ASX ANNOUNCEMENT **10 November 2026**

Q3 delivers key reimbursement, manufacturing and regulatory milestones

Quarterly Activity Report and Form 10-Q submission

Key highlights:

- 40 commercial WiSE® System implants completed during Q3 2026, taking total commercial implants across the pilot launch phase and Limited Market Release to 157
- Positive early results emerging in Q4 following realignment of U.S. commercial organisation, with an active search for a Chief Commercial Officer and renewed focus on account utilisation, procedural frequency and field training
- Santa Clara facility achieved ISO 13485 certification; U.S. Food and Drug Administration (FDA) pre-approval inspection completed
- WiSE Coupler commercially launched in the United States to support procedural workflow and physician use
- Medicare inpatient reimbursement increased for eligible WiSE procedures, effective 1 October 2026
- Proposed National Coverage Determination decision expected in early December 2026
- A$150m capital raising completed to fund commercial operations and manufacturing scale-up, with a focus on financial discipline
- EBR holds cash, cash equivalents, restricted cash and marketable securities of US$95.8m / A$137.4m[1] as at 30 September 2026

Santa Clara, California; 10 November 2026: EBR Systems, Inc. (ASX: **'EBR', 'EBR Systems',** or the **'Company'),** developer of the world's only wireless cardiac pacing device for heart failure, releases its Quarterly Activity Report and Form 10-Q submission for the quarter ended 30 September 2026 ('Q3 2026').

U.S. commercial execution

EBR continued to advance the U.S. commercialisation of the WiSE CRT System during Q3 2026, alongside progress in reimbursement, manufacturing scale-up and regulatory matters.

The WiSE System was implanted in 40 commercial patients during the quarter, increasing total commercial implants across the pilot launch phase and Limited Market Release to 157.

Commercial implant activity was lower in September, with monthly cases approximately half the average monthly volume recorded in July and August. During the quarter, EBR commenced a realignment of its U.S. commercial organisation, with the departure of EBR's Chief Commercial Officer and with President and Chief Executive Officer John McCutcheon assuming responsibility for the commercial organisation.

EBR is actively recruiting a Chief Commercial Officer and other key commercial roles. Consistent with its original strategy, the Company is reinforcing its focus on account utilisation, procedural frequency and field training and support. During and after the quarter, Executive Chairman Allan Will and President and Chief Executive Officer John McCutcheon have spent more time travelling with field personnel and meeting customers.

An additional five purchasing contracts were signed during the quarter, bringing the total number of purchasing contracts to 57. A total of 100 physicians are now trained to implant the WiSE System, including 10 physicians trained during Q3 2026.

[1] Assumes an A$:US$0.697020 exchange rate

EBR remains focused on improving commercial productivity and converting its growing base of trained physicians, activated accounts and purchasing access into more consistent procedural activity over time.



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

"Q3 delivered important progress across reimbursement, manufacturing and regulatory matters, although commercial implant volumes were below our expectations, particularly in September.

'As we actively recruit a new Chief Commercial Officer, our focus is on account utilisation, procedural frequency, field training and support. To reinforce this strategy, both Allan Will, our Executive Chairman, and I have been spending more time travelling with field personnel and visiting with customers. We thank our customers for their continued support.

'Our Q4 priority is commercial execution, with the aim of achieving more consistent procedure activity."

Operational and regulatory progress

EBR made further operational and regulatory progress during Q3 2026 to support manufacturing scale-up, product supply and the broader commercial rollout of WiSE.

The Company's new Santa Clara manufacturing facility achieved ISO 13485 certification during the quarter. Once fully operational, the expanded facility is expected to have capacity to manufacture up to 9,600 WiSE Systems annually. The FDA also completed its pre-approval inspection of the facility in connection with EBR's premarket approval (PMA) supplement to add the site as a WiSE manufacturing location. The FDA identified two observations in its Form 483; EBR selected 'Promised to Correct' for both. EBR continues to anticipate approval of the new manufacturing site by the end of 2026, subject to FDA review.

EBR also progressed its engagement with the FDA regarding the previously disclosed cybersecurity incident and echo-induced pacing risk. The FDA agreed that no immediate field corrective action or recall relating to WiSE was warranted following its cybersecurity review and was aligned with EBR's plan to submit a Changes Being Effected (CBE) PMA supplement in Q4 2026 to increase the visibility of the echo-induced pacing risk and its mitigations within WiSE labelling.

Increased Medicare inpatient reimbursement

In September, the U.S. Centers for Medicare & Medicaid Services (CMS) finalised increased Medicare inpatient reimbursement for eligible WiSE System procedures under the FY2027 Inpatient Prospective Payment System final rule, effective 1 October 2026.

Under the final rule, eligible WiSE procedures were reassigned to higher-value Medicare Severity Diagnosis Related Groups (MS-DRGs), increasing base Medicare inpatient payment rates by approximately 58% and 93% for the relevant categories. Eligible procedures continue to qualify for a New Technology Add-on Payment (NTAP) of up to US$41,145. With the maximum NTAP, total Medicare reimbursement may reach approximately US$77,839 and US$66,566 for the relevant MS-DRGs. Actual payments depend on hospital- and case-specific factors and CMS criteria.

Expected National Coverage Determination (NCD) decision

CMS's proposed National Coverage Determination decision is expected in early December 2026, with a final decision expected in March 2027. A positive decision could establish a uniform national Medicare coverage framework and broaden access for eligible patients, subject to the final coverage criteria. The outcome and timing remain subject to CMS review.

Active investor engagement

During the quarter, EBR continued investor and industry engagement to support market understanding of the Company's commercial scale-up strategy and the clinical role of the WiSE System.

Management attended Canaccord Genuity's 46th Annual Growth Conference in Boston, Massachusetts, on 11–12 August 2026 and Evans & Partners Small Cap Healthcare Conference in Sydney on 16 August 2026.

Following quarter end, management also attended the Canaccord Drug & Device Conference in Noosa on 12–13 October, the Morgans Conference 2026 in Noosa on 14 October and the Evans & Partners 11th Annual Small and Mid-Cap Conference in Melbourne on 28 October. EBR also conducted a retail investor roadshow across Brisbane, Melbourne and Sydney in late October.

Corporate update

On 16 October 2026, EBR appointed Robert C. Canby, M.D., as Chief Medical Officer. Dr Canby is a board-certified cardiac electrophysiologist with extensive experience spanning clinical practice, physician education, cardiovascular research, and medical device innovation.

As Chief Medical Officer, his responsibilities include EBR's medical and clinical strategy, evidence development, physician education and engagement, and collaboration with the Company's research and development and commercial teams.

Dr Canby currently practises at the Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, Texas, and serves as President of the Texas Cardiac Arrhythmia Research Foundation. He plans to continue in his clinical role at St. David's and to work on EBR's behalf as his other duties permit.

Exercising Financial Discipline

The Company remains focused on financial discipline following completion of its fully underwritten A$150 million capital raising. Management plans to allocate funds to commercial activity and manufacturing scale-up, with the aim of improving production efficiency, reducing cost of goods sold and improving gross margins.

As at 30 September 2026, EBR held cash or cash equivalents of US$14.0m / A$20.1m2, US$2.6m / A$3.7m^2 in restricted cash, and US$79.2m / A$113.6m^2 in marketable securities. Investments are made in fixed income instruments, have a weighted average maturity of 4 months, and have a minimum credit rating of A-2/P-2/F2 by at least 2 of 3 Nationally Recognised Statistical Rating Organisations, specifically Standard & Poor's, Moody's or Fitch.

Quarterly activity report

Key highlights

- During the quarter, EBR had net operating cash outflows of US$17.3m / A$24.8m[2].
- Revenue for Q3 2026 was US$2.5m / A$3.6m[2] (compared with US$0.5m / A$0.7m in Q3 2025), reflecting continued commercial activity under the WiSE Limited Market Release and U.S. commercial rollout.
- Gross margin for the quarter ended 30 September 2026 was 10%, compared to 13% for the previous quarter. Excluding the use of previously expensed inventory, the Company would have had a negative gross margin of 8.9% for the quarter ended 30 September 2026, compared to a negative gross margin of 16.9% for the previous quarter. The reduction in gross margin is the result of a lower utilisation of inventory that was previously expensed during our clinical trial. During Q3 2026, we fully utilised inventory that was previously expensed. None of this inventory remains.
- Research and development costs trended higher as a result of increased spending on product enhancements.
- Product manufacturing and operating costs trended lower as a result of decreased purchases of inventory.
- Advertising and marketing costs trended lower as a result of the Heart Rhythm Society meeting occurring during Q2 2026.

Revenue by product

(U.S. Dollars in thousands)	Quarter ended 30 Sep 2026	30 Jun 2026	31 Mar 2026
WiSE CRT System	$ 2,463	$ 2,616	$ 2,320
Surgical tool kits	15	16	20
Battery replacements	33	13	22
Sales	2,511	2,645	2,362
Less rebates	(24)	(8)	-
Net sales	$ 2,487	$ 2,637	$ 2,362

Quarterly cash flow report

(U.S. Dollars in thousands)	Quarter ended 30 Sep 2026	30 Jun 2026	31 Mar 2026
Cash flows from operating activities			
Receipts from customers	$ 2,134	$ 3,618	$ 1,301
Payments for			
research and development	(3,058)	(2,683)	(2,611)
product manufacturing and operating costs	(3,122)	(4,592)	(2,076)
advertising and marketing	(2,113)	(2,427)	(2,699)
leased assets	(326)	(336)	(215)
staff costs	(9,740)	(9,628)	(10,934)
administration and corporate costs	(1,727)	(1,603)	(2,176)
Interest received	579	283	326
Interest and other costs of finance paid	(1,195)	(1,191)	(1,167)
Other	1,314	1,366	-
Net cash from / (used in) operating activities	(17,254)	(17,193)	(20,251)
Cash flows from investing activities			
Payments to acquire property, plant, and equipment	(87)	(2,851)	(3,290)
Payments to acquire investments	(58,281)	(22,208)	-
Proceeds from disposal of investments	6,850	18,876	24,172
Net cash from / (used in) investing activities	(51,518)	(6,183)	20,882

[2] Assumes an A$:US$0.697020 exchange rate

Quarterly cash flow report, continued

(U.S. Dollars in thousands)	Quarter ended 30 Sep 2026	30 Jun 2026	31 Mar 2026
Cash flows from financing activities			
Proceeds from issues of shares	25,078	80,218	-
Proceeds from exercise of share options	8	18	132
Transaction costs related to issues of shares	(1,703)	(4,044)	-
Repayment of borrowings	(3)		
Net cash from / (used in) financing activities	23,380	76,192	132
Cash, cash equivalents, and restricted cash at beginning of period	61,955	9,162	8,398
Net cash from / (used in) operating activities	(17,254)	(17,193)	(20,251)
Net cash from / (used in) investing activities	(51,518)	(6,183)	20,882
Net cash from / (used in) financing activities	23,380	76,192	132
Effect of movement in exchange rates on cash held	26	(23)	1
Cash, cash equivalents, and restricted cash at end of period	$ 16,589	$ 61,955	$ 9,162

Investor Webinar

EBR's senior management team plans to host an investor webinar to discuss these results.

The webinar is scheduled for **Tuesday 10 November 2026 at 12:00pm AEDT (Monday 9 November at 5:00pm PST).**

Investors can register for the webinar via the following link:
https://attendee.gotowebinar.com/register/7619491794842837848

After registering, you should receive a confirmation email containing information about joining the webinar.

For more information about EBR, please visit https://www.ebrsystemsinc.com/.

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 is an investigational device in most markets and is currently only available for sale in the US.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control, subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products and achieve broad market adoption including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products; our expectations with respect to our clinical trials, including enrollment 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. These forward-looking statements are based on EBR Systems' current expectations and inherently involve significant risks and uncertainties. EBR Systems' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of certain risks and uncertainties including those risks described in more detail in its most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and other documents on file with the SEC from time to time and available on the SEC's website at www.sec.gov.

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

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____to

Commission file number: 000-56671

EBR SYSTEMS, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

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

As of November 9, 2026, the registrant had 84,549,836 shares of common stock, par value $0.0001 per share, including shares underlying all issued and outstanding Chess Depository Interests ("CDIs"), outstanding.

EBR SYSTEMS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2026

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PART I — FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

EBR SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share amounts)

	September 30, 2026	December 31, 2025
ASSETS		
Current assets		
Cash and cash equivalents	$ 13,985	$ 5,794
Marketable securities	71,430	47,395
Accounts and other receivables, net	2,697	2,320
Inventory	18,940	13,789
Prepaid expenses	1,263	2,490
Other current assets	2,533	1,323
Total current assets	110,848	73,111
Restricted cash, noncurrent	2,604	2,604
Property and equipment, net	9,137	5,477
Right of use operating lease asset	11,819	12,613
Marketable securities	7,768	1,011
Inventory, noncurrent	4,359	1,864
Other assets	650	546
TOTAL ASSETS	**$ 147,185**	**$ 97,226**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,412	$ 7,049
Accrued expenses and other liabilities	6,601	5,605
Interest payable	198	212
Operating lease liability	974	1,182
Notes payable, current, net	41,354	-
Total current liabilities	52,539	14,048
Other liabilities	320	184
Operating lease liability	17,475	16,520
Notes payable, net	-	40,886
Total liabilities	70,334	71,638
Commitments and contingencies (Note 16)		
STOCKHOLDERS' EQUITY		
Common stock, $0.0001 par value; 600,000,000 shares authorized, 84,546,086 and 45,025,917 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	9	5
Additional paid-in capital	529,381	426,852
Accumulated deficit	(453,387)	(402,216)
Accumulated other comprehensive income	848	947
Total stockholders' equity	76,851	25,588
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 147,185**	**$ 97,226**

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)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Net sales	$ 2,487	$ 512	$ 7,486	$ 682
Cost of goods sold	2,238	288	6,710	374
Gross profit	249	224	776	308
Operating expenses				
Research and development	6,697	6,244	19,734	17,614
Selling, general and administrative	9,800	5,861	29,859	15,488
Total operating expenses	16,497	12,105	49,593	33,102
Loss from operations	(16,248)	(11,881)	(48,817)	(32,794)
Other (expense) income				
Interest expense	(1,358)	(1,425)	(4,009)	(4,253)
Interest income	863	818	1,559	2,065
Other income	106	304	106	304
Loss on foreign currency	(7)	(5)	(10)	(32)
Total other (expense), net	(396)	(308)	(2,354)	(1,916)
Loss before income taxes	(16,644)	(12,189)	(51,171)	(34,710)
Income tax expense	-	-	-	-
Net loss	$ (16,644)	$ (12,189)	$ (51,171)	$ (34,710)
Net loss per share attributable to common stockholders				
Basic and diluted	$ (0.21)	$ (0.27)	$ (0.88)	$ (0.85)
Weighted-average number of common shares outstanding				
Basic and diluted	79,038,271	44,968,101	57,895,459	40,631,064

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)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Net loss	$ (16,644)	$ (12,189)	$ (51,171)	$ (34,710)
Other comprehensive (loss) income				
Change in unrealized loss on marketable securities	(99)	72	(158)	53
Foreign currency translation adjustments	28	6	59	17
Total other comprehensive (loss) income	(71)	78	(99)	70
Comprehensive loss	$ (16,715)	$ (12,111)	$ (51,270)	$ (34,640)

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)
(In thousands, except share amounts)

	Nine Months Ended September 30, 2026					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2025	45,025,917	$ 5	$ 426,852	$ (402,216)	$ 947	$ 25,588
Exercise of stock options	28,573	-	132	-	-	132
Stock-based compensation	-	-	907	-	-	907
Fractional share adjustment	1,246	-	-	-	-	-
Net loss	-	-	-	(17,074)	-	(17,074)
Other comprehensive loss	-	-	-	-	(15)	(15)
Balance at March 31, 2026	45,055,736	$ 5	$ 427,891	$ (419,290)	$ 932	$ 9,538
Exercise of stock options	11,325	-	18	-	-	18
Stock-based compensation	-	-	936	-	-	936
Issuance of common stock, net of issuance costs	30,263,498	3	75,828	-	-	75,831
Net loss	-	-	-	(17,453)	-	(17,453)
Other comprehensive loss	-	-	-	-	(13)	(13)
Balance at June 30, 2026	75,330,559	$ 8	$ 504,673	$ (436,743)	$ 919	$ 68,857
Exercise of stock options	5,000	-	8	-	-	8
Stock-based compensation	-	-	1,004	-	-	1,004
Issuance of common stock, net of issuance costs	9,210,527	1	23,696	-	-	23,697
Net loss	-	-	-	(16,644)	-	(16,644)
Other comprehensive loss	-	-	-	-	(71)	(71)
Balance at September 30, 2026	84,546,086	$ 9	$ 529,381	$ (453,387)	$ 848	$ 76,851

	Nine Months Ended September 30, 2025					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2024	37,107,620	$ 4	$ 376,936	$ (353,459)	$ 874	$ 24,355
Exercise of stock options	182,012	-	264	-	-	264
Stock-based compensation	-	-	505	-	-	505
Net loss	-	-	-	(10,554)	-	(10,554)
Other comprehensive loss	-	-	-	-	(11)	(11)
Balance at March 31, 2025	37,289,632	$ 4	$ 377,705	$ (364,013)	$ 863	$ 14,559
Exercise of stock options	75,588	-	168	-	-	168
Stock-based compensation	-	-	704	-	-	704
Issuance of common stock, net of issuance costs	7,590,000	1	46,229	-	-	46,230
Net loss	-	-	-	(11,967)	-	(11,967)
Other comprehensive income	-	-	-	-	3	3
Balance at June 30, 2025	44,955,220	$ 5	$ 424,806	$ (375,980)	$ 866	$ 49,697
Exercise of stock options	33,725	-	146	-	-	146
Stock-based compensation	-	-	929	-	-	929
Issuance costs	-	-	(10)	-	-	(10)
Net loss	-	-	-	(12,189)	-	(12,189)
Other comprehensive income	-	-	-	-	78	78
Balance at September 30, 2025	44,988,945	$ 5	$ 425,871	$ (388,169)	$ 944	$ 38,651

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)
(In thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (51,171)	$ (34,710)
Adjustment to reconcile net loss to cash used in operating activities		
Depreciation and amortization	601	288
Amortization of deferred loan costs and discount on notes payable	469	465
Lease amortization	794	869
Stock-based compensation	2,847	2,138
Loss on disposal of fixed assets	-	35
Accretion of discount on marketable securities	(359)	(596)
Changes in operating assets and liabilities		
Accounts and other receivables, net	(377)	(2,268)
Inventory	(7,436)	(8,328)
Prepaid expenses	1,228	718
Other assets	(1,392)	(24)
Accounts payable	(2,102)	1,048
Accrued expenses and other liabilities	1,467	67
Interest payable	(14)	(18)
Operating lease liability	747	2,135
Net cash used in operating activities	(54,698)	(38,181)
Cash flows from investing activities		
Purchase of property and equipment	(6,228)	(2,226)
Purchase of marketable securities	(80,489)	(48,173)
Maturities of marketable securities	43,141	43,507
Sales of marketable securities	6,757	6,611
Net cash used by investing activities	(36,819)	(281)
Cash flows from financing activities		
Repayment of notes payable	-	(37)
Repayment of financing lease	(3)	-
Proceeds from exercise of stock options	158	579
Proceeds from issuance of common stock	105,296	48,828
Payment of common stock issuance costs	(5,747)	(2,598)
Net cash provided by financing activities	99,704	46,772
Effect of exchange rate change on cash	4	18
Net change in cash, cash equivalents, and restricted cash	8,191	8,328
Cash, cash equivalents, and restricted cash, beginning of the period	8,398	6,918
Cash, cash equivalents, and restricted cash, end of the period	$ 16,589	$ 15,246
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 3,553	$ 3,807
Cash paid for income taxes	$ 2	$ 1
Supplemental disclosure of non-cash investing and financing activities		
Purchases of property and equipment not yet paid	$ 53	$ 489
Accrued common stock issuance costs	$ 21	$ 11
Leased assets obtained in exchange for finance lease liability	$ 39	$ -
Initial recognition of right of use asset and operating lease liability	$ -	$ 12,838

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 CHESS Depository Interests ("CDIs") 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.

Reverse stock split

The Company held a Special Meeting of Stockholders (the "Special Meeting") on March 11, 2026. In that Special Meeting, stockholders of the Company approved an amendment to the Company's amended and restated certificate of incorporation (the "Amendment") to effect the reverse stock split of its common stock and the transmutation ratio of CDIs to common stock at a ratio in the range of 1-for-5 to 1-for-20, with such ratio to be determined in the discretion of the Company's board of directors and with such reverse stock split to be effected at such time and date, if at all, as determined by the Company's board of directors in its sole discretion.

Pursuant to such authority granted by the Company's stockholders, the Company's board of directors approved a 1-for-10 (1:10) reverse stock split (the "Reverse Stock Split") of the Company's common stock and the filing of the Amendment to effectuate the Reverse Stock Split. The Amendment was filed with the Secretary of State of the State of Delaware and the Reverse Stock Split became effective in accordance with the terms of the Amendment at 4:00 a.m. Eastern Time on April 1, 2026 (the "Effective Time"), and the Company commenced normal trading on ASX on April 13, 2026, on a post-split basis under the existing ticker symbol "EBR". The Amendment provided that, at the Effective Time, every ten shares of the Company's issued and outstanding common stock automatically combined into one issued and outstanding share of common stock, without any change in par value per share, which remained at $0.0001. The Company's CDIs were not consolidated as part of the Reverse Stock Split, but rather the transmutation ratio of the CDIs to shares was changed from 1-to-1 to 10-to-1. See Note 10, "Common Stock" for additional information on CDIs.

The number of authorized shares of common stock remained at 600 million shares. As a result of the Reverse Stock Split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all outstanding stock options and warrants, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options and warrants and a proportional increase in the exercise price of all such stock options and warrants. The Company did not recognize any additional compensation expense as a result of the adjustment to outstanding stock options.

In addition, the number of shares reserved for issuance under the Company's equity incentive plan immediately prior to the Effective Time was reduced proportionately.

No fractional shares were issued as a result of the Reverse Stock Split. Any stockholder who would have been entitled to receive a fractional share as a result of the process was entitled to the rounding up of the fractional share to the nearest whole number.

The Reverse Stock Split has been retroactively adjusted throughout these unaudited condensed consolidated financial statements for all periods presented, including exercise prices and share data. As a result of the Reverse Stock Split, the Company reclassified approximately $41 thousand between common stock par value and additional paid-in capital.

Note 2 - Going concern

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

For the nine months ended September 30, 2026 and 2025, the Company incurred a net loss of $51.2 million and $34.7 million, respectively. During the nine months ended September 30, 2026 and 2025, the Company had negative cash flows from operations of $54.7 million and $38.2 million, respectively. As of September 30, 2026, the Company had working capital of $58.3 million and accumulated deficit of $453.4 million. The Company has $41.8 million of debt obligations coming due within the next twelve months.

Based on the Company's cash, cash equivalents, and marketable securities as of September 30, 2026, and its expectation to generate operating losses and negative operating cash flows in the foreseeable future, as well as potential liquidity to become less than the $2.5 million required under its existing debt covenants during the next twelve months, there exists substantial doubt regarding the Company's ability to continue as a going concern for a period of at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements. The Company was in compliance with its debt covenant as of September 30, 2026. Upon the occurrence of a breach of debt covenants, Runway Growth Finance Corp may, at its option, declare all obligations immediately due and payable.

In an effort to alleviate these conditions, the Company will need to raise capital through the issuance of additional common stock or borrowings from financial institutions. As the Company seeks additional sources of financing, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, or at all. The unaudited condensed consolidated financial statements of the Company do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

Note 3 - Summary of significant accounting policies

Basis of presentation

These unaudited condensed consolidated financial statements as of September 30, 2026, and for the three and nine months ended September 30, 2026 and 2025, 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, 2025.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the included disclosures are adequate, and the accompanying unaudited condensed consolidated financial statements contain all adjustments which are necessary for a fair presentation of our unaudited condensed consolidated financial position as of September 30, 2026, unaudited condensed consolidated results of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025, and unaudited condensed consolidated cash flows for the nine months ended September 30, 2026 and 2025. The unaudited condensed consolidated results of operations for the three and nine months ended September 30, 2026, are not necessarily indicative of the consolidated results of operations that may be expected for the year ending December 31, 2026.

In the fourth quarter of 2025, the Company changed its rounding presentation of these condensed consolidated financial statements to the nearest thousands, except share or per share data or as otherwise indicated. The accompanying notes to the financial statements are denominated in millions of dollars, except share or per share data or as otherwise indicated. The change in rounding presentation has been applied to all prior year amounts presented. In certain circumstances, this change adjusted previously reported balances, however, these changes were not significant, and no other changes were made to previously reported financial information. Additionally, certain columns and rows within the financial statements and tables presented may not add due to rounding. Percentages have been calculated from the underlying whole-dollar amounts for all periods presented.

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. Significant estimates and assumptions made by management include the fair value of stock-based awards issued. Estimates are based on historical experience, where applicable and other assumptions believed to be reasonable by management. Actual results could differ materially from those estimates.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the 2025 Annual Report on Form 10-K. There have been no material changes to these accounting policies, except as noted below.

Revenue Recognition

The following table summarizes net sales from contracts with customers disaggregated by product for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
WiSE CRT System	$ 2,463	$ 482	$ 7,399	$ 628
Surgical tool kits	15	7	51	11
Battery replacements	33	23	68	43
Sales	2,511	512	7,518	682
Less rebates	(24)	-	(32)	-
Net sales	$ 2,487	$ 512	$ 7,486	$ 682

The Company offers volume rebates to certain group purchasing organizations ("GPOs"). Volume rebates offered to customers are recorded as a reduction to sales and an obligation to the customer, which is recorded as accounts payable, as the amounts are expected to be paid within thirty days of the end of the quarter. Due to the introduction of rebate agreements, the Company changed the caption from "Revenue" to "Net sales" in its condensed consolidated statements of operations and related disclosures during the three and nine months ended September 30, 2026 and 2025.

Deferred revenue

The timing of revenue recognition for WiSE CRT System and battery replacements differ from the timing of invoicing to customers. The Company invoices customers upon shipment or delivery of WiSE and battery replacements to the customer, while the revenue is recognized upon completion of the procedure. Therefore, the Company recognizes a contract liability resulting from the timing of revenue recognition and invoicing. Deferred revenue is equivalent to billings for WiSE performance obligations that are unsatisfied as of the balance sheet date. The Company expects to recognize revenue from these unfulfilled performance obligations within one year or less. The movement in the deferred revenue balance during the three and nine months ended September 30, 2026 and 2025, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Balance, beginning of period	$ 1,192	$ 97	$ 502	$ -
Deferral of revenue	2,809	408	8,470	671
Recognition of revenue	(2,496)	(505)	(7,467)	(671)
Balance, end of period	$ 1,505	$ -	$ 1,505	$ -

Interest Income

The Company's interest income was generated from its cash, cash equivalent, and marketable securities, including accretion of discounts. The following table provides a summary of the components of interest income for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Interest income	$ 590	$ 546	$ 1,200	$ 1,469
(Amortization of premium) accretion of discount on marketable securities, net	273	272	359	596
Total interest income	$ 863	$ 818	$ 1,559	$ 2,065

Recently adopted accounting pronouncements

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which amends ASC 326-20 to provide a practical expedient related to the estimation of expected credit losses for current accounts receivable and current contract assets that arise from transactions accounted for under ASC 606. The practical expedient permits all entities to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. The amendments are effective for annual periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. The Company adopted this ASU in the first quarter of 2026, on a prospective basis and elected the practical expedient for the calculation of current expected credit losses. The adoption did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recently issued accounting pronouncements not yet adopted

In December 2025, the FASB issued *ASU 2025-12, Codification Improvements*. ASU 2025-12 addresses suggestions received from stakeholders regarding the Accounting Standards Codification and makes other incremental improvements to U.S. GAAP. The update represents changes to the Codification that clarify, correct errors or make other improvements to a variety of topics. ASU 2025-12 is effective for fiscal years beginning after December 15, 2026, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of this ASU on its unaudited condensed consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270) Narrow-Scope Improvements.* The ASU is intended to clarify the applicability of interim reporting guidance and addresses the form and content of interim financial statements and interim disclosure requirements. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, and early adoption is permitted. The Company is currently evaluating the impact of this ASU on its unaudited condensed 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 4 - Cash, cash equivalents, and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Cash and cash equivalents		
Cash	$ 3,384	$ 1,386
Money market funds	8,101	-
Commercial paper	2,500	4,408
Total cash and cash equivalents	$ 13,985	$ 5,794
Marketable securities, short-term		
Asset backed securities	$ 3,973	$ 1,012
Commercial paper	13,247	9,125
Corporate bonds	22,845	18,171
US Treasury securities	31,365	19,087
Total marketable securities, short-term	$ 71,430	$ 47,395
Marketable securities, long-term		
Asset backed securities	$ 3,727	$ 1,011
Corporate bonds	4,041	-
Total marketable securities, long-term	$ 7,768	$ 1,011
Total cash, cash equivalents, and marketable securities	$ 93,183	$ 54,200

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within our unaudited condensed consolidated balance sheets as of September 30, 2026 and 2025, to the total of such amounts as presented in the unaudited condensed consolidated statements of cash flows (in thousands):

	September 30, 2026	September 30, 2025
Cash and cash equivalents	$ 13,985	$ 12,642
Restricted cash, noncurrent	2,604	2,604
Total cash, cash equivalents, and restricted cash	$ 16,589	$ 15,246

During the nine months ended September 30, 2026 and 2025, marketable securities were sold or matured for proceeds of $49.9 million and $50.1 million, respectively. The Company recorded an immaterial amount of realized gain during the three and nine months ended September 30, 2026 and 2025. See Note 5, “Fair value measurements” for additional information regarding the fair value of cash equivalents and marketable securities.

The following tables summarizes the unrealized gains and losses related to the Company’s available-for-sale marketable securities, by major security type, as of September 30, 2026 and December 31, 2025 (in thousands):

	As of September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
Asset backed securities	$ 7,710	$ -	$ (10)	$ 7,700
Commercial paper	13,265	-	(18)	13,247
Corporate bonds	26,929	-	(43)	26,886
US Treasury securities	31,397	-	(32)	31,365
Total marketable securities	$ 79,301	$ -	$ (103)	$ 79,198

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized (losses)	Fair Value
Marketable securities				
Asset backed securities	$ 2,022	$ 1	$ -	$ 2,023
Commercial paper	9,120	5	-	9,125
Corporate bonds	18,148	23	-	18,171
US Treasury securities	19,062	25	-	19,087
Total marketable securities	$ 48,352	$ 54	$ -	$ 48,406

The following table shows the unrealized losses and fair values for those marketable securities that were in an unrealized loss position as of September 30, 2026 and December 31, 2025, aggregated by major security type and the length of time the marketable securities have been in a continuous loss position (in thousands):

	As of September 30, 2026					
	In Loss Position for Less Than 12 Months		In Loss Position for 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Asset backed securities	$ 7,700	$ (10)	$ -	$ -	$ 7,700	$ (10)
Commercial paper	11,761	(18)	-	-	11,761	(18)
Corporate bonds	26,886	(43)	-	-	26,886	(43)
US Treasury Securities	31,365	(32)	-	-	31,365	(32)
Total	$ 77,712	$ (103)	$ -	$ -	$ 77,712	$ (103)

	As of December 31, 2025					
	In Loss Position for Less Than 12 Months		In Loss Position for 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 1,000	$ -	$ -	$ -	$ 1,000	$ -
Corporate Bonds	298	-	-	-	298	-
Total	$ 1,298	$ -	$ -	$ -	$ 1,298	$ -

Contractual maturities of the Company's marketable securities as of September 30, 2026, were as follows (in thousands):

	Fair Value
One year or less	$ 71,430
Two years to three years	7,768
Total marketable securities	$ 79,198

Note 5 – Fair value measurement

Management's assessment of the significance of a particular input to the fair value measurement requires judgement and may affect the valuation of financial assets and liabilities and their placement within the three-tier fair value hierarchy. As of September 30, 2026 and December 31, 2025, the fair value measurement of the Company's financial assets measured on a recurring basis were as follows (in thousands):

	Fair Values as of September 30, 2026			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 8,101	$ -	$ -	$ 8,101
Commercial paper	-	2,500	-	2,500
Marketable securities				
Asset backed securities	-	7,700	-	7,700
Commercial paper	-	13,247	-	13,247
Corporate bonds	-	26,886	-	26,886
US Treasury securities	-	31,365	-	31,365
Total	$ 8,101	$ 81,698	$ -	$ 89,799

	Fair Values as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 4,408	$ -	$ -	$ 4,408
Marketable securities				
Asset backed securities	-	2,023	-	2,023
Commercial paper	-	9,125	-	9,125
Corporate bonds	-	18,171	-	18,171
US Treasury securities	-	19,087	-	19,087
Total	$ 4,408	$ 48,406	$ -	$ 52,814

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. There are no other financial assets and liabilities that require fair value hierarchy measurements and disclosures for the periods presented.

Note 6 - 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, and reimbursements for leasehold improvements. Accounts and other receivables, net were as follows as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Trade receivables	$ 1,923	$ 452
Non-trade receivables	774	154
Reimbursement for leasehold improvements	-	1,714
Accounts and other receivables	2,697	2,320
Less provision for credit losses	-	-
Accounts and other receivables, net	$ 2,697	$ 2,320

During the three and nine months ended September 30, 2026 and 2025, the Company recorded no provision for credit losses.

Inventory

Inventory consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Raw materials	$ 3,431	$ 2,019
Work in process	15,245	9,168
Finished goods	4,623	4,466
Inventory	$ 23,299	$ 15,653
Inventory – current	$ 18,940	$ 13,789
Inventory – noncurrent	$ 4,359	$ 1,864

The Company's non-current inventory consist of raw materials, and work in process that are expected to be sold or consumed beyond the next twelve months.

Property and equipment, net

Property and equipment consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Equipment	$ 7,263	$ 3,300
Computer software	605	560
Leasehold improvements	5,303	554
Construction in progress	-	4,289
Total property and equipment	13,171	8,703
Less accumulated depreciation and amortization	(4,034)	(3,226)
Total property and equipment, net	$ 9,137	$ 5,477

As of December 31, 2025, construction in progress balance pertained to tenant improvements and manufacturing equipment, not yet available for use for the Company's new corporate headquarters, laboratory, and manufacturing facility in Santa Clara, California. These assets were placed in service as of September 30, 2026. Depreciation and amortization expense for the three months ended September 30, 2026 and 2025 was $0.4 million and $0.1 million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2026 and 2025 was $0.8 million and $0.3 million, respectively.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Accrued compensation and related liabilities	$ 4,457	$ 4,049
Accrued development expenses	364	354
Accrued warranty reserves	110	185
Deferred revenue	1,505	502
Finance lease liability, current	9	-
Accrued other expenses	156	515
Accrued expenses and other liabilities	$ 6,601	$ 5,605

Changes in accrued warranty reserves were as follows for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Beginning of period	$ 327	$ 436	$ 240	$ 692
Warranty reserve accrued during the period	107	211	325	228
Settlement of warranty claims	(122)	(236)	(253)	(509)
End of period	$ 312	$ 411	$ 312	$ 411
Warranty reserve - current	$ 110	$ 383	$ 110	$ 383
Warranty reserve - noncurrent	$ 202	$ 28	$ 202	$ 28

Note 7 – Leases

The Company has an operating lease for its corporate headquarters and laboratory space, located in Sunnyvale, California, with an original lease period expiring June 30, 2024. In January 2024, the Company signed an addendum to the operating lease, extending the expiration of the lease through June 30, 2025. In March 2024, the Company signed an additional addendum to the operating lease, extending the expiration of the lease through December 31, 2025. In July 2024, the Company signed an additional addendum to the operating lease, extending the expiration of the lease through December 31, 2026. The Company accounted for these lease addendums as lease modifications, which resulted in an increase in the right of use operating asset and a corresponding increase in operating lease liabilities.

In October 2026, the Company signed an additional addendum to the operating lease, extending the expiration of the lease through January 31, 2027, on the same terms as the original lease.

In April 2025, the Company signed an addendum to lease additional office space on a short-term basis for an adjacent office space, which expired August 2026. The Company accounted for the modification as a separate contract and recognized associated lease payments in net loss 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 the lease term. As a result of entering into this lease agreement, the Company recorded a right-of-use asset and corresponding lease liability of $12.9 million, net of the tenant improvement allowance of $4.1 million on the commencement date. As of September 30, 2026, the Company had utilized the total tenant improvement allowance and had been fully reimbursed. Lease payments began in January 2026. 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.

The Company also leases office equipment under an immaterial finance lease agreement.

Amounts reported in the unaudited condensed consolidated balance sheets for operating leases in which the Company is the lessee as of September 30, 2026 and December 31, 2025, were as follows (in thousands):

	September 30, 2026	December 31, 2025
Right of use operating lease asset	$ 11,819	$ 12,613
Operating lease liability, current	974	1,182
Operating lease liability, noncurrent	17,475	16,520
Weighted-average remaining lease term	15.25 years	15.71 years
Weighted-average discount rate	6.29%	6.40%

The following table presents the components of lease costs in our unaudited statements of operations for three and nine month ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease costs	$ 506	$ 594	$ 1,665	$ 1,746
Variable lease costs	177	30	504	96
Short-term lease costs	21	6	80	19
Total lease expense	$ 704	$ 630	$ 2,249	$ 1,861

Future lease payments for non-cancelable operating leases as of September 30, 2026, were as follows (in thousands):

Years Ending December 31,	
2026 (remaining three months)	$ 306
2027	936
2028	1,294
2029	1,708
2030	1,791
Thereafter	23,838
Total undiscounted lease payments	29,873
Less effects of discounting	(11,424)
Total operating lease liabilities	$ 18,449

Note 8 - Notes payable

At September 30, 2026 and December 31, 2025, notes payable consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Notes payable, current		
Current portion of notes payable	$ 41,800	$ -
Less unamortized deferred loan costs	(151)	-
Less unamortized discount	(295)	-
Notes payable, current, net	$ 41,354	$ -
Notes payable, noncurrent		
Long-term portion of notes payable	$ -	$ 41,800
Less unamortized deferred loan costs	-	(311)
Less unamortized discount	-	(603)
Notes payable, noncurrent, net	$ -	$ 40,886
Total notes payable, net	$ 41,354	$ 40,886

The following table presents information regarding the Company's notes payable principal repayment obligations as of September 30, 2026 (in thousands):

Years Ended December 31,	
2026	$ -
2027	41,800
Total minimum payments	$ 41,800

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 September 30, 2026 and December 31, 2025, the outstanding principal balance was $41.8 million and $41.8 million, respectively.

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% 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 $1.8 million 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 $0.1 million and $0.1 million for the three months ended September 30, 2026 and 2025, respectively. Amortization of the discount was $0.3 million and $0.3 million for the nine months ended September 30, 2026 and 2025, respectively. This amount was recorded as additional interest expense in the accompanying unaudited condensed consolidated statements of operations. As of September 30, 2026 and December 31, 2025, the note has been shown net of unamortized discounts of $0.3 million and $0.6 million, respectively.

The Company incurred loan costs of $1.0 million, which are being amortized over the life of the loan using the effective interest method. Amortization of loan costs was $0.1 million and $0.1 million for the three months ended September 30, 2026 and 2025, respectively. Amortization of loan costs was $0.2 million and $0.2 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026 and December 31, 2025, the note has been shown net of unamortized loan costs of $0.2 million and $0.3 million, respectively.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of September 30, 2026 and December 31, 2025, the Company was in compliance with all debt covenants.

Note 9 - Convertible preferred stock

As of September 30, 2026 and December 31, 2025, 10,000,000 shares of convertible preferred stock were authorized, of which no shares were issued or outstanding.

Note 10 - Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors. As of September 30, 2026 and December 31, 2025, no dividends have been declared.

As of September 30, 2026 and December 31, 2025, 600,000,000 shares were authorized, of which 84,546,086 shares and 45,025,917 shares, respectively, were outstanding. See Note 1, "Business and organization – *Reverse stock split*" for additional information regarding the Reverse Stock Split that was effective April 1, 2026.

The Company completed its initial public offering and began trading on the ASX on November 24, 2021, under the symbol "EBR". The ASX uses a Clearing House Electronic Subregister System ("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, CDIs are issued. CDIs are units of beneficial ownership in shares and are traded in a manner similar to shares of Australian companies listed on the ASX. The legal title to the shares are held by a depository, CHESS Depositary Nominees ("CDN'), which is a wholly owned subsidiary of the ASX, and is an approved general participant of ASX Settlement.

On May 22, 2025 (Sydney time), the Company completed an institutional placement of 55,900,000 CDIs, representing 5,590,000 shares of common stock, at a purchase price of $0.64 per CDI ($6.40 per share of common stock), for proceeds of $33.5 million, net of $2.5 million of related issuance costs. On June 19, 2025 (Sydney time), 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 2,000,000 shares of common stock, at a purchase price of $0.64 per CDI ($6.40 per share of common stock), for proceeds of $12.8 million, net of $0.1 million of related issuance costs.

On June 5, 2026 (Sydney time), the Company completed a fully underwritten institutional placement to institutional and sophisticated investors ("Institutional Placement"), comprising: (a) an institutional placement to institutional and sophisticated investors ("Tranche 1"); and (b) a conditional placement to BCP3 Pty Ltd, a related party of Dr. Chris Nave, a non-executive director of the Company, which was approved by stockholders at the Special Meeting of Stockholders held on August 18, 2026 ("Tranche 2"). As a result of the Tranche 1 Institutional Placement, the Company issued 77,352,890 CDIs, representing 7,735,289 shares of common stock, at a purchase price of A$0.38 per CDI (A$3.80 per share of common stock), for proceeds of $19.5 million, net of $1.2 million of related issuance costs.

On June 5, 2026 (Sydney time), the Company also completed a fully underwritten 1-for-2 pro rata non-renounceable entitlement offer to eligible institutional stockholders ("Institutional Entitlement Offer"), and issued 110,582,160 CDIs, representing 11,058,216 shares of common stock, at a purchase price of A$0.38 per CDI (A$3.80 per share of common stock), for proceeds of $28.0 million, net of $1.5 million of related issuance costs.

On June 24, 2026 (Sydney time), the Company completed a fully underwritten 1-for-2 pro rata non-renounceable retail entitlement offer to existing retail stockholders ("Retail Entitlement Offer"), and issued 114,699,930 CDIs, representing 11,469,993 shares of common stock, at a purchase price of $0.38 per CDI (A$3.80 per share of common stock), for proceeds of $28.3 million, net of $1.7 million of related issuance costs. Host-Plus Pty Ltd and H.E.S.T. Australia Ltd., related parties of Dr. Chris Nave, a non-executive director of the Company, participated in the Retail Entitlement Offer purchasing 25,630,389 CDIs and 5,027,499 CDIs, respectively.

On August 24, 2026 (Sydney time), the Company completed Tranche 2 of the fully underwritten institutional placement, and issued 92,105,270 CDIs, representing 9,210,527 shares of common stock at a purchase price of A$0.38 per CDI (A$3.80 per share of common stock), for proceeds of $23.7 million, net of $1.4 million of related issuance costs. Host-Plus Pty Ltd and H.E.S.T. Australia Ltd., related parties of Dr. Chris Nave, a non-executive director of the Company, were the only participants in the Tranche 2 placement, purchasing 77,001,190 CDIs and 15,104,080 CDIs, respectively.

Additionally, the Company has reserved the following shares of common stock for issuance as of September 30, 2026:

Conversion of Common Stock warrants	1,944,214
2013 Equity Incentive Plan	1,589,564
Amended 2021 Equity Incentive Plan	5,411,631
Outside of Amended 2021 Equity Incentive Plan	158,180
Total shares of Common stock reserved for issuance	9,103,589

Note 11 - Warrants

The following warrants were outstanding as of September 30, 2026 and December 31, 2025:

Warrant Issuance	Shares of Common Stock Issuable for Outstanding Warrants as of September 30, 2026	Shares of Common Stock Issuable for Outstanding Warrants as of December 31, 2025	Exercise Price	Expiration Date
June 30, 2016	-	3,639	$ 8.20	June 30, 2026
October 30, 2017	195,061	195,061	$ 4.10	October 29, 2027
February 28, 2018	23,418	23,418	$ 8.20	February 28, 2028
August 26, 2019	443,790	443,790	$ 5.90	August 26, 2029
March 13, 2020	442,294	442,294	$ 5.90	March 13, 2030
March 25, 2020	44,150	44,150	$ 1.40	March 24, 2030
February 12, 2021	173,205	173,205	$ 5.90	February 12, 2031
June 25, 2021	288,721	288,721	$ 5.90	June 25, 2031
August 16, 2021	22,427	22,427	$ 5.90	June 25, 2031
October 4, 2021	311,148	311,148	$ 5.90	October 4, 2031
Total	1,944,214	1,947,853		

As of September 30, 2026, the weighted-average exercise price of outstanding warrants was $5.64, with a weighted-average remaining contractual life of 3.60 years.

Note 12 - Stock-based compensation

The Company and its stockholders adopted the 2013 Equity Incentive Plan (the "2013 Plan") June 18, 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 (the "2021 Plan") in connection with its initial public offering. On May 6, 2026, stockholders approved the addition of 1,801,036 shares of common stock, as adjusted for the Reverse Stock Split, to the number of shares of common stock reserved for issuance under the 2021 Plan, by operation of the "evergreen" provision set forth in the 2021 Plan. Under the 2021 Plan, 5,411,631 shares of common stock are reserved. The Company may grant options to purchase common stock, stock appreciation rights, restricted stock awards and other forms of stock-based compensation. Stock options generally vest over four years and expire no later than 10 years from the date of grant. The Board of Directors has the authority to select the employees to whom options are granted and determine the terms of each option, including: i) the number of shares of common stock subject to the option; ii) when the option becomes exercisable; iii) the option exercise price, which must be at least 100% of the fair market value of the common stock as of the date of grant; and iv) the duration of the option, which may not exceed 10 years.

As of September 30, 2026, options to purchase a total of 4,161,118 shares of common stock remained outstanding and 1,250,513 shares remain available for grant under the 2021 Plan and 158,180 remained outstanding outside of the 2021 Plan. As of September 30, 2026, options to purchase a total of 1,589,564 shares of common stock remained outstanding under the 2013 Plan. As of September 30, 2026, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the nine months ended September 30, 2026, was as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2025	4,810,761	$ 4.91	6.76
Granted	1,466,482	3.66	
Cancelled	(323,483)	5.85	
Exercised	(44,898)	3.52	
Outstanding as of September 30, 2026	5,908,862	$ 4.56	6.82
Vested and expected to vest as of September 30, 2026	5,908,862	$ 4.56	6.82
Exercisable as of September 30, 2026	3,608,372	$ 4.16	5.39

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 derived from the combination of the average historical stock volatilities of several publicly traded companies with characteristics similar to those of the Company, and on the Company's stock price, as quoted on the ASX. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The Company uses the straight-line method for expense attribution. The weighted-average grant-date fair values of stock options granted during the nine months ended September 30, 2026 and 2025, was $2.29 per share and $5.52 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,	
	2026	2025
Expected term (in years)	5.73 - 6.08	5.53 - 6.08
Expected volatility	65.31% - 67.16%	65.27% - 67.80%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	3.72% - 5.19%	3.92% - 4.47%

The following table presents classification of stock-based compensation expense within the accompanying unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of goods sold	$ 33	$ -	$ 104	$ -
Research and development	286	346	832	853
Selling, general and administrative	685	583	1,911	1,285
Total	$ 1,004	$ 929	$ 2,847	$ 2,138

At September 30, 2026, there was $7.6 million of unamortized stock-based compensation cost, related to unvested stock options which is expected to be recognized over a weighted-average period of 2.55 years.

Note 13 - Income taxes

During the three and nine months ended September 30, 2026 and 2025, the Company does not have an income tax benefit or expense. The Company has historically incurred net operating losses and maintains a full valuation allowance against its net deferred tax assets. Valuation allowances are recorded when the expected realization of the deferred tax assets does not meet a "more likely than not" criterion. Realization of the Company's deferred tax assets are dependent upon the generation of future taxable income, the amount and timing of which are uncertain.

The Company's effective tax rate was 0% for the three and nine months ended September 30, 2026 and 2025. The difference between the effective tax rate and the federal statutory rate of 21% was primarily due to the full valuation allowance recorded on the Company's net deferred tax assets, state and foreign tax benefits, research and development tax credits, and other non-deductible expenses.

During the three and nine months ended September 30, 2026, there were no material changes to the Company's uncertain tax positions.

The One Big Beautiful Bill Act ("OBBA") includes significant U.S. tax provisions, including 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 from 2025 through 2027. The Company continues to monitor any new tax laws and notes those effective in 2026 do not have a material impact on the Company's unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2026.

Note 14 – Net loss per share

The following tables sets forth the computation of basic and diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2026 and 2025 (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator – basic & diluted:				
Net loss attributable to common stockholders, basic and diluted	$ (16,644)	$ (12,189)	$ (51,171)	$ (34,710)
Denominator:				
Weighted-average number of shares outstanding, basic and diluted	79,038,271	44,968,101	57,895,459	40,631,064
Net loss per share attributable to common stockholders, basic and diluted	$ (0.21)	$ (0.27)	$ (0.88)	$ (0.85)

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:

	September 30,	
	2026	2025
Outstanding warrants	1,944,214	1,978,938
Outstanding stock options	5,908,862	4,720,966
Total dilutive shares	7,853,076	6,699,904

Note 15 - Segment information

The Company's chief operating decision maker ("CODM") is the Chief Executive Officer. The Company has determined that it has a single operating and reportable segment. The CODM uses net sales, gross margin and operating expenses at the consolidated level to allocate resources, monitor budget versus actual results, and manage operations. Significant expenses within operating expenses include engineering and development, clinical and regulatory, sales and marketing, and general and administrative expenses at the consolidated level.

Substantially all of the segment net sales are derived from sales to customers in the U.S. Net sales by geography is based on billing address of the customer. International net sales accounted for less than 1% of the total net sales during the three and nine months ended September 30, 2026. Long-lived assets held and used outside the U.S. are immaterial.

The following table summarizes the Company's net sales by geography for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
United States	$ 2,477	$ 509	$ 7,473	$ 658
International	10	3	13	24
Net sales	$ 2,487	$ 512	$ 7,486	$ 682

The following table disaggregates amounts that comprise research and development, and selling, general and administrative expenses within the accompanying unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Engineering and development	$ 4,220	$ 3,909	$ 12,305	$ 10,604
Clinical and regulatory	2,477	2,335	7,429	7,010
Total research and development	$ 6,697	$ 6,244	$ 19,734	$ 17,614
Sales and marketing	$ 6,039	$ 3,052	$ 18,442	$ 6,969
General and administrative	3,761	2,809	11,417	8,519
Total selling, general and administrative	$ 9,800	$ 5,861	$ 29,859	$ 15,488

The segment's net loss equals the Company’s net loss as presented in the unaudited condensed consolidated statements of operations. Other segment items within net loss include interest expense, interest income, other (expense) / income, and loss on foreign currency at the consolidated level.

Note 16 - Commitments and contingencies

Purchase commitments

The Company purchases raw materials, manufacturing equipment, and various services from a variety of vendors. During the normal course of business, in order to manage manufacturing lead times and help ensure an adequate supply of certain items, we enter into agreements with suppliers that either allow us to procure goods and services when we choose or that establish purchase requirements over the term of the agreement. In certain instances, our purchase agreements allow us to cancel, reschedule, or adjust our purchase requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our purchase commitments are firm and non-cancelable. As of September 30, 2026, the Company’s obligations under such arrangements were approximately $14.0 million.

Cybersecurity

As previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, the Company detected a cybersecurity incident in which an unauthorized third party gained access to certain information systems of the Company on or around February 13, 2026. Upon detection, the Company promptly initiated response protocols and began taking steps to contain, assess and remediate the cybersecurity incident, including launching an investigation with external cybersecurity experts. Although the Company believes that the cybersecurity incident has not had a material impact on its overall financial condition or results of operations, its evaluation and response to this incident are ongoing and the Company may discover other impacts or new events related to this incident may occur that could affect the Company’s financial condition or results of operations. As of September 30, 2026, incurred cybersecurity expenses limited to the Company’s insurance deductibles have been recorded and reflected within the Company’s unaudited condensed consolidated financial statements and such amounts are not material.

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 17 – Related party transactions

See Note 10 “Common stock”

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, 2025. In addition to historical data, this discussion contains forward-looking statements about our business, ability to continue as a going concern, ability to successfully commercialize our WiSE CRT System, results of operations, cash flows, financial condition and prospects based on current expectations that involve risks, uncertainties, assumptions, and other important factors. Our actual results could differ materially from such forward-looking statements. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K. Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future. We use words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "seek," "should," "will," "would," and similar expressions to identify forward-looking statements.

Overview

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

We initially developed 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, hospitals or medical facilities within the U.S. to be followed by select, high-volume hospitals or medical facilities in markets outside the U.S. ("OUS") that we would target after evaluating regulatory and reimbursement considerations. 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. 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 sales representatives and expanding our marketing programs, in the U.S., to help facilitate further adoption among existing hospital accounts as well as broaden awareness of our products to new hospital accounts.

Financial overview

Our WiSE CRT System received approval from the FDA for commercial distribution in April 2025, and we began commercializing WiSE during the second quarter of 2025. During the three months ended September 30, 2026, we had 40 commercial implants at 24 hospitals in the US, and recognized net sales of $2.5 million. During the nine months ended September 30, 2026, we had 127 commercial implants at 41 hospitals in the US, and recognized net sales of $7.5 million. An additional 58 physicians were trained to implant the WiSE CRT System, and 43 additional purchase agreements were signed with target Limited Market Release ("LMR") sites during the nine months ended September 30, 2026. 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.

Since inception, we have incurred significant net losses and expect to continue to incur net losses until we are able to generate sufficient revenue. 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 September 30, 2026, we had $93.2 million in cash, cash equivalents, and marketable securities and an accumulated deficit of $453.4 million. For a more comprehensive discussion see "Liquidity and Capital Resources" and "Future Funding Requirements" below.

In June 2026, the Company completed a fully underwritten institutional placement to institutional and sophisticated investors ("Institutional Placement"), comprising: (a) an institutional placement to institutional and sophisticated investors ("Tranche 1"); and (b) a conditional placement to BCP3 Pty Ltd, a related party of Dr. Chris Nave, a non-executive director of the Company, which was approved by stockholders at the Special Meeting of Stockholders held on August 18, 2026 ("Tranche 2"). Under the Tranche 1 Institutional Placement, we issued 77,352,890 CDIs, representing 7,735,289 shares of common stock, at a purchase price of A$0.38 per CDI (A$3.80 per share of common stock), for proceeds of $19.5 million, net of $1.2 million of related issuance costs.

In June 2026, we completed a 1-for-2 accelerated non-renounceable pro rata entitlement offer, with an institutional and retail component, at a purchase price of A$0.38 per CDI (A$3.80 per share of common stock). Under the institutional entitlement offering, we issued 110,582,160 CDIs, representing 11,058,216 shares of common stock, for proceeds of $28.0 million, net of $1.5 million of related issuance costs. Under the retail entitlement offering, we issued 114,699,930 CDIs, representing 11,469,993 shares of common stock, for proceeds of $28.3 million, net of $1.7 million of related issuance costs.

In August 2026, we completed Tranche 2 of the fully underwritten institutional placement, and issued 92,105,270 CDIs, representing 9,210,527 shares of common stock at a purchase price of A$0.38 per CDI (A$3.80 per share of common stock), for proceeds of $23.7 million, net of $1.4 million of related issuance costs.

Factors Affecting Our Business

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

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

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

Net Sales

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, net of rebates. 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. We account for rebates as a reduction to revenue, calculated based on the terms agreed with the customer. Our revenue fluctuates primarily based on the volume of procedures performed. Our revenue is expected to 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 hospitals 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 net sales. 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, although we have fully utilized inventory that was previously expensed and going forward will receive no additional benefit to gross margin. 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 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 post-approval study, such as expenses associated with our clinical research organization, or CRO, who provided project management, outside service fees paid to third party consultants and contractors related to WiSE engineering, quality assurance and regulatory approval, as well as contract manufacturing of WiSE 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 significantly in the future as we:

- hire and retain additional personnel, including research, clinical, development, manufacturing, quality control, quality assurance and regulatory personnel;
- conduct our post-approval study;
- continue to advance the research and development of our WiSE CRT system or other product candidates; and
- develop 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. 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;
- continue to expand our sales, marketing and administrative function to support the sales adoption of WiSE;
- 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.

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 amortization of premiums and accretion of discounts, generated from our cash, cash equivalent, and marketable securities.

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, 2025. There have been no significant changes to our critical accounting estimates since December 31, 2025.

Recent Accounting Pronouncements

See the sections titled "Recently adopted accounting pronouncements" and "Recently issued accounting pronouncements not yet adopted" in Note 3 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Non- GAAP Financial Measures

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

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Reconciliation of net loss to non-GAAP Adjusted EBITDA				
Net loss	$ (16,644)	$ (12,189)	$ (51,171)	$ (34,710)
Interest expense, net	495	607	2,450	2,188
Depreciation and amortization	301	90	601	288
Stock-based compensation [(a)]	1,004	929	2,847	2,138
Adjusted EBITDA	$ (14,844)	$ (10,563)	$ (45,273)	$ (30,096)

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

Results of Operations

Comparison of the Three Months Ended September 30, 2026, to the Three Months Ended September 30, 2025

We recorded a net loss of $16.6 million in the three months ended September 30, 2026, an increase of $4.5 million, or 36.5%, from the three months ended September 30, 2025. The increased loss in 2026 was due to an increase in selling, general and administrative expenses, and research and development expenses, as discussed below. Other expense, net also increased in 2026 primarily due to a decrease in other income, as discussed below.

The following table summarizes our operating results for the three months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Change	
(in thousands)	2026	2025	Amount	%
Net sales	$ 2,487	$ 512	$ 1,975	385.7%
Cost of goods sold	2,238	288	1,950	677.1%
Gross profit	249	224	25	11.2%
Operating expenses				
Research and development	6,697	6,244	453	7.3%
Selling, general and administrative	9,800	5,861	3,939	67.2%
Total operating expenses	16,497	12,105	4,392	36.3%
Other expense, net	(396)	(308)	(88)	28.6%
Loss before income tax	(16,644)	(12,189)	(4,455)	36.5%
Income tax expense	-	-	-	-
Net Loss	$ (16,644)	$ (12,189)	$ (4,455)	36.5%

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 September 30,		Change	
(in thousands)	2026	2025	Amount	%
United States	$ 2,477	$ 509	$ 1,968	386.6%
International	10	3	7	233.3%
Net sales	$ 2,487	$ 512	$ 1,975	385.7%

Net Sales, Cost of Goods Sold, Gross Profit, and Gross Margin:

	Three Months Ended September 30,		Change	
(in thousands)	2026	2025	Amount	%
Net sales	$ 2,487	$ 512	$ 1,975	385.7%
Cost of goods sold	2,238	288	1,950	677.1%
Gross profit	$ 249	$ 224	$ 25	11.2%
Gross margin	10.0%	43.8%		

Net Sales and Cost of Goods Sold

Net sales and cost of goods sold was $2.5 million and $2.2 million, respectively, during the three months ended September 30, 2026, resulting from the Company completing commercial implants at twenty-four hospitals in the US. Net sales and cost of goods sold were significantly lower during the three months ended September 30, 2025, resulting from the then-recent FDA approval of our WiSE CRT System in April 2025. During the three months ended September 30, 2025, we had commercial implants at four hospitals in the US.

Gross Profit, and Gross Margin

Gross profit increased by $0.03 million, or 11.2% during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, resulting from an increase in sales volume and a higher average selling price. Our gross margin was positively affected by the use of inventory that was previously expensed during our clinical trial, although we have fully utilized inventory that was previously expensed and going forward will receive no additional benefit to gross margin. Gross margin was 10.0% for the three months ended September 30, 2026, compared to 43.8% for the three months ended September 30, 2025. Excluding the use of previously expensed inventory, we would have had a negative gross margin of 8.9% for the three months ended September 30, 2026, compared to a negative gross margin of 25.2% for the three months ended September 30, 2025. The improvement in gross margin, excluding the use of previously expensed inventory, is the result of a higher average selling price, and increased manufacturing efficiencies during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025.

Operating Expenses

Research and Development

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

	Three Months Ended September 30,		Change	
(in thousands)	2026	2025	Amount	%
Research and development expenses				
R&D personnel expense	$ 4,302	$ 4,981	$ (679)	(13.6%)
Clinical expenses	972	599	373	62.3%
Quality assurance	226	103	123	119.4%
Contract manufacturing, materials & components	425	484	(59)	(12.2%)
Facility allocation & depreciation	772	77	695	902.6%
Total research and development expense	$ 6,697	$ 6,244	$ 453	7.3%

Research and development expenses increased by $0.5 million, or 7.3%, during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025. Clinical expenses increased by $0.4 million as a result of higher expenses related to WiSE CRT post-approval study. Facility-related expenses and depreciation increased by $0.7 million as a result of our new laboratory in Santa Clara, CA. Quality assurance expenses increased by $0.1 million due to expenses incurred to support product development projects. These increases were offset by $0.7 million decrease in personnel-related expenses due to the reallocation of employees from research and development to selling and manufacturing activities, as a result of the shift in business focus towards commercialization during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025.

Selling, General and Administrative Expenses

Selling, General and administrative expenses increased by $3.9 million, or 67.2%, during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $2.4 million as a result of the expansion of our workforce to support increased adoption of our WiSE CRT System. Travel-related expenses increased by $0.8 million due to increased travel to support our sales and marketing efforts. Professional fees increased by $0.4 million, primarily resulting from higher legal fees. Corporate expenses increased by $0.2 million, primarily resulting from the higher expenses related to investor relations, insurance premiums, and computer software licenses. Facility related and other expenses increased by $0.1 million, primarily resulting from the higher expenses for our new corporate headquarters and manufacturing facility.

Other expense, net

Other expense, net increased by $0.1 million during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025. This increase was primarily due to a $0.2 million decrease in other income from refundable tax incentives, which was partially offset by a $0.1 million decrease in interest expense.

Comparison of the Nine Months Ended September 30, 2026, to the Nine Months Ended September 30, 2025

We recorded a net loss of $51.2 million in the nine months ended September 30, 2026, an increase of $16.5 million, or 47.4%, from the nine months ended September 30, 2025. The increased loss in 2026 was due to an increase in selling, general and administrative expenses, and research and development expenses, as discussed below. Other expense, net also increased in 2026 primarily due to a decrease in interest income, as discussed below.

The following table summarizes our operating results for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,		Change	
(in thousands)	2026	2025	Amount	%
Net sales	$ 7,486	$ 682	$ 6,804	997.7%
Cost of goods sold	6,710	374	6,336	1,694.1%
Gross profit	776	308	468	151.9%
Operating expenses				
Research and development	19,734	17,614	2,120	12.0%
Selling, general and administrative	29,859	15,488	14,371	92.8%
Total operating expenses	49,593	33,102	16,491	49.8%
Other expense, net	(2,354)	(1,916)	(438)	22.9%
Loss before income tax	(51,171)	(34,710)	(16,461)	47.4%
Income tax expense	-	-	-	-
Net Loss	$ (51,171)	$ (34,710)	$ (16,461)	47.4%

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. Net sales by geography is based on the billing address of the customer.

The table below summarizes our revenue by geography:

(in thousands)	Nine Months Ended September 30, 2026	2025	Change Amount	%
United States	$ 7,473	$ 658	$ 6,815	1,035.7%
International	13	24	(11)	(45.8%)
Net sales	$ 7,486	$ 682	$ 6,804	997.7%

Net Sales, Cost of Goods Sold, Gross Profit, and Gross Margin:

(in thousands)	Nine Months Ended September 30, 2026	2025	Change Amount	%
Net sales	$ 7,486	$ 682	$ 6,804	997.7%
Cost of goods sold	6,710	374	6,336	1,694.1%
Gross profit	$ 776	$ 308	$ 468	151.9%
Gross margin	10.4 %	45.2 %		

Net Sales and Cost of Goods Sold

Net sales and cost of goods sold was $7.5 million and $6.7 million, respectively, during the nine months ended September 30, 2026, resulting from the Company completing commercial implants at forty-one hospitals in the US. Net sales and cost of goods sold were significantly lower during the nine months ended September 30, 2025, resulting from the then-recent FDA approval of our WiSE CRT System in April 2025. During the nine months ended September 30, 2025, we had commercial implants at seven hospitals in the US.

Gross Profit, and Gross Margin

Gross profit increased by $0.5 million, or 151.9% for the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025, resulting from an increase in sales volume and a higher average selling price. Our gross margin was positively affected by the use of inventory that was previously expensed during our clinical trial, although we have fully utilized inventory that was previously expensed and going forward will receive no additional benefit to gross margin. Gross margin was 10.4% for the nine months ended September 30, 2026, compared to 45.2% for the nine months ended September 30, 2025. Excluding the use of previously expensed inventory, we would have had a negative gross margin of 16.9% for the nine months ended September 30, 2026, compared to a negative gross margin of 31.9% for the nine months ended September 30, 2025. The improvement in gross margin, excluding the use of previously expensed inventory, is the result of a higher average selling price, and increased manufacturing efficiencies during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025.

Operating Expenses

Research and Development

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

(in thousands)	Nine Months Ended September 30, 2026	2025	Change Amount	%
Research and development expenses				
R&D personnel expense	$ 12,971	$ 13,829	$ (858)	(6.2%)
Clinical expenses	2,759	1,560	1,199	76.9%
Quality assurance	634	273	361	132.2%
Contract manufacturing, materials & components	1,908	1,744	164	9.4%
Facility allocation & depreciation	1,462	208	1,254	602.9%
Total research and development expense	$ 19,734	$ 17,614	$ 2,120	12.0%

Research and development expenses increased by $2.1 million, or 12.0%, during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025. Clinical expenses increased by $1.2 million as a result of higher expenses related to WiSE CRT post-approval study. Facility-related expenses and depreciation increased by $1.2 million, as a result of our new laboratory in Santa Clara, CA. Quality assurance expenses increased by $0.4 million and contract manufacturing expenses increased by $0.2 million primarily due to higher expenses incurred to support product development projects. These increases were partially offset by a $0.9 million decrease in personnel-related expenses due to the reallocation of employees from research and development to selling and manufacturing activities, as a result of the shift in business focus towards commercialization during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025.

Selling, General and Administrative Expenses

Selling, General and administrative expenses increased by $14.4 million, or 92.8%, during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025. Personnel-related expenses including salaries, bonuses, stock-based compensation and certain fringe benefits increased by $7.9 million, as a result of the expansion of our workforce to support increased adoption of our WiSE CRT System. Travel-related expenses increased by $3.7 million due to increased travel to support our sales and marketing efforts. Professional fees increased by $1.2 million, primarily resulting from higher legal and consulting services fees. Corporate expenses increased by $0.7 million, primarily resulting from the higher expenses related to insurance premiums, investor relations, and computer software licenses. Facility related and other expenses increased by $0.9 million, primarily resulting from the higher expenses for our new corporate headquarters and manufacturing facility.

Other expense, net

Other expense, net increased by $0.4 million during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025. 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, and a $0.2 million decrease in other income from refundable tax incentives, which were partially offset by a $0.3 million decrease in interest expense.

Liquidity and Capital Resources

We manage our cash and capital structure to maximize shareholder return, maintain our financial condition, and maintain flexibility for future strategic initiatives. We continuously assess our working capital needs, debt and leverage levels, debt maturity schedule, capital expenditure requirements and future investments. As of September 30, 2026 and December 31, 2025, we had approximately $93.2 million and $54.2 million, respectively, in cash, cash equivalents, and marketable securities. Based on our cash, cash equivalents, and marketable securities as of September 30, 2026, and our expectation to generate operating losses, negative operating cash flows in the foreseeable future, and the repayment of notes payable, there exists substantial doubt regarding our ability to continue as a going concern for a period of at least twelve months from the date of this Form 10-Q.

Going concern consideration

The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. For the nine months ended September 30, 2026 and 2025, we incurred a net loss of $51.2 million and $34.7 million, respectively. During the nine months ended September 30, 2026 and 2025, we had negative cash flows from operations of $54.7 million and $38.2 million, respectively. As of September 30, 2026, we had working capital of $58.3 million and accumulated deficit of $453.4 million. Additionally, the Company has $41.8 million of debt obligations coming due within the next twelve months. These factors raise substantial doubt about our ability to continue as a going concern. Until we are able to generate consistent and sufficient revenue from sales of our WiSE CRT System, our ability to continue as a going concern is dependent on our ability to raise additional capital through the issuance of additional common stock or borrowings from financial institutions. Our ability to obtain additional financing is subject to several factors, including market and economic conditions, our performance, and investor sentiment with respect to our company and our industry, however no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, or at all.

Loan and Security Agreements

On June 30, 2022, we entered into a loan and security agreement with Runway Growth Finance Corp. The debt is secured against substantially all of our assets, except for intellectual property, but includes all proceeds from the sale of intellectual property. The loan agreement provides three term loan tranches. We received the initial draw of $20.0 million in June 2022. We received positive interim analysis data, sufficient to proceed with the clinical trial and premarket approval submission to the U.S. Food and Drug Administration, which allowed us to draw the second tranche of $20.0 million in June 2023. The final tranche provided $10.0 million from the date of approval from the FDA for the WiSE CRT System and ended on June 30, 2024. We did not receive FDA approval by June 30, 2024, and therefore did not meet the draw requirements of the third and final tranche.

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

As of September 30, 2026 and December 31, 2025, the outstanding principal balance was $41.8 million, which included the principal borrowings under tranche one and tranche two, as well as the final payment of 4.5% of the principal borrowings to date.

We are subject to customary financial and reporting covenants under the loan and security agreement. As of September 30, 2026 and December 31, 2025, we were in compliance with all debt covenants.

Future Funding Requirements

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

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

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

- the degree of success we experience in commercializing our WiSE CRT System;
- the cost, timing and results of our post-marketing trial and regulatory reviews;
- the cost of our research and development activities for new and modified products;
- the cost and timing of growing our sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any contract manufacturing arrangements;
- the timing, receipt and amount of sales from our WiSE CRT System;
- the emergence of competing or complementary technologies;

- the impact of global business, political and macroeconomic conditions, including inflation, rising interest rates, uncertainty with respect to the federal budget, instability in the global banking system, volatile market conditions, supply chain disruptions, cybersecurity events, and global events, including regional conflicts around the world;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

Contractual Obligations and Commitments

As of September 30, 2026, we had $0.2 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 $18.3 million in operating lease obligations as of September 30, 2026.

As of September 30, 2026, the outstanding principal balance under our loan and security agreement described above was $41.8 million, which included the principal borrowings under tranche one and tranche two, as well as the final payment of 4.5% of the principal borrowings to date.

In addition, we have agreements with suppliers and other parties to purchase inventory. Product inventory obligations consist primarily of purchase order commitments for raw materials and sub-assemblies used in the production of the WiSE CRT System. 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. As of September 30, 2026, our obligations under such arrangements were approximately $14.0 million.

Working Capital

September 30, 2026, Compared to December 31, 2025

As of September 30, 2026, we had working capital of $58.3 million, comprised of current assets of $110.8 million and current liabilities of $52.5 million. Current assets, consisting of cash and cash equivalents, marketable securities, accounts and other receivables, inventory, prepaid expenses, and other current assets, increased by $37.7 million as of September 30, 2026, compared to December 31, 2025. The capital raises completed in 2026 contributed to the overall increase in cash, cash equivalents and marketable securities, resulting in a $32.2 million increase in working capital as of September 30, 2026. The capitalization of inventory resulted in a $5.1 million increase in working capital. A $0.4 million increase in accounts receivable was primarily due to a $2.1 million increase in amounts outstanding from customers and contract manufacturers, offset by a $1.7 million decrease accounts receivable from reimbursements for leasehold improvements. Additionally, a $1.2 million increase in other current assets, primarily due to an increase in deferred costs of goods sold, was offset by a $1.2 million decrease in prepaid expenses attributable to higher amortization of prepaid expenses in 2026.

Current liabilities, consisting primarily of accounts payable, accrued liabilities, lease obligations, interest payable, and current portion of notes payable increased by approximately $38.5 million as of September 30, 2026, compared to December 31, 2025. The increase primarily resulted from a $41.4 million increase in notes payable which was reclassified into current liability, as it becomes due within the next twelve months. This increase was partially offset by a $2.7 million decrease in accounts payable and accrued expenses, which were mainly due to the activity related to construction of leasehold improvements at the new corporate headquarters and purchases of raw materials, and a $0.2 million decrease in operating lease liabilities.

Cash Flows

September 30, 2026, Compared to September 30, 2025

The following table summarizes our cash flows for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,	
(in thousands)	2026	2025
Net cash used in operating activities	$ (54,698)	$ (38,181)
Net cash used in investing activities	(36,819)	(281)
Net cash provided by financing activities	99,704	46,772
Effect of exchange rate change on cash	4	18
Net change in cash and cash equivalents	$ 8,191	$ 8,328

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2026, was $54.7 million, compared to $38.2 million during the nine months ended September 30, 2025, representing an increase in use of $16.5 million. This increase is primarily attributed to an increase in net loss of $16.5 million and an increase in use of cash from changes in working capital of $1.2 million, which were partially offset by an increase in non-cash adjustments of $1.2 million.

- The increase in net loss of $16.5 million primarily resulted from an increase in selling, general and administrative expenses, and research and development expenses, as further described under “Results of Operations” above.
- Non-cash items primarily consisted of decrease in accretion of discount on marketable securities of $0.2 million driven by fluctuating interest rates and maturity terms, a $0.7 million increase in stock-based compensation due to new options issuance to new hires and existing employees, and a $0.3 million increase in depreciation expense due to an increase in property and equipment at our new corporate headquarters, laboratory and manufacturing facility in Santa Clara, CA.
- The decrease in changes from working capital activities primarily consisted of $3.1 million increase in cash used for accounts payable due to the timing of invoice payments, $1.4 million increase in cash used for deposits to vendors, and a $1.4 million increase in cash used for the operating lease liability. These increases in the use of cash were partially offset by of $1.9 million increase in cash provided from accounts and other receivables due to collections on reimbursable leasehold improvements and outstanding invoices from customers, a $1.4 million increase in cash provided from accrued expenses, a $0.9 million decrease in cash used for inventory purchases, and a $0.5 million increase in cash from prepaid expenses.

Investing Activities

Net cash used by investing activities during the nine months ended September 30, 2026, was $36.8 million, compared to $0.3 million during the nine months ended September 30, 2025, representing an increase in cash used of $36.5 million. The increase was attributable to a $32.3 million increase in the purchase of marketable securities, as well as a $4.0 million increase in purchases of property and equipment during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2026. In addition, cash provided from the maturities and sales of marketable securities decreased by $0.2 million during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2026 was $99.7 million, compared to $46.8 million during the nine months ended September 30, 2025, representing an increase of $52.9 million. This increase was primarily attributed to the $53.3 million increase in proceeds from a capital raise, net of issuance cost, during the nine months ended September 30, 2026, which was partially offset by a $0.4 million decrease in proceeds from exercise of stock options during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025.

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 September 30, 2026.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended September 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

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

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in Part I, Item 1A. "Risk Factors" of our 2025 Annual Report. The risk factors described in our 2025 Annual Report, as well as other information set forth in this Quarterly Report on Form 10-Q, could materially adversely affect our business, financial condition, results of operations and prospects, and should be carefully considered. The risks and uncertainties that we face, however, are not limited to those described in the 2025 Annual Report. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

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

During the three months ended September 30, 2026, we issued and sold the following unregistered securities:

a) On August 24, 2026 (Sydney time), we completed Tranche 2 of the institutional placement, and issued 92,105,270 CDIs, representing 9,210,527 shares of common stock at a purchase price of A$0.38 per CDI (A$3.80 per share of common stock), for aggregate gross proceeds of $25.1 million. Canaccord Genuity (Australia) Limited, E&P Capital Limited and Morgans Corporate Limited acted as joint underwriters, joint lead managers and joint book runners for the Institutional Placement and Entitlement Offer.

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

		Incorporated by Reference		
Number	**Description**	**Schedule/Form**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of EBR Systems, Inc.	10-K	3.1	3/18/2026
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
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: _____

Name: John McCutcheon
Title: Chief Executive Officer
(Principal Executive Officer)

By: _____

Name: Gary Doherty
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 9, 2026

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2026

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2026

Gary Doherty
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 9, 2026

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 9th day of November 2026.

John McCutcheon Chief Executive Officer (Principal Executive Officer)	Gary Doherty Chief Financial 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."