

APPENDIX 4E (RULE 4.3A)

PRELIMINARY FINAL REPORT FOR THE YEAR ENDED 31 DECEMBER 2022

31 DECEMBER 2022 RESULTS FOR ANNOUNCEMENT TO THE MARKET

(All comparisons to year ended 31 December 2021)

	\$USD	up/down	% movement
Revenue from ordinary activities	Nil	Nil	Nil
Loss after tax from ordinary activities attributable to members	(\$33,088,205)	Up	16.9%
Loss after tax attributable to members	(\$33,088,205)	Up	16.9%

Dividend information

	Amount per security \$USD	Franked amount per security \$USD	Tax rate for franking credit
Dividend	Nil	Nil	N/A
Previous corresponding dividend	Nil	Nil	N/A

Net tangible asset backing

	31 Dec 2022 \$USD	31 Dec 2021 \$USD
Net tangible asset per share of common stock	\$0.16	\$0.28
Net tangible asset per CDI	\$0.16	\$0.28

- Annual financial results:**

This report is based on the accompanying Consolidated Financial Statements for the twelve-month period ended 31 December 2022, which have been audited by Deloitte & Touche LLP with the Independent Auditor's Report included in the Consolidated Financial Statements.

- Changes in control over entities:**

There were no entities over which control has been gained or lost during 2022.

- Details of dividends and dividend reinvestment plans:**

No dividends have been declared or proposed.

- Details of associates or joint ventures:**

N/A

- Set of accounting standards used in compiling the report:**

The audited consolidated financial statement have been prepared in accordance with accounting principles generally accepted in the U.S. (US GAAP) and are denominated in U.S. dollars.

- Details of audit disputes or audit qualification:**

None.

A commentary on the results for the period:

The net loss for the twelve-month period ended 31 December 2022 decreased to US\$33,088,205 compared to US\$39,835,369 for the previous corresponding period. The decrease was primarily due to a US\$17,484,121 reduction in interest expense, which resulted from the accelerated amortization of deferred loan costs and discounts at the conversion of convertible notes payable into stockholders' equity during the twelve-month period ended 31 December 2021. This decrease was offset by a US\$11,252,358 increase in operating expenses during the twelve-month period ended 31 December 2022 compared to the previous corresponding period. The increase in operating expenses was driven by increased research and development, clinical trial costs, and staffing costs.

The Company had cash, cash equivalents, and marketable securities of US\$64,515,314 at 31 December 2022 compared to US\$78,242,340 at 31 December 2021.

The Company operated in one segment only during the period and there were no returns to shareholders or share buy backs.

Please refer to our audited consolidated financial statements, with accompanying notes, which are attached hereto.

Annual Meeting of Stockholders:

The Annual General Meeting of stockholders will be held as a virtual meeting on Tuesday, 23 May 2023 at 9:00am Australian Eastern Standard Time (Monday, 22 May 2023 at 4:00pm U.S. Pacific Daylight

EBR SYSTEMS, INC.

Sunnyvale, California

CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2022 and 2021

EBR SYSTEMS, INC.
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INDEPENDENT AUDITOR'S REPORT

To the Audit and Risk Committee of EBR Systems, Inc.:

Opinion

We have audited the consolidated financial statements of EBR Systems, Inc. and subsidiaries (the "Company"), which comprise the consolidated balance sheet as of December 31, 2022, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the year then ended, and the related notes to the consolidated financial statements (collectively referred to as the "financial statements").

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America (GAAS). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Predecessor Auditor's Opinion on 2021 Financial Statements

The financial statements of the Company as of and for the year ended December 31, 2021 were audited by other auditors whose report, dated February 24, 2022, expressed an unmodified opinion on those statements.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and, therefore, is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control-related matters that we identified during the audit.

Deloitte & Touche LLP

February 27, 2023



INDEPENDENT AUDITOR'S REPORT

To the Board of Directors and Stockholders
of EBR Systems, Inc.

Opinion

We have audited the accompanying consolidated financial statements of EBR Systems, Inc. and Subsidiary, (collectively, "the Company") (a Delaware, USA corporation), which comprise the consolidated balance sheet as of December 31, 2021, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year then ended, and the related notes to the consolidated financial statements.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of EBR Systems, Inc. as of December 31, 2021, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities in accordance with the relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Responsibilities of Management for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are available to be issued.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the consolidated financial statements.

In performing an audit in accordance with generally accepted auditing standards, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the consolidated financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

Price Kong & Co. C.P.A.'s P.A.

Price, Kong, & Co., C.P.A.'s, P.A.
Phoenix, Arizona
February 24, 2022

We have served as the Company's auditor since 2021. In 2022, we became the predecessor auditor.

EBR SYSTEMS, INC.
CONSOLIDATED BALANCE SHEETS

		December 31,	
	Notes	2022	2021
ASSETS			
Current assets			
Cash and cash equivalents	3	\$ 15,456,338	\$ 78,242,340
Marketable securities	3	48,073,019	-
Non-trade receivables and unbilled reimbursements, net	5	443,919	966,123
Prepaid expenses		2,004,441	1,716,878
Other current assets		607,543	173,882
Total current assets		66,585,260	81,099,223
Property and equipment, net	5	1,577,044	1,743,704
Right of use operating lease asset	6	1,941,138	2,143,481
Marketable securities	3	985,957	-
Other assets		589,624	437,660
TOTAL ASSETS		\$ 71,679,023	\$ 85,424,068
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Accounts payable		\$ 2,092,474	\$ 1,710,855
Accrued expenses and other liabilities	5	3,470,107	2,726,024
Interest payable	7	99,167	282,256
Operating lease liability	6	216,817	185,707
Current portion of notes payable, net	7	51,590	2,410,496
Total current liabilities		5,930,155	7,315,338
Other liabilities		482,448	-
Operating lease liability	6	1,921,106	2,137,923
Notes payable, net	7	19,396,221	73,085
Total liabilities		27,729,930	9,526,346
Commitments and contingencies (Note 16)			
STOCKHOLDERS' EQUITY			
Convertible preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and 2021	11	-	-
Common stock, \$0.0001 par value; 600,000,000 shares authorized, 270,752,201 and 267,985,340 shares issued and outstanding at December 31, 2022 and 2021, respectively	12	27,077	26,800
Additional paid-in capital		320,749,696	319,378,429
Accumulated deficit		(277,622,520)	(244,534,315)
Accumulated other comprehensive income		794,840	1,026,808
Total stockholders' equity		43,949,093	75,897,722
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY		\$ 71,679,023	\$ 85,424,068

The accompanying notes are an integral part of these consolidated financial statements.

EBR SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

		Twelve Months Ended December 31,	
	Notes	2022	2021
Operating expenses:			
Research and development		\$ 13,228,782	\$ 7,232,171
Sales and marketing		8,107,645	6,814,151
Clinical and regulatory		7,283,693	5,588,249
General and administrative		5,406,095	3,139,286
Total operating expenses		34,026,215	22,773,857
Loss from operations		(34,026,215)	(22,773,857)
Other income (expense)			
Interest expense	7 & 8	(1,525,795)	(19,009,916)
Other income	2	2,464,922	1,379,860
Gain on sale of equipment		-	3,639
Gain on forgiveness of debt	7	-	1,255,912
Gain on change in fair value of derivative liability	9	-	1,394,000
Gain/(loss) on foreign currency	2	483	(2,085,007)
Total other income (expense)		939,610	(17,061,512)
Loss before income tax		(33,086,605)	(39,835,369)
Income tax expense	15	(1,600)	-
Net loss		\$ (33,088,205)	\$ (39,835,369)
Net loss per common share:			
Basic and diluted	14	\$ (0.12)	\$ (0.95)
Weighted-average number of shares outstanding:			
Basic and diluted	14	269,608,916	42,122,436

The accompanying notes are an integral part of these consolidated financial statements.

EBR SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

		Twelve Months Ended December 31,	
	Notes	2022	2021
Net loss		\$ (33,088,205)	\$ (39,835,369)
Other comprehensive income / (loss):			
Change in unrealized (losses) on marketable securities	3	(118,218)	-
Foreign currency translation adjustments		(113,750)	1,114,645
Other comprehensive (loss) income		(231,968)	1,114,645
Comprehensive loss		<u>\$ (33,320,173)</u>	<u>\$ (38,720,724)</u>

The accompanying notes are an integral part of these consolidated financial statements.

EBR SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

		Convertible Preferred Stock		Common Stock		Additional	Accumulated	Accumulated	Total
	Notes	Shares	Par Value	Shares	Par Value	Paid-in Capital	Deficit	Other Comprehensive Income (Loss)	Stockholders' Equity
Balance at December 31, 2020		84,856,456	\$ 8,486	13,190,604	\$ 1,320	\$ 166,278,889	\$ (203,851,437)	\$ (87,837)	\$ (37,650,579)
Issuance of stock warrants	10	-	-	-	-	3,123,094	-	-	3,123,094
Exercise of stock options	13	-	-	5,375,911	538	828,484	-	-	829,022
Stock-based compensation	13	-	-	-	-	459,180	-	-	459,180
Derivative liabilities settled to equity	9	-	-	-	-	11,979,000	-	-	11,979,000
Convertible notes payable converted into stockholders' equity	8	62,710,518	6,271	-	-	60,719,203	-	-	60,725,474
Convertible preferred stock converted into common stock	11	(147,566,974)	(14,757)	147,566,974	14,757	-	-	-	-
Warrant modifications	10	-	-	-	-	1,096,452	(847,509)	-	248,943
Issuance of common stock, net of issuance costs	12	-	-	101,851,851	10,185	74,894,127	-	-	74,904,312
Net loss		-	-	-	-	-	(39,835,369)	-	(39,835,369)
Other comprehensive income		-	-	-	-	-	-	1,114,645	1,114,645
Balance at December 31, 2021		-	-	267,985,340	26,800	319,378,429	(244,534,315)	1,026,808	75,897,722
Exercise of stock options	13	-	-	2,766,861	277	421,317	-	-	421,594
Stock-based compensation	13	-	-	-	-	869,557	-	-	869,557
Adjustment to common stock issuance costs	12	-	-	-	-	80,393	-	-	80,393
Net loss		-	-	-	-	-	(33,088,205)	-	(33,088,205)
Other comprehensive loss		-	-	-	-	-	-	(231,968)	(231,968)
Balance at December 31, 2022		-	\$ -	270,752,201	\$ 27,077	\$ 320,749,696	\$ (277,622,520)	\$ 794,840	\$ 43,949,093

The accompanying notes are an integral part of these consolidated financial statements.

EBR SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

		Twelve Months Ended December 31,	
	Notes	2022	2021
Cash flows from operating activities:			
Net loss		\$ (33,088,205)	\$ (39,835,369)
Adjustment to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	4	652,432	384,022
Amortization of deferred loan costs and discount on notes payable	7 & 8	210,137	16,901,371
Lease amortization	6	413,518	-
Change in fair value of derivative	9	-	(1,394,000)
Stock-based compensation	13	869,557	459,180
Convertible notes payable issued for services		-	33,935
Gain on forgiveness of debt	7	-	(1,255,912)
Gain on disposal of property and equipment		-	(3,639)
Provision for doubtful accounts	5	(3,685)	-
Accretion of discount on marketable securities	2	(559,563)	-
Effect of exchange rate changes on monetary assets and liabilities denominated in non-functional currency		-	1,451,778
Changes in operating assets and liabilities:			
Non-trade receivables and unbilled reimbursements		507,323	(692,819)
Prepaid expenses		(288,603)	(983,584)
Other assets		(452,964)	(100,045)
Accounts payable		726,456	721,097
Accrued expenses and other liabilities		1,237,650	333,197
Interest payable		(183,089)	1,836,673
Operating lease liability	6	(396,882)	(5,279)
Net cash used in operating activities		(30,355,918)	(22,149,394)
Cash flows from investing activities:			
Purchase of property and equipment	5	(730,179)	(912,009)
Proceeds from sale of property and equipment		-	5,200
Purchase of marketable securities	3	(50,617,631)	-
Maturities of marketable securities	3	2,000,000	-
Net cash used in investing activities		(49,347,810)	(906,809)
Cash flows from financing activities:			
Repayment of notes payable	7	(2,400,000)	(2,404,299)
Proceeds from notes payable	7	20,000,000	-
Proceeds from convertible notes	8	-	22,424,554
Payments of deferred loan costs	7 & 8	(794,317)	(289,913)
Proceeds from exercise of stock options	13	421,594	829,022
Proceeds from initial public offering	12	-	80,099,614
Payment of offering costs	12	(213,326)	(4,901,583)
Net cash provided by financing activities		17,013,951	95,757,395
Effect of exchange rate change on cash		(96,225)	(337,133)
Net (decrease) increase in cash and cash equivalents		(62,786,002)	72,364,059
Cash and cash equivalents, beginning of the period		78,242,340	5,878,281
Cash and cash equivalents, end of the period		\$ 15,456,338	\$ 78,242,340

The accompanying notes are an integral part of these consolidated financial statements.

EBR SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

		Twelve Months Ended December 31,	
	Notes	2022	2021
Supplemental disclosure of cash flow information			
Cash paid for interest expense		\$ 1,498,747	\$ 371,223
Cash paid for income taxes		\$ 1,600	\$ -
Non-cash financing activities			
Issuance of detachable warrants	10	\$ -	\$ 3,123,094
Derivative liabilities settled to equity	9	\$ -	\$ 11,979,000
Convertible notes payable and accrued interest converted to equity	8	\$ -	\$ 60,725,474
Warrant modifications	10	\$ -	\$ 847,509
Accrued financing costs		\$ -	\$ 293,719

The accompanying notes are an integral part of these consolidated financial statements.

EBR SYSTEMS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Business and organization

Business overview

EBR Systems, Inc. and subsidiaries (“EBR” or the “Company”) is a United States-based company dedicated to the superior treatment of cardiac rhythm disease by providing physiologically effective stimulation through leadless endocardial pacing. The Company is in the final phase of its U.S. pivotal trial and expects to release results in 2023.

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

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

Note 2 - Summary of significant accounting policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”).

Principles of consolidation

The consolidated financial statements include the Company’s accounts and those of its wholly-owned foreign subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Foreign currency translation

The functional currencies of our foreign subsidiaries are their local currencies. Accordingly, the Company translates the foreign currency financial statements into US Dollars using the reporting period-end or average exchange rates. Assets and liabilities of these subsidiaries were translated at exchange rates as of the balance sheet dates. Revenues and expenses are translated at average rates in effect for the periods presented. The cumulative translation adjustment is included in the accumulated other comprehensive income / (loss) within stockholders’ equity (deficit). Gains and losses arising from the settlement and remeasurement of monetary assets and liabilities denominated in currencies other than a subsidiary’s functional currency are included in “Gain/(loss) on foreign currency” in the period in which they occur.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, judgments, and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Significant estimates and assumptions made by management include the estimated

EBR SYSTEMS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

lives of long-lived assets, the fair value of stock-based awards issued, clinical trial accrual, fair value of derivative liability, fair value of warrants, and the valuation allowance on deferred taxes.

Employee benefits

The Company maintains an employee retirement/savings plan (the “Retirement Plan”) that permits participants to make tax-deferred contributions by salary reductions pursuant to Section 401(k) of the Internal Revenue Code. The Company may make discretionary contributions. For the twelve-month period ended December 31, 2022, the Company did not make any contributions. For the twelve-month period ended December 31, 2021, the Company made a contribution of \$357,736.

Segment information

Operating segments are defined as components of an entity for which discrete financial information is available that is regularly reviewed by the Chief Operating Decision Maker (“CODM”) in deciding how to allocate resources to an individual segment and in assessing performance. The Company’s Chief Executive Officer is the CODM. The CODM reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As such, management has determined that the Company operates as one operating segment that is focused exclusively on the advancement of the Company’s wireless cardiac pacing system. Net assets outside of the U.S. were less than 10% of total net assets as of December 31, 2022 and 2021.

Cash and cash equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash. Cash equivalents are reported at fair value.

Marketable securities

Marketable securities, all of which are available-for-sale, consist of U.S. treasury bonds, U.S. government notes, and corporate debt securities. Marketable securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income (loss), except for losses from impairments which are determined to be other-than-temporary. For the twelve-month periods ended December 31, 2022 and 2021, there were no losses from impairments. Realized gains and losses and declines in value judged to be other-than-temporary are included in the determination of net loss and are included in other income. Interest and dividends on available-for-sale securities are included in other income. See Note 3, “Cash, cash equivalents, and marketable securities” for additional disclosure on marketable securities.

Derivative liability

The Company’s 2019 and 2021 convertible notes payable issued contain certain features that meet the definition of being embedded derivatives requiring bifurcation from the 2019 and 2021 convertible notes payable as a separate compound financial instrument. The derivative liability is initially measured at fair value on issuance and is subject to remeasurement at each

EBR SYSTEMS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

reporting period with changes in fair value recognized in other income (expense) in the accompanying consolidated statements of operations. See Note 9, “Derivative liabilities” for additional disclosure on derivative liabilities.

Concentration of credit risk

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

Non-trade receivables and unbilled reimbursements

Non-trade receivables are recorded for amounts due to the Company related to reimbursements of clinical trials expenses based upon contracted terms. Unbilled reimbursements represent amounts for services that have been rendered but for which reimbursements have not been billed. See Note 5, “Consolidated balance sheet components” for additional information on non-trade receivables and unbilled reimbursements.

Property and equipment

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

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

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

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for potential impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that carrying value exceeds fair value. Fair value is determined using various valuation techniques, including discounted cash flow models, quoted market values, and third-party independent appraisals, depending on the nature of the asset. For the twelve-month periods ended December 31, 2022 and 2021, the Company did not recognize any impairment charges associated with long-lived assets.

Leases

At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. Leases with a term greater than 12 months are recognized on the balance sheet date as right of use (“ROU”) assets and current and

EBR SYSTEMS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

non-current lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically includes lease renewals in the assessment of the lease arrangement, unless there is reasonable certainty that the Company will not renew.

Lease liabilities and the corresponding right of use assets are recorded based on the present value of lease payments to be made over the lease term. The discount rate used to calculate the present value is the rate implicit in the lease, or if not readily determinable, the Company's incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right of use asset may be required for items such as initial direct costs or incentives received. Lease payments on operating leases are recognized on a straight-line basis over the expected term of the lease. Lease payments on financing leases are recognized using the effective interest method. See Note 6, "Leases" for additional disclosure on leases.

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

Revenue Recognition

To date the Company's sole product is in the late stages of FDA approval, as such no revenue has been recorded from the sale of products. Once the Company receives FDA approval, revenue from product sales will be recognized upon the transfer of control, which is generally upon shipment or delivery, depending on the delivery terms set forth in the customer contract. Provisions for discounts, rebates and sales incentives to customers, and returns and other adjustments will be provided for in the period the related sale is recorded.

Research and development

Research and development costs are expensed when incurred. Research and development costs include costs of other research, engineering, and technical activities to develop a new product or service or make significant improvement to an existing product or manufacturing process.

Stock-based compensation

The Company recognizes stock-based compensation expense related to employees over the requisite service period based on the grant-date fair value of the awards. The fair value of options granted is estimated using the Black-Scholes option valuation model. The Company recognizes the grant-date fair value of an award as compensation expense on a straight-line basis over the requisite service period, which typically corresponds to the vesting period for the award. The Company elects to account for forfeitures as they occur and, upon forfeiture of an award prior to vesting, the Company reverses any previously recognized compensation expense related to that award. See Note 13, "Stock-based compensation" for additional details.

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Other Income

The Company periodically receives reimbursements of clinical trial expenses, which are recorded as other income in the accompanying consolidated statements of operations. During the twelve-month periods ended December 31, 2022 and 2021, the Company recorded reimbursements of \$842,551 and \$1,378,908, respectively. During the twelve-month period ended December 31, 2022, the Company received refundable tax incentives from the Australian Taxation Office of \$504,207, which are recorded as other income in the accompanying consolidated statements of operations. The Company earned interest income, including accretion of discount, from investments in marketable securities of \$1,118,163 and \$952, which is also included in other income for the twelve-month periods ended December 31, 2022 and 2021, respectively.

Income taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities reflect the tax effects of net operating losses, tax credits, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These are determined using enacted tax rates in effect for the year in which such temporary differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date.

The Company records deferred tax assets to the extent the Company believes these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial operations. When we establish or reduce the valuation allowance against our deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period that determination to change the valuation allowance is made.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements on a particular tax position are measured based on the largest benefit that has a greater than a 50% likelihood of being realized upon settlement. The amount of unrecognized tax benefits is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to unrecognized tax benefits in the provision for income taxes.

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Earnings per share

Basic income or loss per share is determined by dividing net income or loss by the weighted average common shares outstanding during the period. Diluted income or loss per share is determined by dividing net income by diluted weighted average shares outstanding during the period. Diluted weighted average shares reflect the dilutive effect, if any, of potential common shares. To the extent their effect is dilutive, employee equity awards and other commitments to be settled in common stock are included in the calculation of diluted income or loss per share based on the treasury stock method. Potential common shares are excluded from the calculation of diluted weighted average shares outstanding if their effect would be anti-dilutive at the balance sheet date based on a treasury stock method or due to a net loss.

Recently adopted accounting pronouncements

In August 2020, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*. This ASU is intended to simplify the accounting for certain convertible instruments with characteristics of both liability and equity. This ASU removes certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. As a result, after the adoption of this guidance, an entity’s convertible debt instrument will be wholly accounted for as debt. This ASU also expands disclosure requirements for convertible instruments and simplifies areas of the guidance for diluted earnings-per-share calculations by requiring the use of the if-converted method. This ASU is effective for fiscal years beginning after December 15, 2023, with early adoption permitted for fiscal years beginning after December 15, 2020 and can be adopted on either a fully retrospective or modified retrospective basis. An entity should adopt the guidance at the beginning of its annual fiscal year. The Company has elected to early adopt this standard on January 1, 2021, on a modified retrospective basis, and it did not have a material effect on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*, which introduced new guidance for an approach based on expected losses to estimate credit losses on certain types of financial instruments. It also modifies the impairment model for available-for-sale debt securities and provides for a simplified accounting model for purchased financial assets with credit deterioration since their origination. Instruments in scope include loans, held-to-maturity debt securities, and net investments in leases as well as reinsurance and trade receivables. In November 2018, the FASB issued ASU 2018-19, which clarifies that operating lease receivables are outside the scope of the new standard. The Company has adopted this standard on January 1, 2021. There was no material impact on the consolidated financial statements.

Recently issued accounting pronouncements

In March 2022, FASB issued Accounting Standards Update (“ASU”) 2022-02, *Troubled Debt Restructurings and Vintage Disclosures*. This ASU eliminates the requirement for creditors

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to recognize and measure certain modifications as troubled debt restructuring, enhances the disclosures by creditors for certain modifications of receivables to debtors experiencing financial difficulty, and requires public companies to disclose current-period write-offs by year of origination for the related financing receivables and net investments in leases. This ASU is effective for fiscal years beginning after December 15, 2022. The Company believes that adoption of ASU 2022-02 will not have a material impact on the Company's consolidated financial statements.

Note 3 – Cash, cash equivalents and marketable securities

Cash, cash equivalents, and marketable securities consisted of the following at December 31, 2022 and 2021:

	2022	2021
Cash and cash equivalents:		
Cash	\$ 332,255	\$ 78,242,340
Money market funds	15,124,083	-
Total cash and cash equivalents	<u>\$ 15,456,338</u>	<u>\$ 78,242,340</u>
Marketable securities, short-term:		
US Treasury securities	\$ 12,341,584	\$ -
Corporate bonds	10,023,089	-
Commercial Paper	23,808,415	-
Asset backed securities	1,899,931	-
Total marketable securities, short-term	<u>\$ 48,073,019</u>	<u>\$ -</u>
Marketable securities, long-term:		
Asset backed securities	\$ 985,957	\$ -
Total marketable securities, long-term	<u>\$ 985,957</u>	<u>\$ -</u>
Total cash, cash equivalents, and marketable securities	<u><u>\$ 64,515,314</u></u>	<u><u>\$ 78,242,340</u></u>

During the year ended December 31, 2022, marketable securities matured for proceeds of \$2,000,000 with no gain or loss realized. During the year ended December 31, 2021, no marketable securities matured. See Note 4, "Fair Value Measurements" for additional information regarding the fair value of cash equivalents and marketable securities.

The following table summarizes the unrealized gains and losses related to the Company's available-for-sale marketable securities, by major security type, as of December 31, 2022:

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

The following table shows the unrealized losses and fair values for those marketable securities that were in an unrealized loss position as of December 31, 2022, aggregated by major security type and the length of time the marketable securities have been in a continuous loss position:

	In Loss Position for Less Than 12 Months		In Loss Position for 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
US Treasury securities	\$ 12,341,584	\$ (40,565)	\$ -	\$ -	\$ 12,341,584	\$ (40,565)
Corporate bonds	10,023,089	(45,679)	-	-	10,023,089	(45,679)
Asset backed securities	2,885,888	(31,974)	-	-	\$ 2,885,888	\$ (31,974)
Total	<u>\$ 25,250,561</u>	<u>\$ (118,218)</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 25,250,561</u>	<u>\$ (118,218)</u>

The contractual maturities of the Company's marketable securities as of December 31, 2022, were as follows:

	Fair Value
One year or less	\$ 48,073,019
One year to two years	985,957
Two years to three years	-
Total	<u>\$ 49,058,976</u>

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Note 4 – Fair value measurement

The fair value measurement guidance establishes a fair value hierarchy which requires the Company to maximize the use of observable inputs when measuring fair value. The following levels of inputs may be used to measure fair value:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Management's assessment of the significance of a particular input to the fair value measurement requires judgement and may affect the valuation of financial assets and liabilities and their placement within the fair value hierarchy. The Company's financial assets that are accounted for at fair value on a recurring bases are presented in the table below:

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

In the Company's consolidated balance sheets, the carrying values of non-trade receivables, other assets, accounts payable and accrued expenses approximated their fair values due to the nature and relatively short maturities. The fair value of debt approximates its carrying value as it is variable rate debt or has relatively short maturities. The fair value measurements of the Company's derivative liability were considered Level 3 measurements under the fair value hierarchy. See Note 9 "Derivative liabilities" for additional disclosure on derivative liabilities.

Note 5 – Consolidated balance sheet components

Non-trade receivables and unbilled reimbursements, net

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Non-trade receivables and unbilled reimbursements include reimbursement of clinical trial expenses incurred. Non-trade receivables and unbilled reimbursements consisted of the following as of December 31, 2022 and 2021:

	2022	2021
Non-trade receivables	\$ 280,457	\$ 233,158
Unbilled reimbursements	265,143	843,879
Non-trade receivables and unbilled services	545,600	1,077,037
Less: allowance for doubtful accounts	(101,681)	(110,914)
Non-trade receivables and unbilled services, net	<u>\$ 443,919</u>	<u>\$ 966,123</u>

During the twelve-month periods ended December 31, 2022 and 2021, provision for doubtful accounts totaled \$3,685 and \$110,914, respectively.

Property and equipment, net

Property and equipment consisted of the following as of December 31, 2022 and 2021:

	2022	2021
Equipment	\$ 2,981,787	\$ 2,439,709
Computer software	572,180	477,685
Leasehold improvements	415,590	415,590
Construction in progress	-	153,548
	3,969,557	3,486,532
Less accumulated depreciation and amortization	(2,392,513)	(1,742,828)
Total property and equipment, net	<u>\$ 1,577,044</u>	<u>\$ 1,743,704</u>

Depreciation and amortization expense on property and equipment was \$652,432 and \$384,022 for the twelve-month periods ended December 31, 2022 and 2021, respectively.

Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following at December 31, 2022 and 2021:

	2022	2021
Accrued compensation and related liabilities	\$ 1,980,453	\$ 1,628,316
Accrued development expenses	697,908	663,288
Accrued warranty reserve	734,400	325,612
Accrued other expenses	57,346	108,808
Accrued expenses and other liabilities	<u>\$ 3,470,107</u>	<u>\$ 2,726,024</u>

Note 6 – Leases

The Company determined that it held an operating lease for its corporate headquarters and laboratory space, located in Sunnyvale, California. The lease expires June 30, 2024, with an option to extend the lease an additional sixty-months, which was used in the calculation of the right of use asset and lease liability. The Company held no other lease agreements.

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Future lease payments for non-cancellable operating leases as of December 31, 2022, were as follows:

Years Ended December 31,	
2023	\$ 408,786
2024	421,050
2025	433,682
2026	446,692
2027	460,093
Thereafter	714,346
Total undiscounted lease payments	2,884,649
Less: effects of discounting	(746,726)
Total operating lease liabilities	<u>\$ 2,137,923</u>

Amounts reported in the consolidated balance sheet for operating leases in which the Company is the lessee as of December 31, 2022 and 2021, were as follows:

	2022	2021
Right of use asset	\$ 1,941,138	\$ 2,143,481
Lease liability, current	216,817	185,707
Lease liability, noncurrent	1,921,106	2,137,923
Remaining lease term	6.50 years	7.50 years
Discount rate	10.00%	10.00%

Operating lease costs for the twelve-month periods ended December 31, 2022 and 2021 was \$413,518 and \$380,041, respectively. Short-term lease costs for the twelve-month periods ended December 31, 2022 and 2021 was \$570 and \$2,415, respectively. Cash paid for operating lease liabilities for the twelve-month period ended December 31, 2022 and 2021 was \$396,882 and \$385,320, respectively.

Note 7 - Notes payable

Runway Growth Finance Corp

On June 30, 2022, the Company entered into a loan and security agreement with Runway Growth Finance Corp. The loan agreement provides three term loan tranches. Term A loan was made available to the Company at the inception of the loan agreement in an aggregate amount of \$20,000,000. Term B loan provides a minimum of \$15,000,000 and a maximum of \$20,000,000. The Term B draw period commences on the date the Company has received positive interim analysis data, sufficient to proceed with the clinical trial and premarket approval submission to the FDA, with respect to the Company's pivotal clinical trial for the WiSE CRT System and ends on June 30, 2023. Term C loan provides a minimum of \$10,000,000 and a maximum of \$20,000,000. The Term C draw period commences on the date the Company has received approval from the FDA for the WiSE CRT System and ends on June 30, 2024. All term loans may not exceed \$50,000,000. At December 31, 2022, the Company has not drawn the Term B or Term C loans as the company has not met the required milestones.

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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. The Company has accounted for the final payment of \$900,000 as a discount of the note that will be amortized over the life of the loan using the effective interest method. Amortization of the discount was \$89,693 during the twelve-month period ended December 31, 2022. This amount was recorded as additional interest expense in the accompanying consolidated statements of operations. If the Company repays the loan prior to maturity, the Company will be required to pay a prepayment fee of 2% - 0.5% if 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 incurred loan costs of \$794,317, which are being amortized over the life of the loan using the effective interest method. As of December 31, 2022, the note has been shown net of unamortized loan costs of \$714,968.

The debt is secured against substantially all assets of the Company, except for the Company’s intellectual property but includes all proceeds from the sale of intellectual property.

The Company is subject to customary financial and reporting covenants under the loan and security agreement. As of December 31, 2022, the Company was in compliance with all debt covenants.

Bank of America Leasing & Capital, LLC

In May 2021, the Company entered into an equipment purchase agreement for the purchase of certain software totaling \$128,974. The purchase agreement requires 30 equal payments of \$4,299 beginning December 1, 2021 through May 1, 2024. At December 31, 2022 and 2021, the outstanding principal balance was \$73,086 and \$124,675, respectively, of which \$51,590 was included in the current portion of notes payable at December 31, 2022 and 2021.

Paycheck Protection Program

On May 20, 2021, the entire principal balance of \$1,242,525 and accrued interest of \$13,387 was forgiven and accounted for as a gain on extinguishment of debt during the twelve-month period ended December 31, 2021.

Silicon Valley Bank – 2020

In March 2020, the Company entered into a loan and security agreement with Silicon Valley Bank and other lenders party thereto. The loan agreement provides for a term loan facility that includes three tranches in a principal amount of \$3,000,000, which if drawn would

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result in an aggregate outstanding principal amount of \$9,000,000. As of December 31, 2021, the Company had borrowed \$6,000,000 of the \$9,000,000 available under the March 2020 loan agreement. As of December 31, 2022, the Company has repaid the outstanding principal balance under the loan agreement. At December 31, 2021, the outstanding principal balance under the loan agreement was \$2,400,000.

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

During the twelve-month periods ended December 31, 2022 and 2021, the Company recorded interest expense of \$61,424 and \$256,892, respectively, which is included in the accompanying consolidated statements of operations. Additionally, the Company was required to make a final payment of \$420,000 at the time the term loan was paid in full. This amount was recorded as additional interest expense over the life of the term loan. During the twelve-month periods ended December 31, 2022 and 2021, the Company recorded interest expense of \$152,727 and \$152,727, respectively, which is included in the accompanying consolidated statements of operations.

The debt is secured against substantially all assets of the Company, except for the Company's intellectual property but includes all proceeds from the sale of intellectual property.

The Company incurred loan costs of \$83,114, these costs are being amortized over the life of the loan. Amortization of the loan costs was \$30,245 and \$30,246 during the twelve-month periods ended December 31, 2022 and 2021, respectively, which is included in interest expense in the accompanying consolidated statements of operations.

The note payable described above was issued with fully vested detachable warrants. The note has been discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. As of December 31, 2021, the note has been shown net of the unamortized discount of \$10,848 on the accompanying consolidated balance sheets. Amortization of the discount was \$10,848 in both twelve-month periods ended December 31, 2022 and 2021, which is included in interest expense in the accompanying consolidated statements of operation.

At December 31, 2022 and 2021, notes payable consisted of the following:

	2022	2021
Current portion of notes payable	\$ 51,590	\$ 2,451,589
Long-term portion of notes payable	20,921,496	73,085
Less: unamortized deferred loan costs	(714,968)	(30,245)
Less: unamortized discount	(810,307)	(10,848)
Notes payable, net	<u>\$ 19,447,811</u>	<u>\$ 2,483,581</u>

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The following table presents information regarding the Company's notes payable principal repayment obligations as of December 31, 2022:

Years Ended December 31,		
2023	\$	51,590
2024		21,496
2025		-
2026		-
2027		20,900,000
Total minimum payments	\$	<u>20,973,086</u>

Note 8 – Convertible Notes Payable

The Company had no outstanding convertible notes payable as of December 31, 2022 and 2021. All previously issued convertible notes payable were converted to equity in 2021. As a result of the Company's Initial Public Offering ("IPO"), as discussed in Note 12, "Common Stock", all warrants issued previously in connection with convertible notes payable transactions are now exercisable for the Company's common stock.

Convertible Notes Payable – 2021

In June 2021, the Company issued the first tranche ("tranche one") of convertible notes payable in the amount of \$8,712,277. In October 2021, the Company issued the second tranche ("tranche two") of convertible notes payable in the amount of \$8,712,277. The convertible notes payable has a maturity date of December 2022. The notes have a stated rate of 10% per annum.

In November 2021, the convertible note holders elected to convert the aggregate principal balance and accrued interest from the tranche one and tranche two convertible notes payable. The principal balance of \$17,424,544 and accrued interest of \$460,677 converted into 21,692,195 shares of the New Series B Convertible Preferred Stock.

As part of the agreement, in June 2021, the Company issued fully vested detachable warrants to purchase 3,111,787 shares of the New Series B Convertible Preferred Stock at \$0.8245 per share to the tranche one convertible note payable holders. On September 26, 2021, the Company amended the tranche one warrants and reduced the exercise price to \$0.589113 per share. In October 2021, the Company issued fully vested detachable warrants to purchase 3,111,787 shares of the New Series B Convertible Preferred Stock at \$0.589113 per share. Both tranches of warrants have an exercise period of 10 years. The Company has classified the warrants as equity. The convertible notes have been discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. Accordingly, the fair value of the tranche one and tranche two warrants at the time of issuance was \$1,128,927 and \$1,369,186, respectively. See Note 10 "Warrants", for additional information regarding the warrants.

In the event the Company raises \$40,000,000 of equity financing, not including the conversion of the notes, then the entire principal amount and accrued interest shall be converted into the qualified financing shares at 80% of the lowest price per share paid by a third party. If a

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qualified financing event is not triggered, the principal amount and accrued interest shall be converted into the New Series B Convertible Preferred Stock at a price per share of \$0.8245. The Company analyzed the conversion feature of the agreement for derivative accounting consideration under FASB ASC Subtopic 815, *Derivatives and Hedging*, and determined that the embedded conversion features should be classified as a derivative liability because the exercise price of these convertible notes are subject to a variable conversion rate. The Company has determined that the conversion feature is not considered to be solely indexed to the Company's own stock and is therefore not afforded equity treatment, as such, the Company has bifurcated the conversion feature of the note and recorded a derivative liability for tranche one and tranche two of the convertible note. See Note 9 "Derivative liabilities", for additional information regarding the derivative liability.

The embedded derivative for the note is carried on the Company's accompanying consolidated balance sheets at fair value. The derivative liability is marked-to-market each measurement period and any unrealized change in fair value is recorded as a component of the consolidated statements of operations and the associated fair value carrying amount on the accompanying consolidated balance sheets is adjusted by the change. The Company measures the fair value of the embedded derivative using the Monte Carlo simulation. The aggregate fair value of the derivative at the issuance date of tranche one and tranche two was \$2,926,000 and \$2,611,000, which was recorded as a derivative liability and debt discount at the time of issuance. Amortization of the discount was \$5,537,000 during the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations.

Convertible Notes Payable – 2019

In August 2019, the Company issued the first of three tranches ("tranche one") of convertible notes payable in the amount of \$12,500,000. In March 2020, the Company issued the second of three tranches ("tranche two") of convertible notes payable in the amount of \$12,458,890. In February 2021, the Company issued the third and final tranche ("tranche three") of the convertible notes payable in the amount of \$5,000,000. The convertible notes payable has a maturity date of December 2021. The notes had a stated rate of 10% per annum.

In May 2021, the convertible note holders elected to convert the aggregate principal balance and accrued interest from the tranche one, tranche two and tranche three convertible notes payable. The principal balance of \$29,958,890 and accrued interest of \$3,860,764 converted into 41,018,323 shares of the New Series B Convertible Preferred Stock.

As part of the agreement, the Company issued fully vested detachable warrants to the tranche one, tranche two, and tranche three convertible note payable holders to purchase 4,438,437 shares, 4,423,389 shares, and 1,732,123 shares, respectively, of the New Series B Convertible Preferred Stock at \$0.8245 per share. The warrants have an exercise period of 10 years. The Company has classified the warrants as equity. The convertible notes have been discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. Accordingly, the fair value of the tranche one, tranche two, and tranche three warrants at the time of issuance was \$1,329,621, \$1,526,399, and \$624,981, respectively.

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Amortization of the discount was \$2,042,378 during the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations. On September 26, 2021, the Company amended the tranche one, tranche two, tranche three warrants and reduced the exercise price to \$0.589113 per share. See Note 10 “Warrants”, for additional information regarding the warrants.

In the event the Company raises \$20,000,000 of equity financing, not including the conversion of the notes, then the entire principal amount and accrued interest shall be converted into the qualified financing shares at 80% of the lowest price per share paid by a third party. If a qualified financing event is not triggered, the principal amount and accrued interest shall be converted into the New Series B Convertible Preferred Stock at a price per share of \$0.8245. The Company analyzed the conversion feature of the agreement for derivative accounting consideration under FASB ASC Subtopic 815, *Derivatives and Hedging*, and determined that the embedded conversion features should be classified as a derivative liability because the exercise price of these convertible notes is subject to a variable conversion rate. The Company has determined that the conversion feature is not considered to be solely indexed to the Company’s own stock and is therefore not afforded equity treatment, as such, the Company has bifurcated the conversion feature of the note and recorded a derivative liability. See Note 9 “Derivative liabilities”, for additional information regarding the derivative liability.

The aggregate fair value of the derivative at the issuance date of tranche one, tranche two, and tranche three was \$3,027,459, \$5,105,000, and \$984,000, respectively, which was recorded as a derivative liability and debt discount at the time of issuance. Amortization of the debt discount was \$5,157,443 during the twelve-month period ended December 31, 2021, which is recorded as interest expense in the accompanying consolidated statements of operations.

Convertible Note Payable – 2017

In October 2017, the Company issued a convertible promissory note for a principal amount of \$9,020,589, with a maturity date of April 2028. The note has a stated interest rate of 8% per annum and is convertible into 12,445,334 New Series B Convertible Preferred Stock. Interest is only due and payable in the event the Company declares a dividend on the New Series B Convertible Preferred Stock. As no such dividends have been declared to date there has been no accrued interest recorded on this convertible note. In connection with the convertible note payable, the Company issued fully vested detachable warrants to purchase 1,950,607 shares of common stock at \$0.41225 per share. The warrants have an exercise period of 10 years. The Company has classified the warrants as equity. The note was discounted using the relative fair value approach for the fair value of the warrants and the fair value of the debt. The notes were converted in November 2021. Amortization of the discount was \$193,833 for the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations.

A beneficial conversion feature discount of \$1,240,800 was recorded at the issuance of the convertible promissory note. The beneficial conversion feature is being amortized as interest expense over the term of the convertible note payable. Amortization of the beneficial conversion

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feature was \$864,851 during the twelve-month period ended December 31, 2021, which is included in interest expense in the accompanying consolidated statements of operations.

Note 9 – Derivative liabilities

In June 2021, the 2019 convertible notes payable, which contained an embedded derivative liability, were converted into convertible preferred stock. In November 2021, the 2021 convertible notes payable, which contained an embedded derivative liability were converted into common stock. At the time of the conversions the related derivative liabilities were settled into equity.

A summary of the activity related to derivative liabilities for the twelve-month period ended December 31, 2021, is as follows:

Balance at January 1, 2021	\$ 6,852,000
Issued during the year	6,521,000
Change in fair value recognized in operations	(1,394,000)
Derivative liabilities settled into equity	(11,979,000)
Balance at December 31, 2021	<u>\$ -</u>

Note 10 – Warrants

Equity classified common stock warrants

The Company has issued the following warrants to purchase shares of its common stock, which are outstanding as of December 31, 2022 and 2021. These warrants are exercisable any time at the option of the holder until their expiration date.

	Number of Shares	Weighted average exercise price	Weighted average remaining contractual term
Balance at January 1, 2021	11,855,331	\$ 0.75	8.42
Issued	7,955,697	0.73	9.85
Exercised	-	-	-
Modification	-	(0.24)	-
Expired/forfeited	-	-	-
Balance at December 31, 2021	19,811,028	0.58	8.27
Issued	-	-	-
Exercised	-	-	-
Expired/forfeited	(21,649)	11.50	-
Balance at December 31, 2022	<u>19,789,379</u>	<u>\$ 0.57</u>	<u>7.28</u>

Warrant Modifications

On September 26, 2021, Company amended certain warrants issued in connection with convertible preferred stock as described in Note 8 and reduced the exercise price to \$0.589113 per share as consideration for the waiver of certain antidilution provisions by holders of the

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warrants. The Company accounted for the modification of the warrants in accordance with ASC 815-40, *Contracts in Entity's Own Equity*. The additional fair value attributed to the warrants related to outstanding convertible notes payable was \$248,943 at the modification date and reflected as an additional discount on the related convertible notes payable. The additional fair value attributed to the warrants related to convertible notes that had previously been converted to preferred stock was \$847,509 at the modification date and reflected as a deemed dividend.

Note 11 – Convertible preferred stock

In connection with the Initial Public Offering (“IPO”), as discussed in Note 12, “Common Stock”, all shares of convertible preferred stock then outstanding were automatically converted into 147,566,974 shares of common stock on a one-for-one basis. As of December 31, 2022 and 2021, 10,000,000 shares of convertible preferred stock were authorized, of which no shares were issued or outstanding.

Note 12 – Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company’s board of directors. As of December 31, 2022 and 2021, no dividends have been declared.

As of December 31, 2022 and 2021, 600,000,000 shares were authorized, of which 270,752,201 shares and 267,985,340 shares, respectively, were outstanding.

The ASX uses an electronic system called CHESS for the clearance and settlement of trades on the ASX. The State of Delaware does not recognize the CHESS system of holding securities or electronic transfers of legal title to shares. To enable companies to have their securities cleared and settled electronically through CHESS, CDIs are issued. CDIs are units of beneficial ownership in shares and are traded in a manner similar to shares of Australian companies listed on the ASX. The legal title to the shares are held by a depository, CDN, which is a wholly-owned subsidiary of the ASX, and is an approved general participant of ASX Settlement. The equity capital raise consisted of 101,851,851 CDIs representing the same number of shares of common stock at \$1.08 Australian dollars per share, for total proceeds of \$74,984,705, net of \$5,114,909 of related offering costs.

Additionally, the Company has reserved the following shares of common stock for issuance as of December 31, 2022:

Conversion of Common Stock warrants	19,789,379
2013 Equity Incentive Plan	24,242,643
2021 Equity Incentive Plan	36,573,978
Total shares of Common stock reserved for issuance	<u>80,606,000</u>

Note 13 – Stock-based compensation

The Company and its stockholders adopted an equity incentive plan (the “2013 Plan”) in 2013, which reserved shares of the Company’s common stock for the granting of incentive and nonqualified stock options to employees, directors, and consultants. On October 14, 2021, the

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Company replaced the 2013 Plan with the 2021 Plan, as the 2013 Plan was expiring. Under the 2021 Plan, 36,573,978 shares of common stock are reserved. The Company may grant options to purchase common stock, stock appreciation rights, restricted stock awards and other forms of stock-based compensation. Stock options generally vest over four years and expire no later than 10 years from the date of grant. The Board of Directors has the authority to select the employees to whom options are granted and determine the terms of each option, including i) the number of shares of common stock subject to the option; ii) when the option becomes exercisable; iii) the option exercise price, which must be at least 100% of the fair market value of the common stock as of the date of grant and iv) the duration of the option, which may not exceed 10 years.

As of December 31, 2022, options to purchase a total of 7,975,284 shares of common stock remained outstanding and 28,598,694 shares remain available for grant under the 2021 Plan. As of December 31, 2022, options to purchase a total of 24,242,643 shares of common stock remained outstanding under the 2013 Plan. As of December 31, 2022, no shares of common stock remain available for grant under the 2013 Plan.

Stock option activity for the twelve-month period ended December 31, 2022, was as follows:

	Shares	Weighted Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)
Outstanding at January 1, 2022	30,708,618	\$ 0.19	7.59
Granted	6,365,250	0.46	
Cancelled	(2,089,080)	0.28	
Exercised	(2,766,861)	0.15	
Outstanding at December 31, 2022	<u>32,217,927</u>	<u>\$ 0.24</u>	<u>7.15</u>
Vested and expected to vest at December 31, 2022	32,217,927	\$ 0.24	7.15
Exercisable at December 31, 2022	23,951,977	\$ 0.17	6.59

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

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options granted during the twelve-month periods ended December 31, 2022 and 2021, was \$0.29 per share and \$0.17 per share, respectively.

The following assumptions were used to calculate the grant-date fair value of employee stock options granted during the twelve-month periods ended December 31, 2022 and 2021:

	2022	2021
Expected term (in years)	7.00	7.00
Expected volatility	58.38% - 79.90%	47.52% - 53.09%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.94% - 3.49%	0.75% - 1.55%

The following table presents classification of stock-based compensation expense within the accompanying consolidated statements of operations for the twelve-month periods ended December 31, 2022 and 2021:

	2022	2021
Research and development	\$ 261,577	\$ 96,835
Sales and marketing	174,799	48,659
Clinical and regulatory	64,024	50,792
General and administrative	369,157	262,894
Total	<u>\$ 869,557</u>	<u>\$ 459,180</u>

At December 31, 2022, there was \$2,223,398 of unamortized stock-based compensation cost, respectively, related to unvested stock options which is expected to be recognized over a weighted average period of 2.80 years.

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 at December 31, 2022 and 2021:

	2022	2021
Numerator – basic & diluted:		
Net loss attributable to common stockholders, basic and diluted	<u>\$ (33,088,205)</u>	<u>\$ (39,835,369)</u>
Denominator:		
Weighted-average number of shares outstanding, basic and diluted	<u>269,608,916</u>	<u>42,122,436</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.95)</u>

The following potentially dilutive shares were not included in the calculation of diluted shares outstanding for the periods presented as the effect would have been anti-dilutive at December 31, 2022 and 2021:

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	2022	2021
Outstanding warrants	19,789,379	19,811,028
Outstanding stock options	32,217,927	30,708,618
Total dilutive shares	<u>52,007,306</u>	<u>50,519,646</u>

Note 15 – Income taxes

The Company did not record any income tax expense for the twelve-month periods ended December 31, 2022 and 2021. The Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets.

The Company's effective tax rate of 0.01% and 0.00% for the twelve-month periods ended December 31, 2022 and 2021, respectively, differs from the statutory U.S. federal rate as follows:

	2022	2021
Statutory tax rate	\$ (6,973,527)	\$ (8,365,182)
R&D credit generation	(370,183)	(49,341)
State and foreign tax benefit	(6,463,619)	(1,162,345)
Other non-deductible expenses	1,554,541	3,451,555
Change in valuation allowance	12,254,388	6,125,313
Effective tax rate	<u>\$ 1,600</u>	<u>\$ -</u>

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

	2022	2021
Deferred tax assets:		
Net operating loss	\$ 48,332,000	\$ 40,097,000
Other accruals	829,000	267,000
Stock based compensation	249,000	111,000
Credit carryforwards	1,967,000	1,531,000
Research & development capitalization	2,686,000	-
Intangible assets	13,409,000	13,202,000
Total deferred tax assets	67,472,000	55,208,000
Deferred tax liability		
Fixed assets	(9,000)	-
Total deferred tax liability	(9,000)	-
Net deferred tax asset before valuation allowance	67,463,000	55,208,000
Valuation allowance	(67,463,000)	(55,208,000)
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

As of December 31, 2022, the Company recorded the portion of its deferred tax assets that was determined to meet the more likely than not threshold. Significant judgment is required in determining the Company's provision for income taxes, recording valuation allowances against

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deferred tax assets and evaluating the Company's uncertain tax positions. Due to net losses since inception and the uncertainty of realizing the deferred tax assets, the Company has a full valuation allowance against its net deferred tax assets. To the extent that the Company generates positive income and expects, with reasonable certainty, to continue to generate positive income, the Company may release all, or a portion of, the valuation allowance in a future period. This release would result in the recognition of all, or a portion of, the Company's deferred tax assets, resulting in a decrease to income tax expense for the period such release is made. As of December 31, 2022, the Company's valuation allowance was \$67,463,000 which increased by approximately \$12,255,000 for the twelve-month period ended December 31, 2022.

On August 16, 2022, the United States enacted the Inflation Reduction Act ("IRA"), which introduces, among other items, an excise tax that would impose a 1% surcharge on stock repurchases, net of stock issuances beginning in 2023. The IRA also introduces a 15% book minimum tax on adjusted financial statement earnings beginning in fiscal 2024. These provisions are not expected to impact the Company based on the Company's current financial positions but will be considered in future years.

Net operating loss ("NOL") carryforwards and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and may become subject to annual limitation due to ownership changes that have occurred previously or that could occur in the future under Section 382 of the Internal Revenue Code, as amended and similar state provisions. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed, and any limitation is known, no amounts are being presented as an uncertain tax position.

As of December 31, 2022, the Company had federal NOL carryforwards of \$164,381,569, available to reduce taxable income, of which \$45,825,483 expire beginning 2023 and \$118,556,086 do not expire. The Company had state NOL carryforwards of \$129,028,475 available to reduce future state taxable income, as of December 31, 2022, which expire beginning 2028.

As of December 31, 2022, the Company had federal and state research and development credit carryforwards of \$1,318,411 and \$1,254,827, respectively. The federal research and development credit carryforwards expire beginning in 2035 and the state credit carryforwards do not expire.

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The Company files income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. In the normal course of business, the Company is subject to examination by taxing authorities throughout the world. Due to NOL carryforwards not being utilized, all periods are open to potential examinations.

The Company's policy is to classify interest and penalties related to unrecognized tax benefits, if and when required, as a component of interest expense, in the accompanying consolidated statements of operations. The Company had not recorded any interest or penalties for the twelve-month periods ended December 31, 2022 and 2021.

As of December 31, 2022, the Company's uncertain tax positions totaled \$1,012,850, which are netted against the underlying deferred tax assets. The entire balance in uncertain tax positions would cause a decrease in the effective income tax rate upon recognition, but that decrease would be offset by a change in the valuation allowance given the full valuation allowance position of the Company.

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

	2022	2021
Balance at January 1	\$ 656,159	\$ 619,152
Increase for current period tax positions	309,267	41,222
Increase/(decrease) for prior period tax positions	47,424	(4,215)
Balance as December 31	<u>\$ 1,012,850</u>	<u>\$ 656,159</u>

Note 16 – Commitments and contingencies

Purchase commitments

The Company purchases raw materials, manufacturing equipment, and various services from a variety of vendors. During the normal course of business, in order to manage manufacturing lead times and help ensure an adequate supply of certain items, we enter into agreements with suppliers that either allow us to procure goods and services when we choose or that establish purchase requirements over the term of the agreement. In certain instances, our purchase agreements allow us to cancel, reschedule, or adjust our purchase requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our purchase commitments are firm and noncancelable. As of December 31, 2022, the Company's obligations under such arrangements were \$2,538,451.

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

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the aggregate, have a material adverse impact on the Company's consolidated financial statements.

Note 17 – Related Party Transactions

In October 2017, the Company entered into a services agreement with a stockholder of the Company. Under the terms of the agreement the stockholder of the Company agreed to provide services including: a) advising on the Australian regulatory, business and healthcare environment; b) advising on the establishment of operation in Australia; c) assisting in the recruitment of key employees; and d) supporting clinical trial operations. In lieu of payment for services received, the Company will remit 10% of the gross Australian R&D Incentive Proceeds, net of accounting fees, to the stockholder of the Company. On October 30, 2021, the Company terminated this agreement. As of December 31, 2022 and 2021, there was no outstanding liability for amounts due to the stockholder of the Company.

Note 18 – Subsequent Events

The Company has evaluated subsequent events that have occurred through February 27, 2023, which is the date that the consolidated financial statements were available to be issued and determined that there were no subsequent events or transactions that required recognition or disclosure in the consolidated financial statements.