

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

**FORM 10-Q**

QUARTERLY REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **December 31, 2023**

TRANSITION REPORT UNDER SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File number **000-30262**



**KNOW LABS, INC.**

(Exact name of registrant as specified in charter)

**Nevada**

(State or other jurisdiction of incorporation or organization)

**90-0273142**

(I.R.S. Employer Identification No.)

**500 Union Street, Suite 810, Seattle, Washington USA**

(Address of principal executive offices)

**98101**

(Zip Code)

**206-903-1351**

(Registrant's telephone number, including area code)

(Former name, address, and fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	KNW	NYSE American LLC

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, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

The number of shares of common stock, \$0.001 par value, issued and outstanding as of February 14, 2024: 81,346,524 shares.

**DOCUMENTS INCORPORATED BY REFERENCE:** None.

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**ITEM 1. FINANCIAL STATEMENTS**

**KNOW LABS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
Unaudited

	December 31, 2023 Unaudited	9/30/2023 (1)
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,821,477	\$ 8,023,716
Total current assets	4,821,477	8,023,716
PROPERTY AND EQUIPMENT, NET	75,298	81,325
OTHER ASSETS		
Other assets	18,767	15,766
Operating lease right-of-use asset	97,567	145,090
<b>TOTAL ASSETS</b>	<b>\$ 5,013,109</b>	<b>\$ 8,265,897</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable - trade	\$ 627,058	\$ 1,292,861
Accrued expenses	95,952	94,062
Accrued expenses - related parties	196,241	218,334
Convertible notes payable, net	2,761,931	2,761,931
Current portion of operating lease right-of-use liability	106,038	154,797
Total current liabilities	3,787,220	4,521,985
COMMITMENTS AND CONTINGENCIES (Note 11)	-	-
STOCKHOLDERS' EQUITY		
Preferred stock - \$0.001 par value, 5,000,000 shares authorized, Series C and D shares issued and outstanding as follows:		
Series C Convertible Preferred stock \$0.001 par value, 30,000 shares authorized, 17,858 shares issued and outstanding at 12/31/2023 and 9/30/2023, respectively	1,790	1,790
Series D Convertible Preferred stock \$0.001 par value, 20,000 shares authorized, 10,161 shares issued and outstanding at 12/31/2023 and 9/30/2023, respectively	1,015	1,015

Common stock - \$0.001 par value, 200,000,000 shares authorized, 81,346,524 and 80,358,463 shares issued and outstanding at 12/31/2023 and 9/30/2023, respectively	81,347	80,358
Additional paid in capital	126,492,778	125,501,537
Accumulated deficit	(125,351,041)	(121,840,788)
Total stockholders' equity	<u>1,225,889</u>	<u>3,743,912</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 5,013,109</b>	<b>\$ 8,265,897</b>

(1) Derived from the audited consolidated balance sheet.

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

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**KNOW LABS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
Unaudited

	Three Months Ended,	
	December 31, 2023	December 31, 2022
OPERATING EXPENSES-		
RESEARCH AND DEVELOPMENT EXPENSES	\$ 1,486,388	\$ 1,743,051
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	2,011,246	1,905,071
Total operating expenses	<u>3,497,634</u>	<u>3,648,122</u>
OPERATING LOSS	<u>(3,497,634)</u>	<u>(3,648,122)</u>
OTHER INCOME (EXPENSE), NET		
Interest income	51,010	-
Interest expense	-	(227,170)
Other (expense) income, net	-	52,433
Total other income (expense), net	<u>51,010</u>	<u>(174,737)</u>
LOSS BEFORE INCOME TAXES	(3,446,624)	(3,822,859)
Income tax expense	-	-
NET LOSS	(3,446,624)	(3,822,859)
Deemed dividends on Series C and D Preferred Stock	<u>(63,629)</u>	<u>-</u>
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	<u>\$ (3,510,253)</u>	<u>\$ (3,822,859)</u>
Basic and diluted loss per share	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>
Weighted average shares of common stock outstanding- basic and diluted	81,094,007	48,187,339

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

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**KNOW LABS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
Unaudited

	Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	\$	Shares	\$	Shares	\$			
Balance as of October 1, 2022	17,858	\$ 1,790	10,161	\$ 1,015	48,156,062	\$ 48,158	\$ 111,209,388	\$ (101,397,738)	\$ 9,862,613
Stock compensation expense - employee options	-	-	-	-	-	-	744,640	-	744,640
Issuance of common stock for stock option exercises	-	-	-	-	1,875	1	2,342	-	2,343
Issuance of common stock for exercise of warrants	-	-	-	-	50,000	50	12,450	-	12,500
Expenses for extension of notes and warrants	-	-	-	-	-	-	206,994	-	206,994
Net loss	-	-	-	-	-	-	-	(3,822,859)	(3,822,859)
Balance as of December 31, 2022	<u>17,858</u>	<u>1,790</u>	<u>10,161</u>	<u>1,015</u>	<u>48,207,937</u>	<u>48,209</u>	<u>112,175,814</u>	<u>(105,220,597)</u>	<u>7,006,231</u>
Balance as of October 1, 2023	17,858	1,790	10,161	1,015	80,358,463	80,358	125,501,537	(121,840,788)	3,743,912

Stock compensation expense - employee options	-	-	-	-	-	-	699,246	-	699,246
Issuance of common stock for services	-	-	-	-	105,000	105	26,145	-	26,250
Deemed dividends on Series C and D Preferred Stock	-	-	-	-	-	-	63,629	(63,629)	-
Issuance of common stock for common stock offering	-	-	-	-	883,061	884	202,221	-	203,105
Net loss	-	-	-	-	-	-	-	(3,446,624)	(3,446,624)
Balance as of December 31, 2023	<u>17,858</u>	<u>\$ 1,790</u>	<u>10,161</u>	<u>\$ 1,015</u>	<u>81,346,524</u>	<u>\$ 81,347</u>	<u>\$ 126,492,778</u>	<u>\$ (125,351,041)</u>	<u>\$ 1,225,889</u>

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

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**KNOW LABS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
Unaudited

	Three Months Ended,	
	December 31, 2023	December 31, 2022
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,446,624)	\$ (3,822,859)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	18,724	103,160
Stock based compensation - stock option grants	699,246	744,640
Issuance of common stock for services	26,250	-
Amortization of operating lease right-of-use asset	47,523	44,404
Interest expense for extension of notes and warrants	-	206,994
Changes in operating assets and liabilities:		
Other long-term assets	(3,001)	(1,998)
Operating lease right-of-use liability	(48,759)	(45,732)
Accounts payable - trade and accrued expenses	(686,006)	(146,026)
<b>NET CASH (USED IN) OPERATING ACTIVITIES</b>	<u>(3,392,647)</u>	<u>(2,917,417)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of research and development equipment	(12,697)	(10,846)
<b>NET CASH (USED IN) INVESTING ACTIVITIES:</b>	<u>(12,697)</u>	<u>(10,846)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock offering, net	203,105	-
Proceeds from issuance of common stock for stock options exercise	-	2,343
Proceeds from issuance of common stock for warrant exercise	-	12,500
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<u>203,105</u>	<u>14,843</u>
<b>NET (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<u>(3,202,239)</u>	<u>(2,913,420)</u>
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	<u>8,023,716</u>	<u>12,593,692</u>
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<u>\$ 4,821,477</u>	<u>\$ 9,680,272</u>
<b>Supplemental disclosures of cash flow information:</b>		
Interest paid	\$ -	\$ -
Taxes paid	\$ -	\$ -
<b>Supplemental disclosure of non-cash financing activity:</b>		
Deemed dividends on Series C and D Preferred Stock	\$ 63,629	\$ -

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

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**KNOW LABS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The accompanying unaudited consolidated condensed financial statements have been prepared by Know Labs, Inc. (“the Company,” “us,” “we,” or “our”) in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial reporting and rules and regulations of the Securities and Exchange Commission (“SEC”). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. In the

opinion of our management, all adjustments, consisting of only normal recurring accruals, necessary for a fair presentation of the financial position, results of operations, and cash flows for the fiscal periods presented have been included.

These financial statements should be read in conjunction with the audited financial statements and related notes included in our Annual Report filed on Form 10-K for the year ended September 30, 2023, filed with the Securities and Exchange Commission on December 19, 2023. The results of operations for the three months ended December 31, 2023 are not necessarily indicative of the results expected for the full fiscal year, or for any other fiscal period.

## 1. ORGANIZATION

Know Labs, Inc. (the “Company”) was incorporated under the laws of the State of Nevada in 1998. The Company currently has authorized 205,000,000 shares of capital stock, of which 200,000,000 are shares of voting common stock, par value \$0.001 per share, and 5,000,000 are shares preferred stock, par value \$0.001 per share. At the annual shareholder meeting held on October 15, 2021, the Company’s authorized shares of common stock were increased to 200,000,000 shares of voting common stock, par value \$0.001 per share.

The Company is focused on the development and commercialization of our proprietary sensor technology utilizing radio and microwave spectroscopy. When paired with our machine learning platform, our technology is capable of uniquely identifying and measuring almost any material or analyte using electromagnetic energy to detect, record, identify, and measure the unique “signature” of said materials or analytes.

The first application of our sensor technology is in a product to non-invasively monitor blood glucose levels. Our device will provide the user with real-time information on their blood glucose levels. We recently announced our Generation 1 working prototype device. This device embodies the sensor which has been used in internal clinical testing. We have also announced the work our R&D team is performing on the development of Generation 2 of our device, which is a wearable format and may be a final form factor, ready for commercialization. That device will be utilized in expanded internal and external testing. The device may be refined over time and will require FDA clearance prior to entering the market.

## 2. LIQUIDITY AND GOING CONCERN

The Company has cash and cash equivalents of \$4,821,477 and net working capital of \$1,034,257 (\$3,796,188 exclusive of convertible notes payable) as of December 31, 2023. The Company anticipates that it will record losses from operations for the foreseeable future. During the end of the quarter ended March 31, 2023, the Company made some adjustments to its staffing level and the impact of those adjustments, plus the departure of our chief technology and executive office, has significantly reduced our monthly burn rate. The Company will further adjust its cost structure if new debt or equity capital is not received. The Company’s ability to transition profitable operations is dependent upon achieving a level of revenues adequate to support its cost structure. The Company believes that it has enough available cash and flexibility with its operating expenses to operate until at least June 30, 2024. Based on current operating levels, the Company will need to raise additional funds by selling additional equity or incurring debt. To date, the Company has funded its operations primarily through issuance of equity securities, and proceeds from the exercise of warrants to purchase common stock and the sale of debt instruments. Additionally, future capital requirements will depend on many factors, including the rate of revenue growth, the selling price of the Company’s products, the expansion of sales and marketing activities, the timing and extent of spending on research and development efforts and the continuing market acceptance of the Company’s products. These factors raise substantial doubt about the Company’s ability to continue as a going concern for the twelve months from the date of this Report.

Management of the Company intends to raise additional funds through the issuance of equity securities or debt. The Company is currently working on some capital fund raising transactions. There can be no assurance that, in the event the Company requires additional financing, such financing will be available at terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations, raise additional capital and reduce discretionary spending could have a material adverse effect on the Company’s ability to achieve its intended business objectives. As a result, the substantial doubt about the Company’s ability to continue as a going concern has not been alleviated. The accompanying condensed consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The proceeds of warrants currently outstanding, which could be exercised on a cash basis, may generate potential proceeds of up to \$16,008,327. The Company expects that portions of these warrants will be exercised but there is no guarantee any portion will be exercised.

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## 3. SIGNIFICANT ACCOUNTING POLICIES: ADOPTION OF ACCOUNTING STANDARDS

**Basis of Presentation** – These unaudited condensed consolidated financial statements were prepared in conformity with U.S. generally accepted accounting principles (“GAAP”).

**Principles of Consolidation** – The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Particle. Intercompany items and transactions have been eliminated in consolidation.

**Cash and Cash Equivalents** – The Company classifies highly liquid temporary investments with an original maturity of three months or less when purchased as cash equivalents. The Company maintains cash balances at various financial institutions. Balances at US banks are insured by the Federal Deposit Insurance Corporation up to \$250,000. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant risk for cash on deposit.

**Property and Equipment** – Equipment consists of machinery, leasehold improvements and furniture and fixtures, which are stated at cost less accumulated depreciation and amortization. Depreciation is computed by the straight-line method over the estimated useful lives or lease period of the relevant asset, generally 2-5 years, except for leasehold improvements which are depreciated over 5 years.

**Long-Lived Assets** – The Company reviews its long-lived assets for impairment annually or when changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Long-lived assets under certain circumstances are reported at the lower of carrying amount or fair value. Assets to be disposed of and assets not expected to provide any future service potential to the Company are recorded at the lower of carrying amount or fair value (less the projected cost associated with selling the asset). To the extent carrying values exceed fair values, an impairment loss is recognized in operating results.

**Revenue Recognition** – The Company determines revenue recognition from contracts with customers through the following steps:

- identification of the contract, or contracts, with the customer;
- identification of the performance obligations in the contract;
- determination of the transaction price;

- allocation of the transaction price to the performance obligations in the contract; and
- recognition of the revenue when, or as, the Company satisfies a performance obligation.

Revenue is recognized when control of the promised goods or services is transferred to the customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services.

**Research and Development Expenses** – Research and development expenses consist of the cost of officers, employees, consultants and contractors who design, engineer and develop new products and processes as well as materials, supplies and facilities used in producing prototypes.

The Company's current research and development efforts are primarily focused on improving its radio frequency spectroscopy technology and its first focus on non-invasive monitoring of blood glucose levels; extending its capacity and developing new and unique applications for this technology. The Company believes that continued development of new and enhanced technologies is essential to its future success. The Company incurred expenses of \$1,486,388 and \$1,743,051 for the three months ended December 31, 2023 and 2022, respectively, on development activities.

**Advertising** – Advertising costs are charged to selling, general and administrative expenses as incurred. Advertising and marketing costs for the three months ended December 31, 2023 and 2022 were \$45,500 and \$51,084, respectively.

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**Fair Value Measurements and Financial Instruments** – ASC Topic 820, *Fair Value Measurement and Disclosures*, defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. This topic also establishes a fair value hierarchy, which requires classification based on observable and unobservable inputs when measuring fair value. The fair value hierarchy distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1 – Quoted prices in active markets for identical assets and liabilities;
- Level 2 – Inputs other than level one inputs that are either directly or indirectly observable; and
- Level 3 – Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The recorded value of other financial assets and liabilities, which consist primarily of cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate the fair value of the respective assets and liabilities as of December 31, 2023 and September 30, 2023 are based upon the short-term nature of the assets and liabilities. The fair value of the Company's convertible notes payable are not readily available given the terms and conditions, including the conversion features, are complex.

The Company has a money market account which is considered a Level 1 asset. The balance as of December 31, 2023 and September 30, 2023 was \$4,787,378, and \$7,836,393, respectively. No other assets or liabilities are required to be recorded at fair value on a recurring nature.

**Derivative Financial Instruments** – Pursuant to ASC 815 "Derivatives and Hedging", the Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company then determines if an embedded derivative must be bifurcated and separately accounted for. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. For stock-based derivative financial instruments, the Company uses a Black-Scholes-Merton option pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

The Company determined that the conversion features for purposes of bifurcation within its currently outstanding convertible notes payable were immaterial and there was no derivative liability to be recorded as of December 31, 2023 and September 30, 2023.

**Stock Based Compensation** – The Company has share-based compensation plans under which employees, consultants, suppliers and directors may be granted restricted stock, as well as options and warrants to purchase shares of Company common stock at the fair market value at the time of grant. Stock-based compensation is measured by the Company at the grant date, based on the fair value of the award, over the requisite service period under ASC 718. The Company recognizes stock compensation costs utilizing the fair value methodology over the related period of benefit.

**Convertible Securities** – Based upon ASC 815-15, the Company has adopted a sequencing approach regarding the application of ASC 815-40 to convertible securities. The Company will evaluate its contracts based upon the earliest issuance date. In the event partial reclassification of contracts subject to ASC 815-40-25 is necessary, due to the Company's inability to demonstrate it has sufficient shares authorized and unissued, shares will be allocated on the basis of issuance date, with the earliest issuance date receiving first allocation of shares. If a reclassification of an instrument were required, it would result in the instrument issued latest being reclassified first.

**Net Loss per Share** – Under the provisions of ASC 260, "Earnings Per Share," basic loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding for the periods presented. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Deemed dividends to preferred shareholders increase the net loss available to common shareholders and impact the net loss per share calculation.

As of December 31, 2023, the Company had 81,346,524 shares of common stock issued and outstanding. As of December 31, 2023, there were options outstanding for the purchase of 28,220,473 shares of our common stock (including unearned stock option grants totaling 4,179,825 shares related to performance targets), warrants for the purchase of 20,984,961 shares of our common stock, 8,108,356 shares of the Company's common stock issuable, collectively, upon the conversion of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock, and approximately 3,201,534 shares of our common stock, collectively, reserved to pay accrued dividends on our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock. In addition, the Company currently has 9,020,264 shares of its common stock at the current price of \$0.25 per share reserved and are issuable upon conversion of convertible debentures of \$2,761,931. Further, under the current terms of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock, and assuming no changes in the ownership thereof, going forward on a quarterly basis the Company will accrete as a preferred dividend the value of approximately 160,000 shares of common stock, which are issuable if such dividends become payable as additional shares of preferred stock, and such

preferred stock is then converted into common stock. All of the foregoing shares could potentially dilute future earnings per share but are excluded from the December 31, 2023, calculation of net loss per share because their impact is antidilutive.

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As of December 31, 2022, the Company had 48,207,937 shares of common stock issued and outstanding. As of December 31, 2022, there were options outstanding for the purchase of 24,480,495 common shares (including unearned stock option grants totaling 9,704,620 shares related to performance targets), warrants for the purchase of 21,736,313 common shares, and 8,108,356 shares of our common stock issuable upon the conversion of Series C and Series D Convertible Preferred Stock. In addition, the Company currently has 9,020,264 common shares at the current price of \$0.25 per share reserved and are issuable upon conversion of convertible debentures of \$2,255,066. All of the foregoing shares could potentially dilute future earnings per share but are excluded from the December 31, 2022, calculation of net loss per share because their impact is antidilutive.

**Comprehensive loss** – Comprehensive loss is defined as the change in equity of a business during a period from non-owner sources. There were no differences between net loss for the three months ended December 31, 2023 and 2022 and comprehensive loss for those periods.

**Dividend Policy** – The Company has never paid any cash dividends and intends, for the foreseeable future, to retain any future earnings for the development of its business. The Company’s future dividend policy will be determined by the board of directors on the basis of various factors, including results of operations, financial condition, capital requirements and investment opportunities.

**Use of Estimates** – The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Recent Accounting Pronouncements**

Based on the Company’s review of accounting standard updates recently issued, those standards not yet required to be adopted and proposed standards for the future, the Company does not believe such items are expected to have a significant impact on the Company’s consolidated financial statements.

**4. PROPERTY AND EQUIPMENT**

Property and equipment as of December 31, 2023 and September 30, 2023 was comprised of the following:

	Estimated Useful Lives	December 31, 2023	September 30, 2023
Machinery and equipment	2-3 years	\$ 226,027	\$ 213,330
Furniture and fixtures	3 years	21,366	21,366
Less: accumulated depreciation		(172,095)	(153,371)
		<u>\$ 75,298</u>	<u>\$ 81,325</u>

Total depreciation expense was \$18,724 and \$103,160 for the three months ended December 31, 2023 and 2022, respectively. Equipment is used primarily for research and development purposes and accordingly \$17,788 and \$98,002 in depreciation is classified in research and development expenses during the three months ended December 31, 2023 and 2022, respectively.

**5. LEASES**

The Company has entered into operating leases for office and development facilities which range from two to three years and include options to renew. The Company determines whether an arrangement is or contains a lease based upon the unique facts and circumstances at the inception of the lease. Operating lease liabilities and their corresponding right-of-use assets are recorded based upon the present value of the lease payments over the expected lease term. As of December 31, 2023 and September 30, 2023, total operating lease liabilities for remaining long term leases was approximately \$106,000 and \$155,000, respectively. Right of use assets totaled approximately \$98,000 and \$145,000 at December 31, 2023 and September 30, 2023, respectively. In the three months ended December 31, 2023 and 2022, the Company recognized \$62,000 and \$82,000, respectively in total lease costs for the leases. Because the rate implicit in each lease is not readily determinable, the Company uses its estimated incremental borrowing rate to determine the present value of the lease payments.

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The weighted average remaining lease term for the operating leases was 6 months at December 31, 2023 and the weighted average discount rate was 7%.

The minimum future lease payments as of December 31, 2023 are as follows:

Year Ended December 31, 2024	
Total remaining payments	\$ 102,267
Less imputed interest	3,771
Total lease liability	<u>\$ 106,038</u>

**6. CONVERTIBLE NOTES PAYABLE AND NOTE PAYABLE**

**Convertible Promissory Notes with Clayton A. Struve**

The Company owes Clayton A. Struve, a significant stockholder, \$1,301,005 under convertible promissory or OID notes. The Company recorded accrued interest of \$95,952 and \$94,062 as of December 31, 2023 and September 30, 2023, respectively. On December 7, 2022, the Company signed Amendments to the convertible promissory or OID notes, extending the due dates to September 30, 2023. On September 15, 2023, the due dates on the notes was further extended to September 30, 2024. The Company expensed \$230,005 as loss on debt extinguishment during the year ended September 30, 2023 related to the extension of the notes. The Company recorded in convertible note payable the



incremental value related to the conversion feature and as such, we recorded the extension value as an expense with an offset to convertible note payable. The extension value will be reclassified to equity upon conversion.

### **Convertible Redeemable Promissory Notes with J3E2A2Z**

The Company owes Ronald P. Erickson and J3E2A2Z, an entity affiliated controlled by Ronald P. Erickson \$1,460,926 under convertible promissory notes. On March 16, 2018, the Company entered into a Note and Account Payable Conversion Agreement pursuant to which (a) all \$664,233 currently owing under the J3E2A2Z Notes was converted to a Convertible Redeemable Promissory Note in the principal amount of \$664,233, and (b) all \$519,833 of the J3E2A2Z Account Payable was converted into a Convertible Redeemable Promissory Note in the principal amount of \$519,833 together with a warrant to purchase up to 1,039,666 shares of common stock of our for a period of five years. The initial exercise price of the warrants described above is \$0.50 per share, also subject to certain adjustments. The Company recorded accrued interest of \$196,241 and \$218,334 as of December 31, 2023 and September 30, 2023, respectively. On December 7, 2022, the Company approved Amendments to the convertible redeemable promissory notes with Ronald P. Erickson and J3E2A2Z, extending the due dates to January 30, 2023. On January 25, 2023, the Company approved Amendments to the convertible redeemable promissory notes with Ronald P. Erickson and J3E2A2Z, extending the due dates to September 30, 2023. On September 15, 2023, the due dates on the notes was further extended to September 30, 2024. The Company expensed \$276,860 as interest during the year ended September 30, 2023 related to the extension of the notes. The Company recorded in convertible note payable the incremental value related to the conversion feature and as such, we recorded the extension value as an expense with an offset to convertible note payable. The extension value will be amortized to equity upon conversion.

Convertible notes payable as of December 31, 2023 and September 30, 2023 are summarized below:

	December 31, 2023	September 30, 2023
Convertible note- Clayton A. Struve	\$ 1,301,005	\$ 1,301,005
Convertible note- Ronald P. Erickson and affiliates	1,460,926	1,460,926
	<u>\$ 2,761,931</u>	<u>\$ 2,761,931</u>

## **7. EQUITY**

The following description summarizes important terms of the classes of our capital stock as of December 31, 2023.

*Authorized Capital Stock.* The Company's authorized capital stock currently consists of:

- 200,000,000 shares of common stock, par value \$0.001 per share; and
- 5,000,000 shares of "blank check" preferred stock, par value \$0.001 per share, of which:
- 30,000 shares have been designated as our Series C Convertible Preferred Stock, \$0.001 par value per share; and
- 20,000 shares have been designated as our Series D Convertible Preferred Stock, \$0.001 par value per share.

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*Outstanding Shares of Capital Stock.* The Company's common stock is the only security of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended. All outstanding shares of the Company's capital stock are fully paid and nonassessable. As of September 30, 2023, there were:

- 81,346,524 shares of common stock issued and outstanding, held by holders of record;
- 17,858 shares of Series C Convertible Preferred Stock issued and outstanding, held by one holder of record; and
- 10,161 shares of Series D Convertible Preferred Stock issued and outstanding, held by one holder of record.

### **Securities Subject to Price Adjustments**

If in the future, the Company sells its common stock at a price below \$0.25 per share, the conversion price of our outstanding shares of series C convertible preferred stock and series D convertible preferred stock would adjust below \$0.25 per share pursuant to the documents governing such instruments. In addition, the conversion price of the convertible promissory notes referred to above and the exercise price of certain outstanding warrants to purchase 7,684,381 shares of common stock would adjust below \$0.25 per share pursuant to the documents governing such instruments.

### **Series C and D Preferred Stock, Warrants and Dividends**

On August 5, 2016, the Company closed a Series C Preferred Stock and Warrant Purchase Agreement with Clayton A. Struve, an accredited investor for the purchase of \$1,250,000 of preferred stock with a conversion price of \$0.70 per share. The preferred stock has a cumulative dividend of 8% and an ownership blocker of 4.99%. Dividends are due and payable in cash when declared by the Company or when the stock is converted. Series C Preferred stock is senior to Series D Preferred stock and is entitled to receive equal dividends paid to Series D. In addition, Mr. Struve received a five-year warrant to acquire 1,785,714 shares of common stock at \$0.70 per share. On August 14, 2017, the price of the Series C Stock and warrant and its conversion price, were adjusted to \$0.25 per share pursuant to the documents governing such instruments. As of December 31, 2023, Mr. Struve owns all of the 17,858 issued and outstanding shares of Series C Preferred Stock. Each holder of Preferred Series C is allowed to vote as a common shareholder as if the shares were converted to common stock up to the ownership blocker of 4.99%.

In 2017 the Company closed a \$750,000 Series D Preferred Stock and Warrant offering with Mr. Struve. As of December 31, 2023, Mr. Struve owns all of the 10,161 issued and outstanding shares of Series D Preferred Stock. Each outstanding share of series D preferred stock will accrue cumulative cash dividends at a rate equal to 8.0% per annum, subject to adjustment as provided in the series D preferred stock certificate of designations. Dividends are due and payable in cash when declared by the Company or when the stock is converted. In addition, On August 14, 2017, the price of the Series D Preferred Stock were adjusted to \$0.25 per share pursuant to the documents governing such instruments. Each holder of Preferred Series D is allowed to vote as a common shareholder as if the shares were converted to common stock up to the ownership blocker of 4.99%.

In August, 2023, as part of a modification of the Series C and Series D Preferred certificates of designation, such preferred stock does not accrue or pay cash dividends. All future dividends will be accrued and paid in Series C or Series D stock, as applicable. As was the case prior to the modifications of the Series C and Series D preferred stock,



although accrual of dividends is required as described below, no dividends are actually paid, and no shares actually issued, until a conversion of such stock or declaration of the dividend by the Board of Directors. Additionally, the Series D Preferred stock will no longer be required to automatically convert to common stock based on listing of the Company's common stock on the NYSE American, except if the volume weighted average price of the common stock is at least \$2.50 per share for 20 trading days and certain other requirements are satisfied. The cumulative dividends accrued and paid in preferred stock will be determined based upon a \$.70 stated value. The conversion from preferred stock into common stock is determined based dividing the \$.70 stated value by the \$.25 conversion price. In June, 2023, as part of the anticipated modification of the certificates of designation of the Series C and Series D preferred stock, at Mr. Struve's request, the Company settled all cash dividends with respect to the Series D preferred stock accrued and accumulated through December 31, 2022 in exchange for the issuance to Mr. Struve of 1,402,784 shares of the Company's common stock in reliance on the exemption from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended. In connection with this transaction, the Company recorded \$1,627,230 in dividends, representing the fair market value of the 1,402,784 shares issued.

Based upon the modified terms and conditions of Series C and D certificates of designations, it was determined that Series C and D preferred dividends need to be accreted going forward. As of December 31, 2023, cumulative unpaid Series C and D dividends totaled approximately \$800,000, which on a converted-to-common-stock basis represents approximately 3,202,000 shares of common stock. Company has recorded \$3,590,283 in cumulative deemed dividends related to Series C and D Preferred Stock which have not been paid, net of the approximately \$351,000 of accumulated dividends with respect to the Series D preferred that were settled for 1,402,784 shares of common stock as noted above. Mr. Struve is subject to an ownership blocker limiting his ownership to 4.99% and thus the number of common shares he can receive for dividends. Unpaid accreted stock dividends will be issued to Mr. Struve if he converts preferred stock or if the Board declares a dividend thereon, limited to his 4.99% ownership blocker. Assuming no changes in the amount of outstanding Preferred Series C or D ownership, going forward on a quarterly basis the Company will accrete as a preferred dividend the value of approximately 160,000 shares of common stock, which are issuable if such dividends become payable as additional shares of preferred stock, and such preferred stock is then converted into common stock.

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**Common Stock**

Each share of common stock entitles its holder to one vote on each matter submitted to the stockholders for a vote, and no cumulative voting for directors is permitted. Stockholders do not have any preemptive rights to acquire additional securities issued by the Company.

Three Months Ended December 31, 2023

On October 10, 2023, the Company issued 105,000 fully vested stock awards total to three directors at an exercise price of \$0.25 per share for director services.

On October 26, 2023, the Company closed an offering of our common stock pursuant to which we sold 883,061 shares of common stock, at a purchase price of \$0.25 per share. After deducting underwriting commissions and other offering expenses, the Company received net proceeds of \$203,105.

**Warrants to Purchase Common Stock**

Three Months Ended December 31, 2023

On September 29, 2023, pursuant to the Underwriting Agreement, the Company issued common stock purchase warrants to Boustead Securities, LLC and The Benchmark Company, LLC to purchase an aggregate of 123,648 shares of Common Stock at an exercise price of \$0.25 per share, subject to adjustments. The Representatives' Warrants are immediately exercisable, and may be exercised at any time and from time to time, in whole or in part, until September 26, 2028 and may be exercised on a cashless basis. The Representatives' Warrants also include customary anti-dilution provisions and immediate piggyback registration rights with respect to the registration of the shares underlying the Representatives' Warrants. The warrants were valued at \$20,896 and recorded in additional paid in capital as costs from common stock offering.

Warrants to purchase 5,000 shares of common stock at \$0.25 per share were forfeited.

A summary of the warrants outstanding as of December 31, 2023 were as follows:

	Shares	Weighted Average Exercise Price
Outstanding October 1, 2023	20,866,313	\$ 1.063
Issued	123,648	0.250
Exercised	-	-
Forfeited	(5,000)	(0.250)
Expired	-	-
Outstanding at end of period	20,984,961	\$ 1.059
Exercisable at end of period	20,984,961	

The following table summarizes information about warrants outstanding and exercisable as of December 31, 2023:

Number of Warrants	Weighted Average Remaining Life ( In Years)	Weighted Average Exercise Price	Shares Exercisable	Weighted Average Exercise Price
9,768,029	1.95	\$ 0.250	9,768,029	\$ 0.250
6,512,207	1.12	1.20-1.85	6,512,207	1.20-1.85
4,694,725	2.34	2.00-3.00	4,694,725	2.00-3.00
10,000	0.18	4.080	10,000	4.080
20,984,961	1.83	\$ 1.059	20,984,961	\$ 1.059

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The significant weighted average assumptions relating to the valuation of the Company's warrants for the three months ended December 31, 2023 were as follows:

Dividend yield	0%
Expected life	3 years
Expected volatility	108%
Risk free interest rate	4.79%

There were vested warrants of 20,984,961 with an aggregate intrinsic value of \$2,539,688.

## 8. STOCK INCENTIVE PLANS

On August 12, 2021, the Company established its 2021 Equity Incentive Plan (the "2021 Plan"), which was adopted by stockholders on October 15, 2021. The Company initially had 20,000,000 shares of its common stock authorized as the maximum number of shares of common stock that may be delivered to participants under the 2021 Plan, subject to adjustment for certain corporate changes affecting the shares, such as stock splits. This number was increased to 22,000,000 shares of common stock as of January 1, 2022 as a result of the automatic share reserve increase described below.

### Three Months Ended December 31, 2023

During the three months ended December 31, 2023, the Company issued stock option grants to twenty six employees and consultants for 13,909,315 shares at an average exercise price of \$0.256 per share. The stock option grants expire in five years. The stock option grants primarily vest quarterly over two to four years.

During the three months ended December 31, 2023, stock option grants for 195,000 shares at an average exercise price of \$2.019 per share were forfeited.

Stock option activity for the three months ended December 31, 2023 and the years ended September 30, 2023 and 2022 was as follows:

	Weighted Average		Proceed \$
	Options	Exercise Price	
Outstanding as of October 1, 2021	15,315,120	\$ 1.565	\$ 23,964,509
Granted	6,636,000	1.815	12,045,330
Exercised	(26,293)	(1.376)	(36,170)
Forfeitures	(1,132,457)	(2.057)	(2,329,267)
Outstanding as of September 30, 2022	20,792,370	1.618	33,644,402
Granted	4,158,333	1.381	5,744,716
Exercised	(166,890)	(0.273)	(45,473)
Forfeitures	(10,277,655)	(1.647)	(16,923,131)
Outstanding as of September 30, 2023	14,506,158	1.546	22,420,514
Granted	13,909,315	0.256	3,555,929
Exercised	-	-	-
Forfeitures	(195,000)	(2.019)	(393,650)
Outstanding as of December 31, 2023	28,220,473	\$ 0.907	\$ 25,582,793

The following table summarizes information about stock options outstanding and exercisable as of December 31, 2023:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Life In Years	Weighted Average Exercise Price Outstanding	Number Exercisable	Weighted Average Exercise Price Exercisable
\$0.25-0.51	13,909,315	4.78	\$ 0.256	535,251	\$ 0.267
\$0.88-1.25	2,161,875	2.91	0.172	1,935,625	3.989
\$1.28 - 1.67	9,684,283	3.02	1.473	3,144,458	1.418
\$1.79-3.67	2,465,000	3.06	2.181	1,210,000	2.137
	28,220,473	3.88	\$ 0.907	6,825,334	\$ 1.134

There are stock option grants of 28,220,473 shares as of December 31, 2023 with an aggregate intrinsic value of \$4,269,089.

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There are 28,220,473 (including unearned stock option grants totaling 4,179,825 shares related to performance milestones) options to purchase common stock at an average exercise price of \$0.907 per share outstanding as of December 31, 2023 under the 2021 Plan. The Company recorded \$699,246 and \$744,640 of compensation expense, net of related tax effects, relative to stock options for the three months ended December 31, 2023 and 2022, respectively, in accordance with ASC 718. As of December 31, 2023, there is \$6,569,469 of total unrecognized costs related to employee granted stock options that are not vested. These costs are expected to be recognized over a period of approximately 3.88 years.

## 9. INCOME TAXES

The Company recorded a provision for income taxes of \$0 for the three months ended December 31, 2023 and 2022.

The Company's effective tax rate was 0.0% for the three months ended December 31, 2023 and 2022. The difference between the effective tax rate and the federal statutory tax rate primarily relates to the valuation allowance on the Company's deferred tax assets.

For interim periods, the Company estimates its annual effective income tax rate and applies the estimated rate to the year-to-date income or loss before income taxes. The Company also computes the tax provision or benefit related to items reported separately and recognizes the items net of their related tax effect in the interim periods in which they occur. The Company also recognizes the effect of changes in enacted tax laws or rates in the interim periods in which the changes occur.

As of December 31, 2023 and 2022, the Company retains a full valuation allowance on its deferred tax assets. The realization of the Company's deferred tax assets depends primarily on its ability to generate taxable income in future periods. The amount of deferred tax assets considered realizable in future periods may change as management continues to reassess the underlying factors it uses in estimating future taxable income.

## 10. SIGNIFICANT AND OTHER TRANSACTIONS WITH RELATED PARTIES

### Transactions with Clayton Struve

See Notes 6 and 7 for related party transactions with Clayton A. Struve, a significant stockholder.

On June 27, 2023, at Mr. Struve's request, the Company settled all cash dividends with respect to the Series D preferred stock accrued and accumulated through December 31, 2022 in exchange for the issuance to Mr. Struve of 1,402,784 shares of the Company's common stock in reliance on the exemption from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended. In connection with this transaction, the Company recorded \$1,627,230 in dividends, representing the fair market value of the 1,402,784 shares issued.

### Related Party Transactions with Ronald P. Erickson

See Notes 6, 7 and 11 for related party transactions with Ronald P. Erickson, the Company's Chairman and Chief Executive Officer and affiliated entities.

On October 10, 2023, the Company issued a stock option grant to Ronald P. Erickson for 4,640,844 shares at an exercise price of \$0.25 per share. The stock option grant expires in five years. The stock option grant vests quarterly over four years.

### Related Party Transactions with Peter J. Conley, Chief Financial Officer and Senior Vice President, Intellectual Property

On October 10, 2023, the Company issued a stock option grant to Peter J. Conley for 3,001,000 shares at an exercise price of \$0.25 per share. The stock option grant expires in five years. The stock option grant vests quarterly over four years.

### Related Party Transactions with Directors

On October 10, 2023, the Company issued 105,000 fully vested stock awards total to three directors at an exercise price of \$0.25 per share for director services.

On October 10, 2023, the Company issued stock option grants to three directors for a total of 238,584 shares at an exercise price of \$0.25 per share. The stock option grant expires in five years. The stock option grants vested at issuance.

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## 11. COMMITMENTS, CONTINGENCIES AND LEGAL PROCEEDINGS

### Legal Proceedings

The Company may from time to time become a party to various legal proceedings arising in the ordinary course of business. The Company is currently not a party to any pending legal proceeding that is not ordinary routine litigation incidental to the Company's business.

### Employment and Related Agreements

#### Employment Agreement with Ronald P. Erickson, Chairman of the Board and Chief Executive Officer

See the Employment Agreement for Ronald P. Erickson that was disclosed in Form 10-K filed with the SEC on December 19, 2023. Mr. Erickson was appointed Chief Executive Officer on January 23, 2023.

#### Employment Agreement with Peter J. Conley, Chief Financial Officer and Senior Vice President, Intellectual Property

See the Employment Agreement for Peter J. Conley that was disclosed in Form 10-K filed with the SEC on December 19, 2023.

### Properties and Operating Leases

The Company is obligated under the following leases for its various facilities.

#### Corporate and Executive Offices

On April 13, 2017, the Company leased its executive office located at 500 Union Street, Suite 810, Seattle, Washington, USA, 98101. The Company leases 943 square feet and the current net monthly payment is \$3,334. The monthly payment increases approximately 3% each year and the lease expired on May 31, 2022. On October 31, 2021, the Company extended the lease from June 1, 2022 to May 31, 2023 at \$2,986 per month. On April 26, 2023, the Company extended the lease from June 1, 2023 to May 31, 2024 at \$2,908.

#### Lab Facilities and Executive Offices

On May 18, 2021, the Company entered into a lease for its lab facilities located at 914 E Pine Street, Suite 212, Seattle, WA 98122 and leased 2,642 square feet. The net monthly lease payment was \$8,697 and increases by 3% annually. The lease was terminated on February 5, 2024.

On October 11, 2021, the Company entered into the First Amendment of Lease and added 2,485 square feet for \$5,000 per month. On September 20, 2022, the Company entered into the Second Amendment of Lease for additional space. The expanded space will be utilized for research and testing. The Amendment of Lease expired on December 31, 2023.

On November 22, 2022, the Company leased an additional 1,800 square feet of lab facilities at 123 Boylston Ave, Suite C, Seattle, WA 98102 with a net monthly payment is \$2,250. The lease was set to expire on November 21, 2023 and has been extended on a month-to-month basis.

During the year ended September 30, 2024, the Company expects to consolidate all offices into one location in downtown Seattle, Washington.

## 12. SEGMENT REPORTING

The Company considers the business to currently have one operating segment; the development of its radio frequency spectroscopy technology with a first focus on non-invasively ascertaining blood glucose levels. Previously, two subsidiary segments were active; (i) Particle, Inc. technology; and (ii) AI Mind sales of NFT products.

On April 30, 2020, the Company incorporated Particle, Inc. in the State of Nevada. Particle was focused on the development and commercialization of the Company's extensive intellectual property relating to electromagnetic energy outside of the medical diagnostic arena which remains the parent company's singular focus. Since incorporation, Particle has engaged in research and development activities on threaded light bulbs that have a warm white light and can inactivate germs, including bacteria and viruses. It is seeking partners to take the product to market.

AI Mind commenced operations during the year ended September 30, 2021. The Company was dissolved on July 25, 2023.

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## 13. SUBSEQUENT EVENTS

The Company evaluated subsequent events, for the purpose of adjustment or disclosure, up through the date the financial statements were issued. Subsequent to December 31, 2023, there were the material transactions that require disclosure:

On February 5, 2024, the Company terminated a lease for its lab facilities located at 914 E Pine Street, Suite 212, Seattle, WA 98122.

On February 8, 2024, the Company issued the following compensation to directors for 2023 and 2024 services:

Stock option grants totaling 2,371,233 at \$0.49 per share. The grants are fully vested and expire in five years.

Stock awards totaling 348,492 shares of the Company's common stock that were valued at \$0.49 per share.

On February 8, 2024, Company extended the following warrants:

Warrants to purchase common stock totaling 1,243,102 shares and due to expire in 2024 were extended by two years.

Warrants to purchase common stock for Ronald P. Erickson and parties affiliated with Mr. Erickson totaling 1,894,666 shares and due to expire on January 30, 2024 were extended by two years.

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

Forward-looking statements in this report reflect the good-faith judgment of our management and the statements are based on facts and factors as we currently know them. Forward-looking statements are subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, but are not limited to, those discussed below as well as those discussed elsewhere in this report (including in Part II, Item 1A (Risk Factors)). Readers are urged not to place undue reliance on these forward-looking statements because they speak only as of the date of this report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this report.

### BUSINESS

#### Overview

Know Labs is an emerging leader in non-invasive medical diagnostics. We are focused on the development and commercialization of our proprietary sensor technology utilizing radio and microwave spectroscopy. When paired with our machine learning platform, our technology is capable of uniquely identifying and measuring almost any material or analyte using electromagnetic energy to detect, record, identify, and measure the unique "signature" of said materials or analytes.

The first application of our sensor technology is in a product to non-invasively monitor blood glucose levels. Our device will provide the user with real-time information on their blood glucose levels. We recently announced our Generation 1 working prototype device. This device embodies the sensor which has been used in internal clinical testing. We have also announced the work our R&D team is doing on the Generation 2 of our device, which is a wearable format and could be a final form factor, ready for commercial application. We are expanding our testing, both internally and externally, and will refine the device over time, which will require FDA clearance before entering the market.

Following FDA clearance of our non-invasive blood glucose monitoring device, Know Labs plans to expand its sensor technology to other non-invasive medical diagnostic applications. As a platform technology, it can identify numerous other analytes in the human body that are important in medical diagnostics and human health and wellness.

While medical diagnostics applications, with blood glucose monitoring paramount, are the focus of Know Labs, the Company's proprietary radio frequency and microwave spectroscopy platform have broad applicability outside of the medical diagnostic realm. Over time, as resources allow, the Company will explore those opportunities.

#### Corporate History and Structure

Know Labs, Inc. was incorporated under the laws of the State of Nevada in 1998. Since 2007, our company has been focused primarily on research and development of proprietary spectroscopic technologies spanning the electromagnetic spectrum.

Know Labs has one wholly owned subsidiary, Particle, Inc. incorporated on April 30, 2020. AI Mind, Inc., Know Lab's former wholly owned subsidiary, was incorporated on September 17, 2021 and dissolved in early 2023. At this time there is no material activity in the Particle subsidiary while the Company gives all of its attention to its focus on its sensor technology and glucose monitoring device development.

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## **The Know Labs Technology**

We have internally and under contract with third parties developed proprietary platform technology to uniquely identify and measure almost any organic and inorganic material or analyte. Our patented technology directs electromagnetic energy in the radio wave and microwave frequencies through a substance or material to capture a unique molecular signature. We then perform analytics which will allow the Company to accurately identify and measure materials and analytes.

Our technology provides a unique platform upon which a myriad of applications can be developed. Our radio frequency spectroscopy technology is an “enabling” technology that brings the science of electromagnetic energy to low-cost, real-world commercialization opportunities across multiple industries. The technology is foundational and, as such, the basis upon which we believe significant businesses can be built. While we are pursuing our core focus on commercializing our non-invasive glucose monitor, we believe non-core clinical, non-clinical and medical research applications represent a multitude of opportunities for strategic collaboration, joint development, and licensing agreements with leading companies in their respective industries.

We believe an important competitive differentiator for our sensor technology to be its ability to not only identify a wide range of organic and inorganic materials and analytes, but to do so non-invasively, and in real-time, which potentially enables new multivariate models of clinical diagnostics, and health and wellness monitoring.

### **Know Labs Sensor Technology: Hardware and Software**

Our sensor technology embodies two key components: hardware and software. The key hardware component includes a sensor which both sends and receives a radio frequency signal. The data obtained by the receiving aspect of the sensor is analyzed by software. Today, the sensor portion of our hardware development is complete. This sensor is currently being used in our internal tests, and has been for the past several months, gathering millions of data points to further refine our algorithm. It is the core component in our Generation 1 working prototype device and the Generation 2 device under development. This sensor technology will be the core component of future versions of our devices.

As a consequence, a significant amount of our focus has shifted to algorithm development. This involves sophisticated development of algorithms which derive meaningful information from the raw data obtained by our sensor. These algorithms are developed through the utilization of machine learning (ML) by means of training various models. We will continue data collection to further refine the accuracy of the algorithm until we feel confident that we can be successful in FDA clinical trials and bring to the market the first non-invasive blood glucose monitor.

### **Early Results**

We previously announced the results of an internal exploratory study comparing tests between our sensor technology and the leading continuous glucose monitors from Abbott Labs (Freestyle Libre®) and DexCom (G6®). These results provided evidence of a high degree of correlation between our technology and the current industry leaders and their continuous glucose monitors. Our patented technology is fundamentally differentiated from these industry leaders as our technology completely non-invasively monitors blood glucose levels. We also believe our technology successfully addresses the limiting qualities of non-invasive optical technologies whose diagnostic capacities may be inhibited by skin tones and other factors.

We are currently underway with an internal study comparing data from our sensor technology and lab-based reference devices, the Nova Primary and Nova Stat Strip. We have also expanded our study to include participants with diabetes, an important step in clinical development. These studies will allow us to further refine our algorithm and obtain results compared to lab-based reference devices, which will be required for future FDA clearance.

We continue to build the internal and external development team necessary to commercialize our technology. Our ability to obtain exacting results from the data collected through our sensor technology is enabled by our trade secret algorithms built through our machine learning platform. We have been and continue to refine these algorithms so they can accurately determine blood glucose levels across a broad population. We believe our algorithms can also provide accurate measurements for blood alcohol and blood oxygen levels, which we have identified in preliminary tests. We expect them to provide the analytics for the long list of other potential analytes in the human body many of which are set forth in our issued patent USPTO 11,033,208 B1.

### **Validation and FDA Clearance**

We are also focused on building strong external validation of the technology. This on-going initiative should provide additional evidence and support as we look to approach FDA approval. Over the past year, we have announced several significant validating studies. They include:

The results of a proof-of-principle study titled, “*Detecting Unique Analyte-Specific Radio Frequency Spectral Responses in Liquid Solutions, Implications for Non-Invasive Physiologic Monitoring.*” This study was conducted in collaboration with Mayo Clinic, sponsored by the Company, and its results were presented at the 2023 American Physiological Society (APS) Summit. The study demonstrated the accuracy of the sensor in quantifying three different analytes in vitro. In the peer-reviewed publication, it was found Bio-RFID achieved 100% accuracy in quantifying these three different analytes in vitro. The study was peer-reviewed by Sensors Journal and American Physiology Society.

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The results of our technical feasibility study titled, “*Technical Feasibility of a Novel Sensor for Non-Invasive Blood Glucose Monitoring Compared to Dexcom G6®.*” These results were presented at the American Association of Clinical Endocrinology (AACE) Annual Meeting in Seattle, WA on May 5, 2023. The study was performed by the Know Labs Clinical Development Team at Know Labs Research Laboratory in Seattle. The purpose of this technical feasibility study was to demonstrate hardware and software infrastructure stability, and to collect additional data to determine the accuracy of the sensor at quantifying BGC in vivo non-invasively using radio frequency by means of training a neural network (NN) model to predict readings of the Dexcom G6® as a proxy for BGC. The study was peer-reviewed by the American Association of Clinical Endocrinology.

The results of a new study titled, "*Algorithm Refinement in the Non-Invasive Detection of Blood Glucose Using Know Labs' Bio-RFID Technology.*" The study demonstrates that algorithm optimization using a light gradient-boosting machine (lightGBM) machine learning model improved the accuracy of Know Labs' Bio-RFID™ sensor technology at quantifying blood glucose using predicted readings of the Dexcom G6® as a proxy for BGC, demonstrating an overall Mean Absolute Relative Difference (MARD) of 12.9% – which is within the range of independently reported values for certain FDA-cleared blood glucose monitoring devices. The study was performed by the Know Labs Clinical Development Team at Know Labs Research Laboratory in Seattle, and reviewed by members of Know Labs' Scientific Advisory Board.

The results from a new study<sup>6</sup> titled, "*Novel data preprocessing techniques in an expanded dataset improve machine learning model accuracy for a non-invasive blood glucose monitor.*" The study demonstrates that continued algorithm refinement and more high-quality data improved the accuracy of Know Labs' proprietary Bio-RFID sensor technology, resulting in an overall Mean Absolute Relative Difference (MARD) of 11.3%. As with all Know Labs' previous research, this study was designed to assess the ability of the Bio-RFID sensor to non-invasively and continuously quantify blood glucose, using the Dexcom G6® continuous glucose monitor (CGM) as a reference device and proxy for BGC. In this new study where data collection was completed in May of 2023, Know Labs applied novel data preprocessing techniques and trained a light gradient-boosting machine (lightGBM) model to predict blood glucose values of Dexcom G6® CGM using 3,311 observations – or reference device values – from over 330 hours of data collected from 13 healthy participants. With this method, Know Labs was able to predict blood glucose in the test set – the dataset that provides a blind evaluation of model performance – with a MARD of 11.3%. The study was performed by the Know Labs Clinical Development Team at Know Labs Research Laboratory in Seattle and reviewed by members of Know Labs' Scientific Advisory Board.

As the Company successfully completed our foundational studies, created a stable sensor that delivers repeatable results, and developed a software infrastructure to manage and interpret large, novel datasets, it will continue to expand its testing and data gathering with larger and more diverse populations in order to continue increasing the accuracy of our algorithms across diverse populations.

We have also begun the internal and external process to pursue FDA clearance for our non-invasive blood glucose monitor. Our Chief Medical Officer, medical and regulatory advisory board, our entire executive team along with external advisors guide us in this process. Additionally, our third-party quality assurance and documentation consultants help ensure that the rigorous requirements of FDA are met. We are unable to estimate the time necessary for FDA approval or the likelihood of success in that endeavor.

### **Product Strategy**

We have announced the development of our non-invasive glucose monitor and our desire to obtain FDA clearance for the marketing of this product. We are currently undertaking internal development work of this product for the commercial marketplace. We have also announced the engagement of several strategic partners and advisors focused on sensor technology, product design, data science, machine learning, manufacturing and regulatory affairs, who we will work with to bring this product to market. The announcement of our Generation 1 working prototype device was a significant milestone for the Company. It has been used in internal testing and sensor characterization work to inform the development of our Generation 2 prototype device. We have also announced the work being done on the Generation 2 prototype device, which is a wearable format and may be a potential final format that would be presented to the FDA for market clearance. We will make further announcements regarding the product as development, testing, manufacturing, and regulatory approval work progresses.

Our efforts are entirely focused on productizing our sensor technology and collecting high quality data for validation purposes, including third-party studies, and appropriate and required clinical trials. At this point in our development cycle, the hardware continues to be miniaturized and optimized, the product form factor is moving in the direction of a final product that will be used for FDA clinical trials and the algorithms which provide results from the data collected by our sensor are being refined to improve accuracy.

### **Sales and Marketing**

While we continue with our internal development efforts and the move toward clinical trials for FDA clearance of our non-invasive blood glucose monitor, we will explore the several potential avenues for moving our first product and potential follow-on products into the marketplace. The avenues being explored include direct to consumer, initial launch partners, broad distribution partners, licensing partners and private label approaches to the market, among others. As part of our growth strategy, we have begun discussions around joint development agreements with potential biopharma, medical device, and consumer electronics partners. These would be strategic collaborations that could help us accelerate development and commercial launch. In parallel, we have begun to build our internal commercial and marketing team in preparation for detailed strategic thinking about the optimal approach to the marketplace. We attend and engage in conferences focused on diabetes management and technology, which are valuable for building Know Labs' reputation and network in the space.

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### **Competition**

The technology industry, generally, and blood glucose monitoring and other medical diagnostic markets in particular, are intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities by industry participants. To compete successfully, we will need to demonstrate the advantages of our products and technologies over well-established alternative solutions, products, and technologies, including legacy providers of blood glucose monitoring technology, as well as newer ones that are working to achieve a non-invasive solution or more acceptable blood glucose monitoring solutions which may or may not be similar to our technology, and convince consumers and enterprises of the advantages of our products and technologies.

We group our competition into three large categories. Those are (i) large global technology companies who may enter the blood glucose monitoring and other medical diagnostic markets, (ii) legacy providers of blood glucose monitoring technology, and (iii) new entrants working to achieve a non-invasive solution or more acceptable blood glucose monitoring solutions which may or may not be similar to our technology. With regard to companies in each category, we perform due diligence from all publicly available sources of information on their relevant technologies and their product plans. This information informs and refines our activities and underscores our sense of urgency as we work to bring our own technology to the marketplace. As it relates to all competitors, we continue to focus on building the world's most robust patent portfolio in this space. PatSnap Research and ipCapital Group, two leading patent analytic firms, have ranked Know Labs #1 for global patent leadership in non-invasive glucose monitoring patents. We have retained both organizations to perform patent related work. We continue to build out our patent portfolio and grow our trade secret AI and ML driven algorithms. Patents issued, pending, and in-process increased from 107 to 264 YoY (+147% vs. market +35%) reflecting our high rate of innovation.

With respect to our planned non-invasive glucose monitor, we will face direct and indirect competition from a number of competitors who have developed or are developing products for continuous monitoring of glucose levels. These competitors include DexCom, Inc., Abbott Laboratories, Medtronic plc, Roche Diagnostics, LifeScan, Inc., Ascensia Diabetes Care Holdings AG, Senseonics Holdings, Inc., Integrity Applications, Inc., Nemaura Medical, Biolinq Inc., and Profusa, Inc. Our planned solution will also compete with traditional glucometers, which remain an inexpensive alternative. We also compete with companies who are seeking to create non-invasive glucose monitors, such as Movano, Inc., Hagar, and DiaMonTech AG. Because of the large size of the potential market for our products, it is possible that new or existing competitors may develop competing products, procedures, or clinical solutions that could prove to be more effective, safer, or less costly than our solution. The introduction of new products, procedures, or clinical solutions by competitors may result in price reductions, reduced margins, or loss of market share, or may render our products obsolete. Many of the companies we will compete with enjoy significantly greater name recognition and have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and sales and marketing of approved products than we have.



Mergers and acquisitions in the medical device, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Other small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. There are also several academic and other institutions involved in various phases of technology development regarding blood glucose monitoring devices.

### **Competitive Advantages**

We believe our key competitive strengths include:

- Through first principles, our sensor technology's ability to not only identify a wide range of organic and inorganic materials and analytes, but to do so non-invasively, accurately, and in real time, which potentially enables new multivariate models of clinical diagnostics, and health and wellness monitoring.
- Our sensor technology is non-invasive, using radio waves to identify and measure what is going on inside the body.
- Our sensor technology platform can be integrated into a variety of wearable, mobile, or counter-top form factors, and we believe eventual interoperability with existing products from current market leaders.
- No needles nor invasive transmitters in your body, making our sensor convenient and pain-free.

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- No expensive supplies, such as test strips and lancets, are required to operate our device.
- A core focus on accessibility and affordability for the populations we will serve around the globe.
- The current prototype sensor collects approximately 1.5 million data points per hour, which allows us to potentially build a deep understanding of health and wellness that other sensors may not be able to.
- Know Labs is the world intellectual property leader in non-invasive blood glucose monitoring, according to ipCG Capital and PatSnap.

### **Growth Strategy**

The key elements of our strategy to grow our business include:

- Initially, entering the diabetes glucose monitoring market with our non-invasive glucose monitoring device.
- Following our entry into the glucose monitoring market, entering other clinical monitoring markets for continuous, non-invasive hormone, medication metabolites, endocrinology components, and biomolecular monitoring.
- Applying our platform technology to lifestyle analysis, clinical trials, and chronic illnesses. We believe that potential use cases include real-time wearable medication monitoring and detection of, for example, ovulation and hormone deficiency.
- With a potential ever-growing body of non-invasively determined analytes available from individuals utilizing our technology we believe, over time, with longitudinal data we will be able to engage in so-called "predictive health" and provide early warnings of the onset of disease.
- Significantly, every new application will likely function utilizing the same sensor. We expect that hardware changes will not be required to target new analytes, so you will not need a new device, but an updated software algorithm will be required.
- Each new application provides potential new opportunities for monetization of the platform technology. Each additional analyte we identify over time may require its own subsequent FDA clearance.

### **Research and Development**

Our current research and development efforts are primarily focused on improving our radio frequency spectroscopy technology for the monitoring of blood glucose. As part of this effort, we continuously perform clinical testing of our devices following IRB-approved protocols, and we conduct on-going laboratory testing to ensure that application methods are compatible with the end-user and regulatory requirements, and that they can be implemented in a cost-effective manner. As resources permit, we plan to focus on extending the capacity of our sensor technology to identify new analytes and applications. Our current internal team along with outside consultants have considerable experience working with the application of our technologies. We engage third party experts as required to supplement our internal team. We incurred expenses of \$1,486,000 and \$1,743,000 for the three months ended December 31, 2023 and 2022, respectively, on development activities.

The cornerstone of our foundational platform technology is our intellectual property portfolio. We have pursued an active intellectual property strategy which includes focus on patents where appropriate and a diligent protection of trade secrets. To date, we have been granted 33 patents and 26 design patents. These include 13 patents on our early work on the visible and near visible portions of the electromagnetic spectrum, which were a point of creative departure as we explored and invented our current radio frequency sensor technology. These also include 9 patents related to our Particle subsidiary. We currently have a number of patents pending and continue, on a regular basis, with the filing of new patents. If we include pending patents, our IP portfolio reaches 261 patents issued and pending, which positions the company as the top worldwide IP holder in non-invasive blood glucose monitoring, according to ipCapital Group, a leading IP and innovation consulting firm. We possess all rights, title and interest to the issued patents.

Our issued patents will expire at various times between 2027 and 2047. Pending patents, if and when issued, may have expiration dates that extend further in time. The duration of our trademark registrations varies from country to country. However, trademarks are generally valid and may be renewed indefinitely as long as they are in use and/or their registrations are properly maintained.

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The issued patents cover the fundamental aspects of our radio frequency spectroscopy technology and a number of unique applications. We have filed patents, which are pending, on the additional fundamental aspects of our technology and growing number of unique applications. We will continue, over time, to expand our patent portfolio.

Additionally, significant aspects of our technology are maintained as trade secrets which may not be disclosed through the patent filing process. We are diligent in maintaining and securing our trade secrets, in particular as they involve our AI and ML driven algorithms.

We shall also have an exclusive, perpetual and royalty free right to any patent(s) or other intellectual property which Phillip Bosua, someone working under direction of Phillip Bosua, or any successor or assignee develops, relating to Know Labs' technology within a period of five years after January 23, 2023.

#### **Related Patent Assets**

Inherent in a platform technology is the ability to develop or license technology in diverse fields of use apart from our core focus. We focus on human health and wellness with a first focus on the non-invasive monitoring of blood glucose. We plan to pursue the identification of a multitude of analytes in the human body that are important to diagnostics over time. We also plan to identify, over time, opportunities for our intellectual property to be deployed in areas outside of human health and wellness.

We may, although we cannot guarantee that we will, create other such subsidiaries over time. Additionally, we may license our intellectual property to third parties so that they may pursue activities that are not a part of our core focus.

#### **Employees**

As of December 31, 2023, we had 12 full-time and part-time employees. Our senior management and other personnel are co-located in our Seattle, Washington offices and remote. The Company expanded its utilization of consulting firms and individual contractors to supplement our reduced workforce in an effort to reduce fixed expenses and extend operating resources.

### **RESULTS OF OPERATIONS**

#### **Overview**

We are focused on the development and commercialization of our proprietary sensor technology utilizing radio and microwave spectroscopy. When paired with our machine learning platform, our technology is capable of uniquely identifying and measuring almost any material or analyte using electromagnetic energy to detect, record, identify, and measure the unique "signature" of said materials or analytes. The first application of our sensor technology is in a product to non-invasively monitor blood glucose levels. This device will require US Food and Drug Administration (FDA) clearance before entering the market.

On April 30, 2020, we incorporated our wholly owned subsidiary, Particle, Inc. Particle was focused on the development and commercialization of our extensive intellectual property relating to electromagnetic energy outside of the medical diagnostic arena, which remains our company's singular focus. Since incorporation, Particle was engaged in research and development activities on threaded light bulbs that have a warm white light and can inactivate germs, including bacteria and viruses. Particle is now looking for partners to take this product to market.

On September 17, 2021, we incorporated our wholly owned subsidiary, AI Mind, Inc., for the purpose of identifying and capitalizing on market opportunities for our AI deep learning platform (discussed below). The first activity undertaken by AI Mind was the creation of graphical images expressed as non-fungible tokens, or NFTs, utilizing the AI deep learning platform. During the year ended September 30, 2022, AI Mind, operating our AI deep learning platform, began generating revenue from digital asset sales of NFT's and had sales of \$4,360,000. AI Mind was dissolved on July 25, 2023.

#### **Recent Developments**

On April 21, 2023, we announced the publication of a peer-reviewed study in Sensors Journal. The manuscript described the proof-of-principle study of Bio-RFID technology that quantified three different analytes in vitro. In the peer-reviewed publication, it was found Bio-RFID achieved 100% accuracy in quantifying these three different analytes in vitro. This study was conducted in collaboration with Mayo Clinic.

On May 5, 2023, we announced the results of a technical feasibility study that was presented at the American Association of Clinical Endocrinology (AACE) Annual Meeting. The study demonstrated that the Bio-RFID sensor can deliver stable, repeatable results in predicting blood glucose concentrations obtained by a reference device.

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On June 7, 2023, we revealed the portable Generation 1 prototype for non-invasive glucose monitoring. The Generation 1 prototype is a portable research lab, designed to be a powerful data collection device. This device should allow Know Labs to scale data collection, including testing across more diverse participant populations and scenarios.

In June of 2023, the Company issued 1,402,784 shares of common stock as dividends to the holder of Series D Convertible Preferred stock as settlement of cumulative unpaid dividends through December 2022.

On July 26, 2023, we announced the completion of a new study demonstrating that continued algorithm refinement and more high-quality data improved the accuracy of the Bio-RFID sensor technology, resulting in an overall Mean Absolute Relative Difference (MARD) of 11.27%.

On August 9, 2023, we authorized the Company to file a series of amendments to the certificates of designation for certain series of our preferred stock, and the restatement of its articles of incorporation, as described below, each of which were filed with the Nevada Secretary of State effective August 11, 2023. Based upon the June 2023 issuance of common stock dividends to Series D Convertible Preferred Stockholder and the modified terms and conditions of Series C and D certificates of designation, it was determined that Series C and D preferred dividends need to be accreted for the cumulative unpaid dividends. As of September 30, 2023, cumulative unpaid Series C and D totaled approximately \$800,000 which converts to approximately 3,202,000 shares of common stock. We have recorded \$3,590,283 in cumulative deemed dividends related to Series C and D Preferred Stock which have not been paid.

In connection with the amendment and restatement of our preferred stock, we effected a reverse split of our outstanding Series C Convertible Preferred Stock and Series D Convertible Preferred Stock by a factor of 1-for-100. No changes were made to the 5 million total shares of "blank-check" preferred stock authorized in our Articles. Prior to such reverse split, there were 1,785,715 and 1,016,004 shares of Series C Convertible Preferred Stock and Series D Convertible Preferred Stock designated and outstanding, respectively. To account for the reverse split, but in order to provide the ability to issue "pay in kind" dividends in lieu of cash dividends, at the time of the reverse split, we designated 30,000 shares of Series C Convertible Preferred Stock and 20,000 shares of Series D Convertible Preferred Stock, of which 17,858 and 10,161 shares were,

respectively, outstanding immediately after such reverse split. In order to maintain the economic rights of the Series C Convertible Preferred Stock and Series D Convertible Preferred Stock, the definition of “Stated Value” was multiplied by 100, to offset the reverse split factor.

On September 15, 2023, we signed amendments to the convertible promissory or OID notes, held by Clayton A. Struve and Ron Erickson, to extend the due dates to September 30, 2024.

On September 29, 2023, we closed an offering of our common stock pursuant to which we sold 28,000,000 shares of common stock, at a purchase price of \$0.25 per share via an S-1 registration statement. After deducting underwriting commissions and other offering expenses, we received net proceeds of \$5,472,791. As part of the offering, we issued common stock purchase warrants to the Underwriter Representatives to purchase an aggregate of 1,960,000 shares of Common Stock at an exercise price of \$0.25 per share, subject to adjustments. The Representatives’ Warrants are immediately exercisable and may be exercised at any time and from time to time, in whole or in part, until September 26, 2028 and may be exercised on a cashless basis.

On October 26, 2023, we closed an offering of our common stock pursuant to which we sold 883,061 shares of common stock, at a purchase price of \$0.25 per share. After deducting underwriting commissions and other offering expenses, we received net proceeds of \$203,105. We issued common stock purchase warrants to Boustead Securities, LLC and The Benchmark Company, LLC to purchase an aggregate of 123,648 shares of Common Stock at an exercise price of \$0.25 per share, subject to adjustments.

### Principal Factors Affecting Our Financial Performance

Our operating results are primarily affected by the following factors:

- the ability of our research and development team to produce an FDA clearance quality technology;
- our ability to recruit and maintain quality personnel with the talent to bring our technology to the market;
- the production of market ready products that can sustain FDA clearance quality results;
- the clearance by FDA after their rigorous clinical trial process of our products for the marketplace;
- the receptivity of the marketplace and the addressable diabetes community to our new non-invasive glucose monitoring technology; and
- access to sufficient capital to support us until our products achieve FDA clearance and are accepted in the marketplace.

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### Segment Reporting

The Financial Accounting Standards Board, or FASB, Accounting Standard Codification, or ASC, Topic 280, *Segment Reporting*, requires that an enterprise report selected information about reportable segments in its financial reports issued to its stockholders. The Company considers the business to currently have one operating segment: the development of its radio frequency spectroscopy technology with a first focus on non-invasively ascertaining blood glucose levels. Previous segments included (i) Particle, Inc. technology; and (ii) AI Mind, Inc. sales of NFT products. Particle commenced operations in the year ended September 30, 2020. It is now looking for partners to take the product to market. AI Mind commenced operations during the year ended September 30, 2022. AI Mind was dissolved on July 25, 2023.

### Results of Operations

The following table sets forth key components of our results of operations during the three months ended December 31, 2023 and 2022.

(dollars in thousands)

	Three Months Ended December 31,			
	2023	2022	\$ Variance	% Variance
Operating expenses-				
Research and development and operating expenses-				
Research and development expenses	\$ 1,487	\$ 1,743	\$ 256	14.7%
Selling, general and administrative expenses	2,011	1,905	(106)	-5.6%
Total operating expenses	3,498	3,648	150	4.1%
Operating loss	(3,498)	(3,648)	150	4.1%
Other expense:				
Interest income	51	-	51	100.0%
Interest expense	-	(227)	227	100.0%
Other (expense) income, net	-	52	(52)	-100.0%
Total other income (expense), net	51	(175)	226	129.1%
Loss before income taxes	(3,447)	(3,823)	376	9.8%
Income tax expense	-	-	-	0.0%
Net loss	\$ (3,447)	\$ (3,823)	\$ 376	9.8%

**Research and Development Expenses.** Research and development expenses for the three months ended December 31, 2023 decreased \$256,000 to \$1,487,000 as compared to \$1,743,000 for the three months ended December 31, 2022. The decrease was due to decreased personnel, use of consultant, expenditures related to the development of our radio frequency spectroscopy Bio-RFID™ technology. During the year ended September 30, 2023, we reduced our headcount by nine and operating expenses and used external consultants to reduce the future cost of the development of our Bio-RFID™ technology.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended December 31, 2023 increased \$106,000 to \$2,011,000 as compared to \$1,905,000 for the three months ended December 31, 2022. The increase primarily was due to (i) an increase of \$280,000 in salaries; (ii) a decrease in insurance of \$101,000; and (iii) a decrease in other expenses of \$73,000. As part of the selling, general and administrative expenses for the three months ended December 31, 2023 and 2022, we recorded \$69,000 and \$52,000, respectively, of investor relationship and business development expenses.

Other Income (Expense), Net. Other income (expense), net for the three months ended December 31, 2023 was \$51,000 as compared to other expense net of \$175,000 for the three months ended December 31, 2022. The other income, net for the three months ended December 31, 2023 included interest income of \$51,000.

The other expense, net for the three months ended December 31, 2022 included (i) interest expense of \$227,000, offset by (ii) interest income of \$52,000.

Net Loss. Net loss for the three months ended December 31, 2023 was \$3,447,000 as compared to \$3,823,000 for the three months ended December 31, 2022. The net loss for the three months ended December 31, 2023 included non-cash expenses of \$792,000. The non-cash items include (i) depreciation and amortization of \$19,000; (ii) stock based compensation- stock options of \$699,000; (iii) issuance of common stock for services of \$26,000; and (iv) amortization of operating lease right-of-use asset of \$48,000.

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The net loss for the three months ended December 31, 2022 included non-cash expenses of \$1,097,000. The non-cash items include (i) depreciation and amortization of \$103,000; (ii) stock based compensation- stock options of \$744,000; (iii) expenses for extension of notes and warrants of \$207,000; (iv) amortization of operating lease right-of-use asset of \$44,000 and offset by (v) other of \$1,000.

**Liquidity and Capital Resources**

Liquidity is the ability of a company to generate funds to support its current and future operations, satisfy its obligations, and otherwise operate on an ongoing basis. Significant factors in the management of liquidity are funds generated by operations, levels of accounts receivable and accounts payable and capital expenditures.

We have cash and cash equivalents of \$4,821,000 and net working capital of approximately \$3,796,000 (exclusive of convertible notes payable) as of December 31, 2023. We anticipate that we will record losses from operations for the foreseeable future. As of December 31, 2023, our accumulated deficit was \$125,351,000 and net losses in the amount of \$3,447,000, \$15,289,000 and \$20,071,000 during the three months ended December 31, 2023 and years ended September 30, 2023 and 2022, respectively. We incurred non-cash expenses of \$792,000, \$4,768,000, and \$12,164,000 during the three months ended December 31, 2023 and the years ended September 30, 2023 and 2022, respectively.

We have financed our corporate operations and our technology development through the issuance of convertible debentures, the issuance of preferred stock, the sale of common stock and the exercise of warrants. During the remainder of 2024, we expect to raise additional funds through the issuance of preferred stock, convertible debentures or equity.

On September 29, 2023, we closed an offering of our common stock pursuant to which we sold 28,000,000 shares of common stock, at a purchase price of \$0.25 per share. After deducting underwriting commissions and other offering expenses, we received net proceeds of \$5,472,791.

During the end of the quarter ended June 30, 2023, the Company made some adjustments to its staffing level, and the impact of those adjustments, plus the departure of our chief technology and executive officer, has significantly reduced our monthly burn rate. The Company will further adjust its cost structure if new debt or equity capital is not received. We believe that we have enough available cash to operate until June 30, 2024.

The proceeds of warrants currently outstanding, to the extent not exercised on a cashless basis, may generate potential proceeds. We cannot provide assurance that any of these warrants will be exercised.

**Operating Activities**

Net cash used in operating activities for the three months ended December 31, 2023 and 2022 was \$3,393,000 and \$2,917,000, respectively. The net cash used in operating activities for the three months ended December 31, 2023 was primarily related to (i) a net loss of \$3,447,000; (ii) working capital changes of \$738,000; and offset by (iii) non-cash expenses of \$792,000. The non-cash items include (iv) depreciation and amortization of \$19,000; (v) stock based compensation- stock options of \$699,000; (vi) issuance of common stock for services of \$26,000; and (vii) amortization of operating lease right-of-use asset of \$48,000.

The net cash used in operating activities for the three months ended December 31, 2022 was primarily related to (i) a net loss of 3,823,000; (ii) working capital changes of \$194,000; and (iii) non-cash expenses of \$1,097,000.

**Investing Activities**

Net cash used in investing activities for the three months ended December 31, 2023 and 2022 was \$13,000 and \$11,000, respectively. There amounts were primarily related to the investment in equipment for research and development.

**Financing Activities**

Net cash provided by financing activities for the for the three months ended December 31, 2023 and 2022 was \$203,000 and \$15,000, respectively. The net cash provided by financing activities for the three months ended December 31, 2023 was primarily related to issuance of common stock for a common stock offering, net of expenses of \$203,000. On October 26, 2023, we closed an offering of our common stock pursuant to which we sold 883,061 shares of common stock, at a purchase price of \$0.25 per share. After deducting underwriting commissions and other offering expenses, we received net proceeds of \$203,105.

The net cash provided by financing activities for the three months ended December 31, 2022 was primarily related to (i) proceeds from the issuance of common stock for the exercise of warrants of \$13,000; and (ii) proceeds from the issuance of common stock for the exercise of stock option grants of \$2,000.

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Our contractual cash obligations as of December 31, 2023 are summarized in the table below:

Contractual Cash Obligations (1)	Less Than	
	Total	1 Year
Operating leases	\$ 85,748	\$ 85,748
Convertible notes payable	2,255,066	2,255,066

(1) Convertible notes payable includes \$2,255,066 (excluding \$506,865 adjustment for debt extinguishment accounting) that can be converted into common stock upon demand. We expect to incur capital expenditures related to the development of the “Bio-RFID™” and “ChromaID” technologies. None of the expenditures are contractual obligations as of December 31, 2023.

### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as that term is defined in Item 303 of Regulation S-K) that are reasonably likely to have a current or future material effect on our financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

### Critical Accounting Policies Involving Significant Estimates

The following discussion relates to critical accounting policies for our Company which involve significant estimates. The preparation of financial statements in conformity with United States generally accepted accounting principles, or GAAP, requires our management to make assumptions, estimates and judgments that affect the amounts reported, including the notes thereto, and related disclosures of commitments and contingencies, if any. We have identified certain accounting policies that are significant to the preparation of our financial statements. These accounting policies are important for an understanding of our financial condition and results of operation. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require management’s difficult, subjective, or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Certain accounting estimates are particularly sensitive because of their significance to financial statements and because of the possibility that future events affecting the estimate may differ significantly from management’s current judgments. We believe the following critical accounting policies involve the most significant estimates and judgments used in the preparation of our financial statements:

**Revenue Recognition.** We determine revenue recognition from contracts with customers through the following steps:

- identification of the contract, or contracts, with the customer;
- identification of the performance obligations in the contract;
- determination of the transaction price;
- allocation of the transaction price to the performance obligations in the contract; and
- recognition of the revenue when, or as our company satisfies a performance obligation.

Revenue is recognized when control of the promised goods or services is transferred to the customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services.

**Research and Development Expenses.** Research and development expenses consist of the cost of officers, employees, consultants and contractors who design, engineer and develop new products and processes as well as materials, supplies and facilities used in producing prototypes.

**Fair Value Measurements and Financial Instruments.** ASC Topic 820, *Fair Value Measurement and Disclosures*, defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. This topic also establishes a fair value hierarchy, which requires classification based on observable and unobservable inputs when measuring fair value. The fair value hierarchy distinguishes between assumptions based on market data (observable inputs) and an entity’s own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1 – Quoted prices in active markets for identical assets and liabilities;
- Level 2 – Inputs other than level one inputs that are either directly or indirectly observable; and
- Level 3 - Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

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The recorded value of other financial assets and liabilities, which consist primarily of cash and cash equivalents, accounts receivable, other current assets, and accounts payable and accrued expenses approximate the fair value of the respective assets and liabilities as of December 31, 2023 and September 30, 2023 are based upon the short-term nature of the assets and liabilities.

We have a money market account which is considered a Level 1 asset. The balance as of December 31, 2023 and September 30, 2023 was \$4,787,378, and \$7,836,393, respectively. No other assets or liabilities are required to be recorded at fair value on a recurring nature.

**Derivative Financial Instruments.** Pursuant to ASC 815 “Derivatives and Hedging”, we evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. We then determine if embedded derivative must be bifurcated and separately accounted for. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. For stock-based derivative financial instruments, we use a Black-Scholes-Merton option pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date. We determined that the conversion features for purposes of bifurcation within convertible notes payable issued during 2020 and 2021 were immaterial and as of December 31, 2023 all such convertible notes have been converted to common stock.

**Stock Based Compensation.** We have share-based compensation plans under which employees, consultants, suppliers and directors may be granted restricted stock, as well as options and warrants to purchase shares of common stock at the fair market value at the time of grant. Stock-based compensation cost to employees is measured by us at the grant date, based on the fair value of the award, over the requisite service period under ASC 718. For options issued to employees, we recognize stock compensation costs utilizing the fair value methodology over the related period of benefit.

**Convertible Securities.** Based upon ASC 815-15, we have adopted a sequencing approach regarding the application of ASC 815-40 to convertible securities to determine if an instrument should be accounted for as equity or a liability. We will evaluate our contracts based upon the earliest issuance date.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We had no holdings of derivative financial or commodity instruments at December 31, 2023.

We are exposed to financial market risks, including changes in interest rates. We do not use any financial instruments for speculative or trading purposes. Fluctuations in interest rates would not have a material effect on our financial position, results of operations or cash flows.

### ITEM 4. CONTROLS AND PROCEDURES

#### *a) Evaluation of Disclosure Controls and Procedures*

We conducted an evaluation, under the supervision and with the participation of our management, of the effectiveness of the design and operation of our disclosure controls and procedures. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (“Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures also include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2023, our disclosure controls and procedures are effective at the reasonable assurance level.

#### *b) Inherent Limitations on Internal controls*

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. A control system, no matter how well designed and operated can provide only reasonable, but not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their cost.

#### *c) Changes in Internal Control over Financial Reporting*

During the three months ended December 31, 2023, there were no other changes in our internal controls over financial reporting, which were identified in connection with our management's evaluation required by paragraph (d) of rules 13a-15 and 15d-15 under the Exchange Act, that materially affected, or is reasonably likely to have a material effect on our internal control over financial reporting.

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## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

We may from time to time become a party to various legal proceedings arising in the ordinary course of our business. We are currently not a party to any pending legal proceeding that is not ordinary routine litigation incidental to our business.

### ITEM 1A. RISK FACTORS

#### Summary of Risk Factors

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. These risks are discussed more fully in the “*Risk Factors*” section immediately following this summary. These risks include, but are not limited to, the following:

#### Risks Related to Our Business and Industry

- We might not be able to continue as a going concern. We believe that our cash on hand will be sufficient to fund our operations at least through June 30, 2024;
- We are still in the early stages of commercialization, refining our technology. Our success depends on our ability to conclude development and market devices that are recognized as accurate, safe, and cost-effective as other options currently available in the market and cleared by FDA.
- We are subject to extensive regulation by FDA, which could restrict the sales and marketing of our products and could cause us to incur significant costs;

#### Risks Related to Ownership of Our Common Stock

- The market price of our common stock may fluctuate, and you could lose all or part of your investment.
- We may not be able to maintain a listing of our common stock on the NYSE American.
- We do not expect to declare or pay dividends in the foreseeable future.
- Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock-up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our securities to decline and would result in the dilution of your holdings.
- Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect the level of return you may be able



to achieve from an investment in our common stock.

## RISK FACTORS

*An investment in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, together with all of the other information contained or referred to in this report, before making an investment decision with respect to our common stock. If any of the following events occur, our financial condition, business and results of operations (including cash flows) may be materially adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment.*

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### Risks Related to Our Business and Industry

***We need additional financing to support our technology development and ongoing operations, pay our debts and maintain ownership of our intellectual property.***

We are currently operating at a loss and using substantial cash to fund our operation. We believe that our cash on hand will be sufficient to fund our operations through June 30, 2024. We may need additional financing to implement our business plan and to service our ongoing operations, pay our current debts (described below) and maintain ownership of our intellectual property. There can be no assurance that we will be able to secure any needed funding, or that if such funding is available, the terms or conditions would be acceptable to us. If we are unable to obtain additional financing when it is needed, we will need to restructure our operations and/or divest all or a portion of our business. We are seeking additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt. Equity financing, if obtained, could result in dilution to our then-existing stockholders and/or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back, eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. There can be no assurance that we will be able to sell that number of shares, if any.

***We need to continue as a going concern if our business is to succeed.***

Because we have generated limited revenues and currently operate at a loss, we are completely dependent on the continued availability of financing in order to continue our business. There can be no assurance that financing sufficient to enable us to continue our operations will be available to us in the future.

We have cash and cash equivalents of \$4,821,000 and net working capital of approximately \$3,796,000 (exclusive of convertible notes payable) as of December 31, 2023. We anticipate that we will record losses from operations for the foreseeable future. We believe that we have enough available cash to operate until June 30, 2024. As of December 31, 2023, our accumulated deficit was \$125,351,000. We intend to seek additional cash via equity and debt offerings. As a result of not having at least twelve months of cash available and not having any firm commitment for debt or equity financing, substantial doubt about the Company's ability to continue on a going concern exists.

We have financed our corporate operations and our technology development through the issuance of convertible debentures, the issuance of preferred stock, the sale of common stock and the exercise of warrants. During the remainder of 2024, we expect to raise additional funds through the issuance of preferred stock, convertible debentures or equity.

The proceeds of warrants currently outstanding, to the extent not exercised on a cashless basis, may generate potential proceeds. We cannot provide assurance that any of these warrants will be exercised.

***As of December 31, 2023, we owed approximately \$2,958,000 and if we do not satisfy these obligations, the lenders may have the right to demand payment in full or exercise other remedies.***

We owe \$2,762,000 under various convertible promissory notes as of December 31, 2023, including \$1,301,000 to Clayton Struve who owns 100% of outstanding Series C and D Preferred stock, and \$1,461,000 owed to entities controlled by Ronald P. Erickson, our CEO and Chairman. Mr. Erickson and/or entities with which he is affiliated also have accounts payable and accrued liabilities \$196,000 as of December 31, 2023 related to accrued interest. We may need additional financing, to service and/or repay these debt obligations. If we raise additional capital through borrowing or other debt financing, we may incur substantial interest expense. If and when we raise more equity capital in the future, it will result in substantial dilution to our current stockholders.

***We have a history of operating losses and there can be no assurance that we can achieve or maintain profitability.***

We have experienced net losses since inception. As of December 31, 2023, we had an accumulated deficit of \$125,351,000 and net losses in the amount of \$3,447,000, \$15,289,000 and \$20,071,000 during the three months ended December 31, 2023 and years ended September 30, 2023 and 2022, respectively. There can be no assurance that we will achieve or maintain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital. Our operating expenses may increase as we spend resources on growing our business, and if our revenue does not correspondingly increase, our operating results and financial condition will suffer. Our businesses have produced minimal revenues and may not produce significant revenues in the near term, or at all, which would harm our ability to continue our operations or obtain additional financing and require us to reduce or discontinue our operations. You must consider our business and prospects in light of the risks and difficulties we will encounter as business with an early-stage technology in a new and rapidly evolving industry. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results, financial condition and common stock price per share.

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***We may not be able to generate sufficient revenue from the commercialization of our technology and related products to achieve or sustain profitability.***

We are in the early stages of commercializing our technology. Failure to develop and sell products based upon our technology could have a material adverse effect on our business, financial condition and results of operations. To date, we have not generated revenue from sales of our technology or products. We believe that our commercialization success is dependent upon our ability to significantly increase the number of customers that will use our products. In addition, demand for our products may not materialize, or increase as quickly as planned, and we may therefore be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in introducing our technology and related products to our target markets, we may not be able to generate sufficient revenue to achieve or sustain profitability.

*We are subject to extensive regulation by the U.S. Food and Drug Administration, which could require us to take significant time and could cause us to incur significant costs.*

Our KnowU and UBand glucose monitoring products are subject to extensive regulation by FDA. These regulations relate to manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new intended use of a legally marketed device, can be marketed in the United States, it must be cleared or approved by FDA through the applicable premarket review process (510(k), PMA, or de novo classification), unless an exemption applies.

The KnowU and UBand glucose monitoring products and substantially equivalent devices of this type that may later receive marketing authorization are similar to products referred to as integrated continuous glucose monitoring (CGM) systems. Integrated continuous glucose monitoring systems are generally classified by FDA as Class II devices and have established special controls outlining requirements for assuring CGM accuracy, reliability, and clinical relevance. FDA also has descriptions of the types of studies and data required to demonstrate acceptable CGM performance. Though it is our current belief that our initial product, the KnowU and UBand glucose monitoring products, are appropriate for a de novo classification request (i.e., a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device that is described in more detail below), we expect similar classification, special controls, and testing.

If we receive 510(k) clearance for our KnowU and UBand glucose monitoring products, we may be required to obtain new 510(k) clearances for significant post-market modifications. Each premarket submission and review process can be expensive and lengthy, and entail significant user fees, unless exempt. The classification and special controls for all other products using the Company's proprietary radio frequency and microwave spectroscopy platform will be dependent on product type and explored as applicable.

In addition, regulatory clearance or approval by FDA does not ensure registration, clearance, approval, or certification by regulatory authorities or notified bodies internationally. While the regulatory requirements for marketing in international markets may require that we obtain clearance, approval, or certification by an international specified regulatory body or notified body. Complying with foreign regulatory requirements, including obtaining registrations, clearances, approvals, or certifications, can be expensive and time consuming, and we may not receive regulatory clearances, approvals, or certifications in each country or region in which we plan to market our products or we may be unable to do so on a timely basis. In turn, this could limit our expected international growth and profitability, which could have a material adverse effect on our business, financial condition, and results of operations.

*The clinical trial process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.*

Clinical trials are generally required to support an application for clearance of a new device type such as our KnowU and UBand glucose monitoring products. All clinical trials must be conducted in accordance with FDA's Investigational Device Exemption (IDE) regulations, which govern investigational device labeling, prohibit promotion, and specify an array of Good Clinical Practice requirements, which include among other things, recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by FDA.

Results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for FDA to grant approval or clearance of a product. In addition, the commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following:

- we may be required to submit an investigational device exemption application, or IDE, to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE and notify us that we may not begin clinical trials;

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- the cost of clinical trials may be greater than we anticipate;
- FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to our products;
- we may not reach agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- institutional review boards and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or other FDA requirements;
- data collection, monitoring, and analysis is not performed in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions applicable to our trial protocols, including, for example, recent legislation passed by Congress requiring clinical trial sponsors to increase engagement with FDA on matters related to appropriate representation of racial and ethnic minorities in clinical trial data for pivotal studies;

- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; and
- FDA concludes that the results from our trial and/or trial design are inadequate to demonstrate safety and effectiveness of the product.

Additionally, the ability of FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, the availability of industry-paid user fees, and statutory, regulatory, and policy changes. Average review times for product approvals at FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at FDA and other agencies, including those resulting from global concerns (e.g., the ongoing COVID-19 global pandemic), may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, if a prolonged government shutdown and/or government employee furloughs were to occur, or if FDA's response to a global issue diverts FDA resources and attention to other regulatory efforts, then the ability of FDA to timely review and process our regulatory submissions could be significantly impacted, which could have a material adverse effect on our business, financial condition, and results of operations. Further, in our operations as a public company, future government shutdowns, furloughs, or public health emergencies could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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Moreover, even if our products are cleared in the U.S., commercialization of our products in foreign countries would require clearance or approval by regulatory authorities in those countries. Clearance or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials.

***The safety and efficacy of our products is not yet supported by long-term clinical data, which could limit sales, and our products might therefore prove to be less safe or effective than initially thought.***

Given the regulatory environment in which we operate, we lack the breadth of published long-term clinical data supporting the safety and efficacy of The KnowU and UBand glucose monitoring products and the benefits it offers that might have been generated in connection with other marketing authorization pathways. For these reasons, clinicians may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our product does not improve patient outcomes. Such results would slow the adoption of our product by physicians, would significantly reduce our ability to achieve expected sales, and could prevent us from achieving and maintaining profitability.

In addition, because the KnowU and UBand glucose monitoring products have never been marketed, we have limited complaints or patient success rate data with respect to using these products. If future patient studies or clinical testing do not support our belief that our products offer a more advantageous blood glucose monitoring, then market acceptance of our products could fail to increase or could decrease, and our business could be harmed. Moreover, if future results and experience indicate that our product has potentially recurring malfunctions or causes unexpected or serious complications or other unforeseen negative effects, then we could be subject to mandatory or voluntary product recalls, suspension or withdrawal of FDA clearance, as well as significant legal liability or harm to our business reputation and financial results.

If we choose to, or are required to, conduct additional clinical studies and the outcome of such studies are not positive, then this could reduce the rate of coverage and reimbursement for the KnowU and UBand glucose monitoring products. This may slow the market adoption of our product by physicians, significantly reduce our ability to achieve expected revenues and prevent us from becoming profitable.

We believe that publications of scientific and medical results in peer-reviewed journals and presentations at leading conferences are critical to the broad adoption of our products. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our products sufficiently novel or worthy of publication. The failure to be listed in physician guidelines or to be published in peer-reviewed journals could limit the adoption of our products. Unless specifically stated to be "peer-reviewed," the studies referred to in this filing are not peer reviewed.

***We are subject to extensive regulation which could restrict the sales and marketing of our products and could cause us to incur significant costs.***

Medical devices may be marketed only for the indications for which they are approved or cleared. Further, clearances can be revoked if safety or effectiveness problems develop once the device is on the market.

The current regulatory requirements to which we are subject may change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by FDA, which may include any of the following sanctions:

- modification to our training and promotional materials;
- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;
- administrative detention by FDA of medical devices believed to be adulterated or misbranded;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for clearance, PMA or *de novo* classification of any new products, new intended uses or modifications to our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- withdraws or suspension of 510(k) clearance that has already been granted, resulting in prohibitions on sales of our products; and
- criminal prosecution.

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The occurrence of any of these events would have a material adverse effect on our business, financial condition and results of operations and could result in stockholders losing their entire investment.

Additionally, any relationships we may have with healthcare professionals, clinical investigators, and payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers and payors play a primary role in the recommendation and/or prescription of any product candidates for which we obtain future marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, payors, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services (CMS) starting in 2022 information regarding payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported will be publicly available on a searchable website, with disclosure required annually; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

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Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, then we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, temporary or permanent debarment, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, then they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

*A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.*

We may seek regulatory approval of our product candidates outside of the U.S., and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

***We may face difficulties with respect to coverage and reimbursement by various payors.***

Sales of any medical device depend often, in part, on the extent to which the product will be covered and reimbursed by government payors (e.g., federal and state healthcare programs), third-party payors (e.g., commercial insurance and managed healthcare organizations), and other payors (e.g., foreign government healthcare programs). In the United States, various glucose monitoring products are covered for individuals with both Type 1 and Type 2 diabetes by Medicare and Medicaid in the majority of states and by commercial insurers, subject to satisfaction of certain eligibility and coverage criteria.

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But significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. For example, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by payors, that an adequate level of reimbursement will be established even if coverage is available, or that the payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Decisions regarding the extent of coverage and reimbursement amount are generally made on a plan-by-plan basis meaning one payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. As a result, the coverage determination process can require manufactures to provide scientific and clinical support for the use of a product, and require providers to show medical necessity for use, to each payor separately. This process can be time-consuming, with no assurance that coverage and adequate reimbursement will be applied consistently or even obtained.

Payors are also increasingly reducing reimbursements for devices through continued implementation of cost-containment programs, including price controls and restrictions on coverage and reimbursement, which could further limit sales of any product. In addition, payors continue to question safety and efficacy while also challenging the prices charged, examining medical necessity and reviewing the cost effectiveness of devices in an effort to avoid coverage and reimbursement. But decreases of this nature surrounding the reimbursement for any product or a decision by a government and third-party payor not to cover a product could result in reduced physician usage and patient demand for the product.

Moreover, in international markets, reimbursement and healthcare payment systems vary significantly by country, with many countries have instituted price ceilings on specific products and therapies.

***The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of FDA or another governmental authority, could have a negative impact on us.***

We are subject to FDA's medical device reporting regulations, which require us to report to FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event.

We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the initial use of the device. If we fail to comply with our reporting obligations, FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, seizure of our products, or, if premarket review is required in the future, delay in clearance of future products.

FDA and foreign regulatory bodies have the authority to require the recall of commercialized medical device products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. We cannot assure you that product defects or other errors will not occur in the future. Recalls involving our products could have a material adverse effect on our business, financial condition, and results of operations.

Moreover, medical device manufacturers are required to maintain certain records of recalls and corrections, even if they are not reportable to FDA. We may initiate voluntary withdrawals or corrections for our devices in the future that we determine do not require notification of FDA. If FDA disagrees with our determinations, then it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability and malpractice claims against us and negatively affect our sales.

***We may face difficulties from changes to current regulations and future legislation, both in the U.S. as well as in other foreign jurisdictions where we may be operating.***



Existing regulations and regulatory policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. Legislative changes may impact our future business and operations, including those that may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our business, financial condition, and results of operations.

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Both before and after a product is commercially released, we have ongoing responsibilities under various laws and regulations. If a regulatory authority were to conclude that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable risk for the end-user, then the authority may ban such devices, detain or seize adulterated or misbranded devices, order a recall, repair, replacement, or refund of such instruments, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. A regulatory authority may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The regulatory authority may also recommend prosecution by law enforcement agencies. Any governmental law or regulation, existing or imposed in the future, or enforcement action taken may have a material adverse effect on our business, financial condition, and results of operations.

We cannot predict the likelihood, nature, or extent of any legislative changes will be enacted or government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. Similarly, we cannot predict whether FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, then we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***Our industry is highly competitive and subject to significant or rapid technological change.***

Our fields of therapeutic interest is highly competitive and subject to significant and rapid technological change. Accordingly, our success may depend, in part, on our ability to respond quickly to such change through the development and introduction of new products.

If our product candidates are approved by FDA, then potential competitors who seek to introduce similar product candidates may seek to take advantage of a shorter and less costly development program for a product that competes with our products. Our ability to compete successfully against currently existing and future alternatives to our product candidates and systems and competitors who compete directly with us may depend, in part, on our ability to attract and retain skilled scientific and research personnel, develop technologically superior products, develop competitively priced products, obtain patent or other required regulatory approvals for our products, be an early entrant to the market and manufacture, market, and sell our products, independently or through collaborations.

***We currently rely upon external resources for many engineering and product development services. If we are unable to secure engineering or product development partners or establish satisfactory engineering and product development capabilities, we may not be able to successfully commercialize our technology.***

Our success depends upon our ability to develop products that are accurate and provide solutions for our customers. Achieving the desired results for our customers requires solving engineering issues in concert with them. Any failure of our technology or related products to meet customer expectations could result in customers choosing to retain their existing methods or to adopt systems other than ours.

Historically, we have not had sufficient internal resources to work on all necessary engineering and product development matters. We have used third parties in the past and will continue to do so. These resources are not always readily available, and the absence of their availability could inhibit our research and development efforts and our responsiveness to our customers. Our inability to secure those resources could impact our ability to provide engineering and product development services and could have an impact on our customers' willingness to use our technology. Moreover, third parties have their own internal demands on time and resources which may not always align with ours. Hence, our own expectations for development and product timelines may not be shared by third parties upon whom we rely.

***We are in the early stages of commercialization and our technology and related products may never achieve significant commercial market acceptance.***

Our success depends on our ability to develop and market devices that are recognized as accurate, safe and cost-effective. They must be safe and deliver the required level of accuracy under any condition, regardless of the user, as determined by their intended use. This will be achieved through continued refinement of our technology. Before presenting it to the FDA, additional development is needed to increase its generalizability.

Many of our potential customers may be reluctant to use our new technology. Market acceptance will depend on many factors, including our ability to convince potential customers that our technology and related products are an attractive alternative to existing technologies. We will need to demonstrate that our products provide accurate and cost-effective alternatives to existing technologies. Compared to most competing technologies, our technology is new, and most potential customers will have limited knowledge of, or experience with, our products. Prior to implementing our technology and related products, some potential customers may be required to devote significant time and effort to testing and validating our products. Any failure of our technology or related products to meet customer expectations could result in customers choosing to retain their existing methods or to adopt systems other than ours.

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Many factors influence the perception of a new technology including its use by leaders in the industry. If we are unable to induce industry leaders in our target markets to implement and use our technology and related products, acceptance and adoption of our products could be slowed. In addition, if our products fail to gain significant acceptance in the marketplace and we are unable to expand our customer base, we may never generate sufficient revenue to achieve or sustain profitability.

Additionally, we may not be able to penetrate or successfully operate in international markets or encounter difficulty expanding into international markets because of limited brand recognition in certain parts of the world, which may lead to delayed acceptance of our products by consumers in these international markets. If we are unable to expand internationally and manage the complexity of international operations successfully, then it could have a material adverse effect on our business, financial condition, and results of operations. If our efforts to introduce our products into foreign markets are not successful, then we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

***We are dependent on key personnel.***



Our success depends to a significant degree upon the continued contributions of key management and other personnel, some of whom could be difficult to replace. While our continued operation and ultimate success is not dependent upon one individual, our success does depend on the performance of our officers, our ability to retain and motivate our officers, our ability to integrate new officers into our operations, and the ability of all personnel to work together effectively as a team. Our failure to retain and recruit officers and other key personnel could have a material adverse effect on our business, financial condition and results of operations. Our success also depends on our continued ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial, manufacturing, administrative and sales and marketing personnel. Competition for these individuals is intense, and we may not be able to successfully recruit, assimilate or retain sufficiently qualified personnel. In particular, we may encounter difficulties in recruiting and retaining a sufficient number of qualified technical personnel, which could harm our ability to develop new products and adversely impact our relationships with existing and future customers. The inability to attract and retain necessary technical, managerial, manufacturing, administrative and sales and marketing personnel could harm our ability to obtain new customers and develop new products and could adversely affect our business and operating results.

***We rely on the timely supply of components and parts and could suffer if suppliers fail to meet their delivery obligations, raise prices or cease to supply us with components or parts.***

The manufacture of our products is complex and requires the integration of a number of components from several sources of supply. We rely on numerous critical suppliers for various key components that are used in the manufacturing of our products. We can make no assurance that we will be able to maintain such supply arrangements. If we are unable to maintain supply arrangements, our access to key components could be reduced, which could harm our business.

Additionally, if demand for our products decreases, we may have excess inventory and inventory that may expire, which could result in inventory write-offs that would have a material adverse effect on our business, financial condition, and results of operations. We may also encounter defects in materials and/or workmanship, which could lead to a failure to adhere to regulatory requirements. Any defects could delay operations at our contract manufacturers' facilities, lead to regulatory fines, or halt or discontinue manufacturing indefinitely. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations.

This reliance also adds additional risks to the manufacturing process that are beyond our control. For example, the occurrence of epidemics or pandemics may cause one or more of our suppliers to close or reduce the scope of their operations either temporarily or permanently. In addition, these suppliers may provide components and products to our competitors. The medical device industry's reliance on a limited number of key components and product suppliers subjects us to the risk that in the event of an increase in demand, our suppliers may fail to provide supplies to us in a timely manner while they continue to supply our competitors, many of which have greater purchasing power than us, or seek to supply components to us at a higher cost.

The failure of our suppliers to deliver components or products in a timely fashion could have disruptive effects on our ability to produce our products in a timely manner, or we may be required to find new suppliers at an increased cost.

Moreover, our reputation and the quality of our products are in part dependent on the quality of the components that we source from third-party suppliers. If we are unable to control the quality of the components supplied to us or to address known quality problems in a timely manner, then our reputation in the market may be damaged and sales of our products may suffer. As a result, we may experience a material adverse effect on our business, financial condition, and results of operations.

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***We have limited insurance which may not cover claims by third parties against us or our officers and directors.***

We have directors' and officers' liability insurance and commercial liability insurance policies. Claims, however, by third parties against us may exceed policy amounts and we may not have amounts to cover these claims. Any significant claims would have a material adverse effect on our business, financial condition and results of operations. In addition, our limited directors' and officers' liability insurance may affect our ability to attract and retain directors and officers.

***Our inability to effectively protect our intellectual property would adversely affect our ability to compete effectively, our revenue, our financial condition and our results of operations.***

We rely on a combination of patent, trademark, and trade secret laws, and confidentiality procedures to protect our intellectual property rights. Creating and maintaining a strong patent portfolio is important to our business. Patent law relating to the scope of claims in the technology fields in which we operate is complex and uncertain, so we cannot be assured that we will be able to obtain or maintain patent rights, or that the patent rights we may obtain will be valuable, provide an effective barrier to competitors or otherwise provide competitive advantages. Others have filed, and in the future are likely to file, patent applications that are similar or identical to ours or those of our licensors. To determine the priority of inventions or demonstrate that we did not derive our invention from another, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office or in court that could result in substantial costs in legal fees and could substantially affect the scope of our patent protection. We cannot be assured our patent applications will prevail over those filed by others. Also, our intellectual property rights may be subject to other challenges by third parties. Patents we obtain could be challenged in litigation or in administrative proceedings such as *ex parte* reexam, *inter partes* review, or post grant review in the United States or opposition proceedings in Europe or other jurisdictions.

There can be no assurance that:

- any of our existing patents will continue to be held valid, if challenged;
- patents will be issued for any of our pending applications;
- any claims allowed from existing or pending patents will have sufficient scope or strength to protect us;
- our patents will be issued in the primary countries where our products are sold in order to protect our rights and potential commercial advantage; or
- any of our products or technologies will not infringe on the patents of other companies.

If we are prevented from selling our products, or if we are required to develop new technologies or pay significant monetary damages or are required to make substantial royalty payments, our business and results of operations would be harmed.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of

a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or interferences against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could have a material adverse effect on our results of operations and business.

***Claims by others that our products infringe their patents or other intellectual property rights could prevent us from manufacturing and selling some of our products or require us to pay royalties or incur substantial costs from litigation or development of non-infringing technology.***

In recent years, there has been significant litigation in the United States involving patents and other intellectual property rights. We may receive notices that claim we have infringed upon the intellectual property of others. Even if these claims are not valid, they could subject us to significant costs. Any such claims, with or without merit, could be time-consuming to defend, result in costly litigation, divert our attention and resources, cause product shipment delays or require us to enter into royalty or licensing agreements. Such royalty or licensing agreements, if required, may not be available on terms acceptable to us or at all. We have not been engaged in litigation but litigation may be necessary in the future to enforce our intellectual property rights or to determine the validity and scope of the proprietary rights of others. Litigation may also be necessary to defend against claims of infringement or invalidity by others. A successful claim of intellectual property infringement against us and our failure or inability to license the infringed technology or develop or license technology with comparable functionality could have a material adverse effect on our business, financial condition and operating results.

The analysis of our patent portfolio by PatSnap Research and ipCapital Group is not a legal analysis and does not predict the outcome of any legal challenges we or others might make in regard to patents, nor does it constitute a view on the overall legal strength of our patents.

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***If we are unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities at our company, we may not be able to successfully commercialize our technology.***

If we are not successful entering into appropriate collaboration arrangements or recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing our technology, which would adversely affect our business, operating results and financial condition.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. In addition, we must compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize technology without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

***We may engage in acquisitions, mergers, strategic alliances, joint ventures and divestitures that could result in final results that are different than expected.***

In the normal course of business, we engage in discussions relating to possible acquisitions, equity investments, mergers, strategic alliances, joint ventures and divestitures. Such transactions are accompanied by a number of risks, including the use of significant amounts of cash, potentially dilutive issuances of equity securities, incurrence of debt on potentially unfavorable terms as well as impairment expenses related to goodwill and amortization expenses related to other intangible assets, the possibility that we may pay too much cash or issue too many of our shares as the purchase price for an acquisition relative to the economic benefits that we ultimately derive from such acquisition, and various potential difficulties involved in integrating acquired businesses into our operations.

From time to time, we have also engaged in discussions with candidates regarding the potential acquisitions of our product lines, technologies and businesses. If a divestiture such as this does occur, we cannot be certain that our business, operating results and financial condition will not be materially and adversely affected. A successful divestiture depends on various factors, including our ability to effectively transfer liabilities, contracts, facilities and employees to any purchaser; identify and separate the intellectual property to be divested from the intellectual property that we wish to retain; reduce fixed costs previously associated with the divested assets or business; and collect the proceeds from any divestitures.

If we do not realize the expected benefits of any acquisition or divestiture transaction, our financial position, results of operations, cash flows and stock price could be negatively impacted.

***We may make strategic acquisitions in the future, and if the acquired companies do not perform as expected, this could adversely affect our operating results, financial condition and existing business.***

We may continue to expand our business through strategic acquisitions. The success of any acquisition will depend on, among other things:

- the availability of suitable candidates;
- higher than anticipated acquisition costs and expenses;

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- competition from other companies for the purchase of available candidates;

- our ability to value those candidates accurately and negotiate favorable terms for those acquisitions;
- the availability of funds to finance acquisitions and obtaining any consents necessary under our credit facility;
- the ability to establish new informational, operational and financial systems to meet the needs of our business;
- the ability to achieve anticipated synergies, including with respect to complementary products or services; and
- the availability of management resources to oversee the integration and operation of the acquired businesses.

We may not be successful in effectively integrating acquired businesses and completing acquisitions in the future. We also may incur substantial expenses and devote significant management time and resources in seeking to complete acquisitions. Acquired businesses may fail to meet our performance expectations. If we do not achieve the anticipated benefits of an acquisition as rapidly as expected, or at all, investors or analysts may not perceive the same benefits of the acquisition as we do. If these risks materialize, our stock price could be materially adversely affected.

***Government regulatory approval may be necessary before some of our products can be sold and there is no assurance such approval will be granted.***

Our technology will have a number of potential applications in fields of use that will require prior governmental regulatory approval before the technology can be introduced to the marketplace. For example, we are exploring the use of our technology for certain medical diagnostic applications, with an initial focus on the monitoring of blood glucose. There is no assurance that we will be successful in developing glucose monitoring medical applications for our technology. If we were to be successful in developing glucose monitoring medical applications of our technology, prior clearance by FDA and other governmental regulatory bodies will be required before the technology could be introduced into the marketplace. Our devices leverage Machine Learning (ML) and Artificial Intelligence (AI) to process the massive data collected through the Bio-RFID sensor. ML/AI also controls the sensor operation, enabling the device to emit and capture data, and, ultimately, to identify and measure blood glucose levels. Machine learning-enabled device software functions (ML-DSF) continue to be evaluated by FDA, which recently released new guidance proposing a science-based approach for AI/ML-enabled medical devices to be modified and improved more quickly. There is no assurance that such regulatory approval would be obtained for a glucose monitoring medical diagnostic device or other applications requiring such approval. FDA can refuse to grant, delay, and limit or deny approval of an application for clearance of marketing a glucose monitoring device for many reasons. We may not obtain the necessary regulatory approvals or clearances to market these glucose monitoring systems in the United States or outside of the United States. Any delay in, or failure to receive or maintain, approval or clearance for our products could prevent us from generating revenue from these products or achieving profitability.

***We or our manufacturers may be unable to obtain or maintain international regulatory clearances or approvals for our current or future products, or our distributors may be unable to obtain necessary qualifications, which could harm our business thus limited sales to the U.S.***

Sales of our products internationally are subject to foreign regulatory requirements that vary widely from country to country. In addition, FDA regulates exports of medical devices from the U.S. Complying with international regulatory requirements can be an expensive and time-consuming process, and marketing approval or clearance is not certain. The time required to obtain clearances or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We may rely on third-party distributors to obtain regulatory clearances and approvals required in other countries, and these distributors may be unable to obtain or maintain such clearances or approvals. Our distributors may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or clearances, which could increase the difficulty of attracting and retaining qualified distributors. If our distributors experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the U.S., or if they fail to receive those qualifications, clearances or approvals, then we may be unable to market our products or enhancements in international markets effectively, or at all.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products outside of the U.S., we may be subject to rigorous international regulation in the future. In these circumstances, we would be required to rely on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our product in foreign countries.

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***Cybersecurity risks and cyber incidents could result in the compromise of confidential data or critical data systems and give rise to potential harm to customers, remediation and other expenses, expose us to liability under consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations.***

Cyber incidents can result from deliberate attacks or unintentional events. We collect and store on our networks sensitive information, including intellectual property, proprietary business information and personally identifiable information of our customers. The secure maintenance of this information and technology is critical to our business operations. We have implemented multiple layers of security measures to protect the confidentiality, integrity and availability of this data and the systems and devices that store and transmit such data. We utilize current security technologies, and our defenses are monitored and routinely tested internally and by external parties. Despite these efforts, threats from malicious persons and groups, new vulnerabilities and advanced new attacks against information systems create risk of cybersecurity incidents. These incidents can include, but are not limited to, gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these incidents or techniques, timely discover them, or implement adequate preventative measures.

These threats can come from a variety of sources, ranging in sophistication from an individual hacker to malfeasance by employees, consultants or other service providers to state-sponsored attacks. Cyber threats may be generic, or they may be custom crafted against our information systems. Over the past several years, cyber-attacks have become more prevalent and much harder to detect and defend against. Our network and storage applications may be vulnerable to cyber-attack, malicious intrusion, malfeasance, loss of data privacy or other significant disruption and may be subject to unauthorized access by hackers, employees, consultants or other service providers. In addition, hardware, software or applications we develop or procure from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information security. Unauthorized parties may also attempt to gain access to our systems or facilities through fraud, trickery or other forms of deceiving our employees, contractors and temporary staff.

There can be no assurance that we will not be subject to cybersecurity incidents that bypass our security measures, impact the integrity, availability or privacy of personal health information or other data subject to privacy laws or disrupt our information systems, devices or business, including our ability to deliver services to our customers. As a result, cybersecurity, physical security and the continued development and enhancement of our controls, processes and practices designed to protect our enterprise, information systems and data from attack, damage or unauthorized access remain a priority for us. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any cybersecurity vulnerabilities.

Additionally, the U.S. may institute additional cybersecurity requirements especially for medical devices. For example, the data security requirements in the Food and Drug Omnibus Reform Act (“FDORA”), enacted in December 2022, that among other provisions, requires developers of certain “cyber devices” to design and implement plans to monitor, identify and address cybersecurity vulnerabilities of those devices and to submit those plans to FDA as part of every new 510(k) or PMA for a cyber device. “Cyber devices” are defined as devices that include software, connect to the internet, and contain any technological features that could be vulnerable to cybersecurity threats. This provision entered into effect on March 29, 2023, and FDA has indicated that it expects sponsors of cyber devices to begin to comply with these requirements as of October 1, 2023. FDA has stated that failure to comply with these requirements will result in FDA denying approval of the cyber device application.

***We are subject to corporate governance and internal control requirements, and our costs related to compliance with, or our failure to comply with existing and future requirements could adversely affect our business.***

We must comply with corporate governance requirements under the Sarbanes-Oxley Act of 2002 and the Dodd–Frank Wall Street Reform and Consumer Protection Act of 2010, as well as additional rules and regulations currently in place and that may be subsequently adopted by the Securities and Exchange Commission, or the SEC, and the Public Company Accounting Oversight Board. These laws, rules, and regulations continue to evolve and may become increasingly stringent in the future. The financial cost of compliance with these laws, rules, and regulations is expected to remain substantial.

We cannot assure you that we will be able to fully comply with these laws, rules, and regulations that address corporate governance, internal control reporting, and similar matters in the future. Failure to comply with these laws, rules and regulations could materially adversely affect our reputation, financial condition, and the value of our securities.

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### **Risks Related to Ownership of Our Common Stock**

***If we are unable to comply with the continued listing requirements of the NYSE American, then our common stock would be delisted from the NYSE American, which would limit investors’ ability to effect transactions in our common stock and subject us to additional trading restrictions.***

Our common stock is currently listed on the NYSE American and the continued listing of our common stock on the NYSE American is contingent on our continued compliance with a number of listing requirements. If we are unable to comply with the continued listing requirements of the NYSE American, our common stock would be delisted from the NYSE American, which would limit investors’ ability to effect transactions in our common stock and subject us to additional trading restrictions. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders’ equity and a minimum number of public stockholders, as well as satisfy other listing requirements of the NYSE American. In addition to these objective standards, NYSE American may delist the securities of any issuer for other reasons involving the judgment of NYSE American.

We have been informally advised by the staff of NYSE American that, given our current stockholders equity and history of net losses, we may be subject to the equity standards set forth in Section 1003(a)(ii) and (iii) of the NYSE American Company Guide, and that we may not satisfy these standards or the exemption criteria for these standards. There is no assurance that we will be able to maintain compliance with the NYSE American continued listing rules and/or continue its listing on the NYSE American in the future.

If the NYSE American delists our common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect the common stock would qualify to be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- substantially impair our ability to raise additional funds;
- result in a loss of institutional investor interest and a decreased ability to issue additional securities or obtain additional financing in the future;
- a determination that our common stock is a “penny stock,” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- potential breaches of representations or covenants of our agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements, which, regardless of merit, could result in costly litigation, significant liabilities and diversion of our management’s time and attention and could have a material adverse effect on our financial condition, business and results of operations.

The price of our common stock is volatile, which may cause investment losses for our stockholders.

The market price of our common stock has been and is likely in the future to be volatile. Our common stock price may fluctuate in response to factors such as:

- Announcements by us regarding liquidity, significant acquisitions, equity investments and divestitures, strategic relationships, addition or loss of significant customers and contracts, capital expenditure commitments and litigation;
- Issuance of convertible or equity securities and related warrants for general or merger and acquisition purposes;
- Issuance or repayment of debt, accounts payable or convertible debt for general or merger and acquisition purposes;
- Sale of a significant number of shares of our common stock by stockholders;
- General market and economic conditions;
- Quarterly variations in our operating results;
- Investor and public relation activities;

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- Announcements of technological innovations;
- New product introductions by us or our competitors;
- Competitive activities;
- Low liquidity; and
- Additions or departures of key personnel.

These broad market and industry factors may have a material adverse effect on the market price of our common stock, regardless of our actual operating performance. These factors could have a material adverse effect on our business, financial condition, and results of operations.

***The sale of a significant number of our shares of common stock could depress the price of our common stock.***

As of December 31, 2023, we had 81,346,524 shares of common stock issued and outstanding. As of December 31, 2023, there were options outstanding for the purchase of 28,220,473 shares of our common stock (including unearned stock option grants totaling 4,179,825 shares related to performance targets), warrants for the purchase of 20,984,961 shares of our common stock, 8,108,356 shares of the Company's common stock issuable, collectively, upon the conversion of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock, and approximately 3,201,534 shares of our common stock, collectively, reserved to pay accrued dividends on our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock. In addition, the Company currently has 9,020,264 shares of its common stock at the current price of \$0.25 per share reserved and are issuable upon conversion of convertible debentures of \$2,761,931. Further, under the current terms of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock, and assuming no changes in the ownership thereof, going forward on a quarterly basis the Company will accrete as a preferred dividend the value of approximately 160,000 shares of common stock, which are issuable if such dividends become payable as additional shares of preferred stock, and such preferred stock is then converted into common stock. All of the foregoing shares could potentially dilute future earnings per share but are excluded from the December 31, 2023, calculation of net loss per share because their impact is antidilutive.

Significant shares of common stock are held by our principal stockholders, other company insiders and other large stockholders. As "affiliates," as defined under Rule 144 under the Securities Act, our principal stockholders, other of our insiders and other large stockholders may only sell their shares of common stock in the public market pursuant to an effective registration statement or in compliance with Rule 144.

These options, warrants, convertible notes payable and convertible preferred stock could result in further dilution to common stockholders and may affect the market price of the common stock.

***Future capital raises or other issuances of equity or debt securities may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.***

Pursuant to our articles of incorporation, we are authorized to issue 200,000,000 shares of common stock. To the extent that common stock is available for issuance, subject to compliance with applicable stock exchange listing rules, our board of directors has the ability to issue additional shares of common stock in the future for such consideration as the board of directors may consider sufficient. The issuance of any additional shares could, among other things, result in substantial dilution of the percentage ownership of our stockholders at the time of issuance, result in substantial dilution of our earnings per share and adversely affect the prevailing market price for our common stock.

Pursuant to our articles of incorporation, we are also authorized to issue 5,000,000 shares of blank check preferred stock of which 30,000 shares have been designated as our Series C Convertible Preferred Stock and 20,000 shares have been designated as our Series D Convertible Preferred Stock. Such preferred stock is senior to our common stock in terms of dividend priority and liquidation preference. Any preferred stock that we issue in the future may rank ahead of our common stock in terms of dividend priority or liquidation preference and may have greater voting rights than our common stock. In addition, such preferred stock may contain provisions allowing those shares to be converted into shares of common stock, which could dilute the value of our common stock to current stockholders and could adversely affect the market price, if any, of our common stock. In addition, the preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our company. Although we have no present intention to designate or issue any shares of our authorized blank check preferred stock, there can be no assurance that we will not do so in the future.

As a result of the modifications of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock (see *Description of Securities—Preferred Stock*), assuming no changes in the amount of outstanding Preferred Series C or D ownership, going forward on a quarterly basis the Company will accrete as a preferred dividend the value of approximately 160,000 shares of common stock. Future accreted dividends will be settled by issuing additional shares of preferred stock which can then be converted to common stock.

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In the future, we may also attempt to increase our capital resources by offering debt securities. These debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets.

Because our decision to issue securities or incur debt in our future offerings will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings and debt financing. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future. Thus, you will bear the risk of our future offerings reducing the value of your shares and diluting your interest in us.

***The exercise prices of certain warrants, and the conversion prices of our outstanding convertible notes payable and our preferred stock may require further adjustment.***

If in the future, the Company sells its common stock at a price below \$0.25 per share, the conversion price of our outstanding shares of series C convertible preferred stock and series D convertible preferred stock would adjust below \$0.25 per share pursuant to the documents governing such instruments. In addition, the conversion price of the convertible promissory notes referred to above and the exercise price of certain outstanding warrants to purchase 7,684,381 shares of common stock would adjust below \$0.25 per share pursuant to the documents governing such instruments.

*If our company were to dissolve or wind-up operations, holders of our common stock would not receive a liquidation preference.*

If we were to wind up or dissolve our company and liquidate and distribute our assets, our common stockholders would share in our assets only after we satisfy any amounts we owe to our creditors and preferred equity holders. If our liquidation or dissolution were attributable to our inability to profitably operate our business, then it is likely that we would have material liabilities at the time of liquidation or dissolution. Accordingly, it is very unlikely that sufficient assets will remain available after the payment of our creditors and preferred equity holders to enable common stockholders to receive any liquidation distribution with respect to any common stock.

*We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.*

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business, and we do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

During the three months ended December 31, 2023, we had the following sales of unregistered sales of equity securities:

On October 10, 2023, we issued 105,000 shares total to three directors at an exercise price of \$0.25 per share for director services.

On October 26, 2023, we closed an offering of our common stock pursuant to which we sold 883,061 shares of common stock, at a purchase price of \$0.25 per share. After deducting underwriting commissions and other offering expenses, we received net proceeds of \$203,105.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

## ITEM 5. OTHER INFORMATION

None.

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## ITEM 6. EXHIBITS

The exhibits required to be filed herewith by Item 601 of Regulation S-K, as described in the following index of exhibits, are attached hereto unless otherwise indicated as being incorporated by reference, as follows:

### (a) Exhibits

Exhibit No.	Description
<a href="#">31.1*</a>	<a href="#">Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">31.2*</a>	<a href="#">Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">32.1**</a>	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">32.2**</a>	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because iXBRL 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 Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	The Cover Page Interactive Data File, formatted in Inline XBRL (included within the Exhibit 101 attachments)

\* Filed herewith

\*\* Furnished herewith

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## SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KNOW LABS, INC.  
(Registrant)

Date: February 14, 2024

By: /s/ Ronald P. Erickson  
Ronald P. Erickson



Chief Executive Officer, and Director  
(Principal Executive Officer)

Date: February 14, 2024

By: /s/ Peter J. Conley  
Peter J. Conley  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**EXCHANGE ACT RULES 13a-14(a) and 15d-14(a),  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ronald P. Erickson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Know Labs, 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(s) 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(s) 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: February 14, 2024

*/s/ Ronald P. Erickson*  
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Ronald P. Erickson  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO  
EXCHANGE ACT RULES 13a-14(a) and 15d-14(a),  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter J. Conley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Know Labs, 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(s) 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(s) 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: February 14, 2024

*/s/ Peter J. Conley*

\_\_\_\_\_  
Peter J. Conley

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with Quarterly Report of Know Labs, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Ronald P. Erickson, Chief Executive Officer (Principal Executive Officer) of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 14, 2024

/s/ Ronald P. Erickson  
\_\_\_\_\_  
Ronald P. Erickson  
Chief Executive Officer  
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Know Labs, Inc. and will be retained by Know Labs, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with Quarterly Report of Know Labs, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Peter J. Conley, Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 14, 2024

*/s/ Peter J. Conley*

\_\_\_\_\_  
Peter J. Conley

Chief Financial Officer

*(Principal Financial and Accounting Officer)*

A signed original of this written statement required by Section 906 has been provided to Know Labs, Inc. and will be retained by Know Labs, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.