

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

LMR objective 2: Expansion and Optimization

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

LMR objective 3: Increase Implants Per Site

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

Full Market Release

Our full market release strategy includes the following objectives:

- 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 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 approved of the New Technology Add-On Payment ("NTAP") for WiSE, commencing October 1, 2025. The NTAP is designed to bridge the financial gap between the costs of innovative technologies and the standard Medicare severity Diagnosis Related Groups ("MS-DRG" or "DRG") payment structure in place, while encouraging early adoption of the breakthrough medical advancements used in the inpatient setting for Medicare patients. NTAP secures the maximum reimbursement rate of 65% of the cost of WiSE. This is in addition to the DRG payments, which are intended to cover the procedure and the remaining device cost. In June 2025, we received preliminary approval for Transitional Pass-Through ("TPT") reimbursement scheme of WiSE. Preliminary approval for the TPT reimbursement scheme, which is expected to commence in October 2025 and if approved will be effective for three years, is expected to provide hospitals with Medicare reimbursement when treating patients in an outpatient setting. In combination, if approved, these reimbursements are intended to fully cover the cost of WiSE in a hospital setting.

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 June 30, 2025, we had $87.2 million in cash, cash equivalents, restricted cash, and marketable securities and an accumulated deficit of $376.0 million.

In May 2025, we completed an institutional placement of 55,900,000 CDIs representing the same number of common stock at $0.64 per share, for proceeds of $33,468,468, net of $2,497,592 of related issuance costs. In June 2025, we completed a non-underwritten rights offering to existing stockholders, or Security Purchase Plan, and issued an additional 20,000,000 CDIs representing the same number of common stock at $0.64 per share, for proceeds of $12,760,947, net of $101,053 of related issuance costs.

Our WiSE CRT System has been approved by the FDA for commercial distribution in April 2025, and we began 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 the U.S of the WiSE CRT System will be sufficient to fund our projected operating requirements into the first quarter of 2027.

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 WiSE and gain wide acceptance of WiSE by continuing to make physicians and other hospital staff aware of the benefits of WiSE 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, and preliminary approval for TPT reimbursement scheme 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

Revenue

We derive most of our revenue from sales of WiSE to the hospital facilities that implant our WiSE CRT System. We recognize revenue upon the transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. Specifically, revenue from the sale of WiSE is recognized at an amount that reflects the expected consideration upon notice that our products have been used in a surgical procedure. Our revenue fluctuates primarily based on the volume of procedures performed. Our revenue is expected continue to fluctuate in the future from quarter-to-quarter due to a variety of factors, including the success of our sales force in expanding adoption of WiSE in new accounts and the number of physicians who are aware of and implant WiSE.

Nearly all our revenue results from sales in the United States, but we also have limited sales of replacement batteries for our WiSE CRT System to hospital facilities with patients who have been or are currently enrolled in our clinical study in the United Kingdom ("UK").

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of costs related to materials, components and subassemblies, personnel-related expenses for our manufacturing and quality assurance employees, manufacturing overhead and charges for excess, obsolete and non-sellable inventories. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision and management personnel, an allocation of facilities and information technology expenses, including rent and utilities, and equipment depreciation. Cost of goods sold also includes certain indirect costs such as those incurred for shipping our WiSE CRT System. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily by our manufacturing costs, pricing, and the use of inventory that was previously expensed during our clinical trial. Our gross margin is expected to decrease over the near term as we continue to utilize inventory that was previously expensed, but over the long term our gross margin may increase to the extent our production volume increases as our fixed manufacturing costs would be spread over a larger number of units, thereby reducing our per-unit manufacturing costs. We expect our gross margin will fluctuate from period to period, however, based upon the factors described above.

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.

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").

Selling, General and Administrative Expenses

Selling, 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 sales and marketing, executive, finance, legal and other administrative functions, as well as losses on the disposal of property and equipment. Selling, 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 selling, general and administrative expenses will increase significantly in the future as we:

- hire and retain additional sales, general and administrative personnel to support the expected growth in our sales and marketing activities, research and development activities and the preclinical and clinical development of our product candidates;
- continue to expand our sales, marketing and administrative function to support the sales adoption of WiSE;
- 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.

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, except as discussed below.

Revenue Recognition

In accordance with Accounting Standards Codification 606 *Revenue from Contracts with Customers* ("ASC 606"), we recognize revenue when control is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for the goods or services. To recognize revenue, we apply the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied.

We recognize all of our revenue from contracts with customers at a point in time. As the majority of revenue consists of sales of WiSE and battery replacements, where our sales representative provides assistance at the point of implantation at hospitals or medical facilities, we recognize revenue upon completion of the procedure. We also generate a small portion of our revenue from the sale of surgical tool kits that are ordered in advance of a procedure. As the performance obligation is the delivery of the product, we recognize revenue for the surgical tool kits upon shipment to the customers. For all performance obligations, the standalone selling price is directly observable as these goods are sold separately by us. Sales prices are specified in the executed customer contract and purchase order prior to the transfer of control to the customer. Our standard payment terms are generally net 30 days.

Recent Accounting Pronouncements

See the section titled "Summary of Significant Accounting Policies—Recently issued accounting pronouncements" in Note 2 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, stock-based compensation, and expenses associated with our Form 10 filling. Adjusted EBITDA is intended as a supplemental measure of our performance and provides useful information to management and investors regarding our operating results.

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2025	2024	2025	2024
Reconciliation of net loss to non-GAAP Adjusted EBITDA				
Net loss	$ (11,967)	$ (11,495)	$ (22,522)	$ (20,645)
Interest expense, net	817	752	1,581	1,335
Depreciation and amortization	118	182	197	396
Stock-based compensation [(a)]	704	423	1,209	780
Expenses associated with Form 10 filling [(b)]	-	673	-	673
Adjusted EBITDA	$ (10,328)	$ (9,465)	$ (19,535)	$ (17,461)

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

Results of Operations

Comparison of the Three Months Ended June 30, 2025, to the Three Months Ended June 30, 2024

We recorded a net loss of $12.0 million in the three months ended June 30, 2025, an increase of $0.5 million, or 4.1%, from the three months ended June 30, 2024. The increased loss in 2025 was due to an increase in selling, general and administrative expenses in 2025, which was partially offset by a decrease in research and development expenses, as discussed below. Other (expense) income, 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 June 30, 2025 and 2024:

	Three Months Ended June 30,		Change	
(in thousands)	2025	2024	Amount	%
Revenue	$ 170	$ -	$ 170	100.0%
Cost of goods sold	85	-	85	100.0%
Gross profit	85	-	85	100.0%
Operating expenses				
Research and development	5,951	7,472	(1,521)	(20.4%)
Selling, general and administrative	5,265	3,270	1,995	61.0%
Total operating expenses	11,216	10,742	474	4.4%
Other (expense) income, net	(836)	(753)	(83)	11.0%
Loss before income tax	(11,967)	(11,495)	(472)	4.1%
Income tax expense	-	-	-	-
Net Loss	$ (11,967)	$ (11,495)	$ (472)	4.1%

We derive the majority of our revenue from sales to customers in the United States. International revenue is attributable to the battery replacements for clinical trial patients in the UK. Revenue by geography is based on the billing address of the customer. The table below summarizes our revenue by geography:

	Three Months Ended June 30, 2025		Three Months Ended June 30, 2024	
(in thousands)	Amount	%	Amount	%
United States	$ 150	88.2%	$ -	-
International	20	11.8%	-	-
Total Revenue	$ 170	100.0%	$ -	-

Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin:

	Three Months Ended June 30,		Change	
(in thousands)	2025	2024	Amount	%
Revenue	$ 170	$ -	$ 170	100.0%
Cost of goods sold	85	-	85	100.0%
Gross profit	85	-	85	100.0%
Gross margin	50.0%	-	50.0%	100.0%

Revenue and Cost of Goods Sold

Revenue and cost of goods sold increased to $0.2 million and $0.1 million, respectively, or 100%, during the three months ended June 30, 2025, as compared to the three months ended June 30, 2024, resulting from the recent FDA approval of our WiSE CRT System. During the three months ended June 30, 2025, we had commercial implants at three hospitals in the US.

Gross Profit, and Gross Margin

Gross profit increased to $0.1 million, or 100% for the three months ended June 30, 2025, as compared to the three months ended June 30, 2024, resulting from the recent FDA approval of our WiSE CRT System. Gross margin was 50.0% for the three months ended June 30, 2025. Our gross margin was positively affected and will continue to be affected in the near future by the use of inventory that was previously expensed during our clinical trial. Excluding the use of previously expensed inventory, we would have had a negative gross margin of 51.2%.

Operating Expenses

Research and Development

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

	Three Months Ended June 30,		Change	
(in thousands)	2025	2024	Amount	%
Research and development expenses:				
R&D personnel expense	$ 4,665	$ 4,432	$ 233	5.3%
Clinical expenses	568	546	22	4.0%
Quality assurance	83	64	19	29.7%
Contract manufacturing, materials & components	530	1,992	(1,462)	(73.4%)
Facility allocation & depreciation	105	438	(333)	(76.0%)
Total research and development expense	$ 5,951	$ 7,472	$ (1,521)	(20.4%)

Research and development expenses decreased by $1.5 million, or 20.4%, during the three months ended June 30, 2025, as compared to the three months ended June 30, 2024. The decrease was primarily due to a $1.5 million decrease in contract manufacturing, materials and components, resulting from a decrease in professional services related to the development testing of WiSE, as well as capitalization of inventory. Facility-related expenses decreased by $0.3 million, as we capitalized certain overhead costs to inventory during the three months ended June 30, 2025. These decreases were partially offset by a $0.2 million increase in personnel-related expenses, including salaries, bonuses, and certain fringe benefits, resulting from workforce expansion.

Selling, General and Administrative Expenses

Selling, General and administrative expenses increased by $2.0 million, or 61.0%, during the three months ended June 30, 2025, as compared to the three months ended June 30, 2024. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $1.6 million as a result of the expansion of our workforce to support our sales and marketing efforts after the FDA approval of WiSE. Facility-related expenses increased by $0.6 million, primarily resulting from higher non-cash rent expense due to a new lease agreement entered in 2025. Corporate expenses increased by $0.2 million, primarily resulting from the higher expenses related to insurance premiums, investor relations, and computer software licenses. These increases were offset by $0.4 million decrease in professional fees, as we did not incur any additional accounting and legal fees in connection with preparation for Form 10 filing in the current period, as we did during the three months ended June 30, 2024.

Other (expense) income, net

Other (expense) income, net increased by $0.1 million during the three months ended June 30, 2025, as compared to the three months ended June 30, 2024. This increase primarily resulted from a $0.2 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.

Comparison of the Six Months Ended June 30, 2025, to the Six Months Ended June 30, 2024

We recorded a net loss of $22.5 million in the six months ended June 30, 2025, an increase of $1.9 million, or 9.1%, from the six months ended June 30, 2024. The increased loss in 2025 was due to an increase in general and administrative expenses in 2025, which was partially offset by a decrease in research and development expenses, as discussed below. Other (expense) income, 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 six months ended June 30, 2025 and 2024:

(in thousands)	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024	Change Amount	Change %
Revenue	$ 170	$ -	$ 170	100.0%
Cost of goods sold	85	-	85	100.0%
Gross profit	85	-	85	100.0%
Operating expenses:				
Research and development	11,370	13,873	(2,503)	(18.0%)
Selling, general and administrative	9,628	5,443	4,185	76.9%
Total operating expenses	20,998	19,316	1,682	8.7%
Other (expense) income, net	(1,609)	(1,329)	(280)	21.1%
Loss before income tax	(22,522)	(20,645)	(1,877)	9.1%
Income tax expense	-	-	-	-
Net Loss	$ (22,522)	$ (20,645)	$ (1,877)	9.1%

We derive the majority of our revenue from sales to customers in the United States. International revenue is attributable to the battery replacements for clinical trial patients in the UK. Revenue by geography is based on the billing address of the customer. The table below summarizes our revenue by geography:

(in thousands)	Six Months Ended June 30, 2025 Amount	Six Months Ended June 30, 2025 %	Six Months Ended June 30, 2024 Amount	Six Months Ended June 30, 2024 %
United States	$ 150	88.2%	$ -	-
International	20	11.8%	-	-
Total Revenue	$ 170	$ 100%	$ -	-

Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin:

(in thousands)	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024	Change Amount	Change %
Revenue	$ 170	$ -	$ 170	100.0%
Cost of goods sold	85	-	85	100.0%
Gross profit	85	-	85	100.0%
Gross margin	50.0 %	-	50.0 %	100.0%

Revenue and Cost of Goods Sold

Revenue and cost of goods sold increased to $0.2 million and $0.1 million, respectively, or 100%, during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024, resulting from the recent FDA approval of our WiSE CRT System. During the six months ended June 30, 2025, we had commercial implants three hospitals in the US.

Gross Profit, and Gross Margin

Gross profit increased to $0.1 million, or 100% for the six months ended June 30, 2025, as compared to the six months ended June 30, 2024, resulting from the recent FDA approval of our WiSE CRT System. Gross margin was 50.0% for the six months ended June 30, 2025. Our gross margin was positively affected and will continue to be affected in the near future by the use of inventory that was previously expensed during our clinical trials. Excluding the use of previously expensed inventory, we would have had a negative gross margin of 51.2%.

Operating Expenses

Research and Development

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

(in thousands)	Six Months Ended June 30, 2025	2024	Change Amount	%
Research and development expenses:				
R&D personnel expense	$ 8,848	$ 8,292	$ 556	6.7%
Clinical expenses	961	838	123	14.7%
Quality assurance	170	124	46	37.1%
Contract manufacturing, materials & components	1,260	3,724	(2,464)	(66.2%)
Facility allocation & depreciation	131	895	(764)	(85.4%)
Total research and development expense	$ 11,370	$ 13,873	$ (2,503)	(18.0%)

Research and development expenses decreased by $2.5 million, or 18.0%, during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024. The decrease was primarily due to a $2.5 million decrease in contract manufacturing, materials and components, resulting from a decrease in professional services related to the development testing of the WiSE CRT System, as well as capitalization of inventory. Facility-related expenses decreased by $0.8 million, as we capitalized certain overhead costs to inventory during the six months ended June 30, 2025. These decreases were partially offset by a $0.6 million increase in personnel-related expenses, including salaries, bonuses, and certain fringe benefits, resulting from the normal annual salary increases and workforce expansion, 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.

Selling, General and Administrative Expenses

Selling, General and administrative expenses increased by $4.2 million, or 76.9%, during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $2.8 million as a result of the expansion of our workforce to support increased adoption of our WiSE CRT System. Facility-related expenses increased by $0.9 million, primarily resulting from the higher rent expense due to a new lease agreement entered in 2025. Corporate expenses increased by $0.3 million, primarily resulting from the higher expenses related to insurance premiums, investor relations, and computer software. Professional fees increased by $0.2 million, primarily resulting from higher accounting and legal related services associated with being a public reporting company in the US.

Other (expense) income, net

Other (expense) income, net increased by $0.3 million during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024. This increase primarily resulted from a $0.5 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 $0.2 million decrease in interest expense.

Liquidity and Capital Resources

We believe that our cash and cash equivalents, and marketable securities, and anticipated revenues from sales of our WiSE CRT System will be sufficient to fund our operations for at least the next 12 months from the date of this filing. We manage our cash and capital structure to maximize shareholder return, maintain its financial condition and maintain flexibility for future strategic initiatives. We continuously assess our working capital needs, debt and leverage levels, debt maturity schedule, capital expenditure requirements and future investments. As of June 30, 2025 and December 31, 2024, we had approximately $84.6 million and $66.0 million, respectively, in cash, cash equivalents, and marketable securities. In the long-term, our ability to support our working capital and capital expenditure requirements will depend on many factors, including:

- our ability to successfully commercialize our WiSE CRT System;
- the cost, timing and results of our clinical trials and regulatory reviews;

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

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

Loan and Security Agreements

On June 30, 2022, we entered into a loan and security agreement with Runway Growth Finance Corp. The debt is secured against substantially all of our assets, except for intellectual property, but includes all proceeds from the sale of intellectual property.

As of June 30, 2025 and December 31, 2024, the outstanding principal balance was $41,800,000, which includes final payment of 4.5% of the principal borrowings to date.

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.

We are subject to customary financial and reporting covenants under the loan and security agreement. As of June 30, 2025 and December 31, 2024, we were in compliance with all debt covenants.

Recent Financings

In May 2025, we completed an institutional placement of 55,900,000 CDIs representing the same number of common stock at $0.64 per share, for proceeds of $33,468,468, net of $2,497,592 of related issuance costs. In June 2025, we completed a non-underwritten rights offering to existing stockholders, or Securities Purchase Plan, and issued an additional 20,000,000 CDIs representing the same number of common stock at $0.64 per share, for proceeds of $12,760,947, net of $101,053 of related issuance costs.

Contractual Obligations and Commitments

As of June 30, 2025, we had $0.8 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 $14.8 million in operating lease obligations as of June 30, 2025.

As of June 30, 2025, the outstanding principal balance under our loan and security agreement described above was $41,800,000, which includes the final payment of 4.5% of the principal borrowings to date.

In addition, we enter into contracts in the normal course of business with third-party contract organizations for clinical trials, manufacturing and other services and products for operating purposes. In certain instances, our purchase agreements allow us to cancel, reschedule, or adjust our purchase requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our purchase commitments are firm and noncancelable. As of June 30, 2025, our obligations under such arrangements were approximately $13.5 million.

Working Capital

June 30, 2025, Compared to December 31, 2024

As of June 30, 2025, we had working capital of $80.7 million, comprised of current assets of $90.3 million and current liabilities of $9.7 million. Current assets, consisting of cash and cash equivalents, marketable securities, accounts and other receivables, inventory, prepaid expenses, and other current assets, increased by $25.9 million as of June 30, 2025, compared to December 31, 2024. The sale of CDIs discussed above contributed to the overall increase in cash, cash equivalents and marketable securities, resulting in a $21.0 million increase in working capital as of June 30, 2025. Additionally, the capitalization of inventory resulted in a $3.7 million increase in working capital, and an increase in the accounts and other receivables primarily due to the reimbursements for leasehold improvements resulted in a $1.7 million increase in working capital as of June 30, 2025. Current liabilities, consisting primarily of accounts payable, accrued liabilities, lease obligations, and interest payable, increased by approximately $1.4 million as of June 30, 2025, compared to December 31, 2024. The increase primarily resulted from an increase in accounts payable from December 31, 2024 to June 30, 2025, which was mainly due to the activity related to construction of leasehold improvements at the new corporate headquarters.

Cash Flows

June 30, 2025, Compared to June 30, 2024

The following table summarizes our cash flows for the six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,	
(in thousands)	2025	2024
Net cash used in operating activities	$ (25,040)	$ (20,386)
Net cash provided by investing activities	18,802	13,989
Net cash provided by financing activities	46,910	195
Effect of exchange rate change on cash	7	(12)
Net change in cash and cash equivalents	$ 40,679	$ (6,214)

Operating Activities

Net cash used in operating activities during the six months ended June 30, 2025, was $25.0 million, compared to $20.4 million during the six months ended June 30, 2024, representing an increase in use of $4.6 million. This increase is primarily attributed to an increase in net loss of $1.9 million and an increase in use of cash from changes in working capital of $4.2 million, which were partially offset by an increase in non-cash adjustments of $1.5 million.

- The increase in net loss of $1.9 million primarily resulted from an increase in personnel costs, which was partially offset by a decrease in contract manufacturing, materials and components, as further described under "Results of Operations" above.

- Non-cash adjustments increased due to decrease in gain in accretion of discount on marketable securities of $0.7 million driven by fluctuating interest rates and maturity term, $0.4 million increase in the adjustment to lease amortization due to the Company entering into a new lease agreement in 2025, and $0.4 million increases in stock-based compensation due to new options issuance to new hires and existing employees.

- The decrease in changes from working capital activities primarily consisted of $4.6 million use of cash for inventory purchases during the six months ended June 30, 2025, a $1.5 million decrease in cash provided from accounts and other receivables due to the timing of collections on reimbursable leasehold improvements, and a $0.4 million decrease in accounts payable due to the timing of invoice payments. These decreases were partially offset by a $1.8 million increase in operating lease liability due to the Company entering into a new lease agreement in 2025, a $0.4 million increase in cash from prepaid expenses and other assets due to decreased vendor prepayment requirements for raw materials purchases and professional services, and a $0.1 million increase in cash from accrued expenses primarily driven by lower clinical trial expenses.

Investing Activities

Net cash provided by investing activities during the six months ended June 30, 2025, was $18.8 million, compared to $14.0 million the six months ended June 30, 2024, representing an increase in cash provided of $4.8 million. The increase was attributable to a $10.6 million decrease in the purchase of marketable securities, as well as a $5.0 million net increase in cash from the maturities and sales of marketable securities during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024. These increases in cash provided from investing activities were partially offset by $0.8 million increase in cash used for purchases of property and equipment during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024.

Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2025 was $46.9 million, compared to $0.2 million during the six months ended June 30, 2024, representing an increase of $46.7 million. This increase was primarily attributed to the $46.5 million in proceeds from a capital raise, net of issuance cost, during the six months ended June 30, 2025, as well as by a $0.3 million increase in proceeds from exercise of stock options. These increases were partially offset by $0.1 million decrease in proceeds from borrowings on notes payable during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024.

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 June 30, 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 June 30, 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 factors 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.

We are subject to ongoing FDA post-marketing obligations concerning our WiSE CRT System, which may result in significant additional expense, and we may be subject to penalties or product withdrawal if we fail to comply with these regulatory requirements and commitments or if we experience unanticipated regulatory issues with WiSE CRT System.

Our WiSE CRT System's regulatory approval in the United States is subject to certain post-marketing obligations and commitments to the FDA. We are required to conduct a prospective, real-world, observational study aimed at understanding acute and long-term product performance, including patient safety, clinical outcomes, and CRT response information associated with the use of the market released WiSE. We expect to begin enrollment for this post-marketing study in December 2025, and it is scheduled to be concluded in December 2027. Participants enrolled in the study will be monitored at one month, six month, and annual follow-up visits for up to five years post implant. Failure to complete the study to the satisfaction of the FDA could result in withdrawal of WiSE's application approval, which would have a material adverse effect on our business, results of operations, financial condition and prospects. The results of the post-marketing study may also result in additional warnings or precautions for the WiSE CRT System label, or expose additional safety concerns that may result in product liability, reputational damage with physicians and/or withdrawal of the product from the market, any of which would have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for WiSE are subject to extensive and ongoing regulatory requirements in the United States. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices ("cGMP"), good clinical practices ("GCP"), and good laboratory practices ("GLP"). If we are not able to meet and maintain regulatory compliance for WiSE, we may lose marketing approval and be required to withdraw our product. Withdrawal of our product would have a material adverse effect on our business.

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

In addition to previously disclosed issuance of securities on our Current Report on Form 8-K filed on May 29, 2025, the three months ended June 30, 2025, we sold the following unregistered securities:

a) On June 19, 2025, we issued 20,000,000 CHESS Depository Interests, with each CDI representing one share of common stock, in connection with a non-underwritten rights offering to existing stockholders, or Security Purchase Plan, at a purchase price of $0.64 per share. We raised approximately $12.8 million, net of issuance costs of approximately $0.1 million.

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

		Incorporated by Reference		
Number	**Description**	**Schedule/Form**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of EBR Systems, Inc.	10-12G	3.1	11/21/2024
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of EBR Systems, Inc.	8-K	3.1	5/23/2025
3.3	Amended and Restated Bylaws of EBR Systems, Inc.	8-K	3.1	3/20/2025
10.1	Addendum "E" to the Oakmead Lease, dated April 2025, between the Company and 480 Oakmead Properties, LLC.	10-Q	10.3	5/13/2025
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: August 12, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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

I, John McCutcheon, certify that:

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2025

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

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

I, Gary Doherty, certify that:

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2025

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

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2025, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: August 12, 2025

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 12th day of August 2025.

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

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