



# KNOW LABS

## **TRANSFORMING NON-INVASIVE MEDICAL DIAGNOSTICS**

December 19, 2023

Q4 FY2023 Earnings Call  
NYSE American: KNW

# DISCLOSURE

## CAUTION ABOUT FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements that are based on the Company management's beliefs and assumptions and on information currently available to the Company. All statements other than statements of historical facts are forward-looking statements. These statements relate to future events or to the Company's future financial performance and involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about: goals and strategies; future business development, financial condition and results of operations expected product development outcomes, including obtaining regulatory clearance, expected changes in revenue, costs or expenditures; growth of and competition trends in industry, and expectations regarding demand for, and market acceptance of, our products. You can identify forward looking statements by terms such as "may," "could," "will," "should," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "project" or "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond the Company's control and which could materially affect results. . In evaluating these forward-looking statements, you should consider various factors, including: Company management's ability to change the direction of the company, ability to keep pace with new technology and changing market needs, and the competitive environment of the business. These and other factors may cause the Company's actual results to differ materially from any forward-looking statement. Forward-looking statements are only predictions. The forward-looking events discussed in this document and other statements made from time to time by the Company or its representatives, may not occur, and actual events and results may differ materially and are subject to risks, uncertainties and assumptions about the Company. The Company is obligated to publicly update or revise any forward-looking statement, whether as a result of uncertainties and assumptions, the forward-looking events discussed in this document and other statements made from time to time by the Company or its representatives might not occur. See offering documents for further risks and disclosures. Past performance is not indicative of future results. There is now guarantee that any specific outcome will be achieved. Investments may be speculative, illiquid and there is a total risk of loss.

### **General securities market uncertainties resulting in economic considerations.**

Recent unease regarding the aforementioned geo-political considerations and increasing inflation has caused the United States and worldwide national securities markets to have undergone unprecedented stress due to the uncertainties of regarding the economy and the resulting reactions and outcomes of governments, businesses, and the general population. These uncertainties have resulted in declines in all market sectors, increases in volumes due to flight to safety and governmental actions to support the markets. As a result, until economic outlook has stabilized, the markets may not be available to the Company for purposes of raising required capital. Should we not be able to obtain financing when required, in the amounts necessary to execute on our plans in full, or on terms which are economically feasible, we may be unable to sustain the necessary capital to pursue our strategic plan and may have to reduce the planned future growth and/or scope of our operations.

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

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 September 30, 2024. We will 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 may seek 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. Strategic collaborations may include features which could limit the Company's ultimate potential. If such financings 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.

### **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 June 30, 2023, we had an accumulated deficit of \$118,715,000 and net losses in the amount of \$12,353,000, \$20,071,000 and \$25,360,000 during the nine months ended June 30, 2023 and the years ended September 30, 2022 and 2021, respectively. There can be no assurance that we will achieve or maintain 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 and financial condition.

### **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.

### **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 which 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 the 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 the 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. The 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.

# FY2023 In Review (Slide 1 of 2):

## ORGANIZATION

- Leadership changes and resources re-alignment to core focus, NIGM
- Expanded Board of Directors, appointing three new Directors with deep scientific, intellectual property, and medical expertise
- Appointed four new members to the Medical Advisory Board, bringing extensive clinical diabetes management and FDA expertise
- Added experienced resources in critical functions to achieve a commercial device, such as machine learning, software management, and clinical research

## PRODUCT DEVELOPMENT

- Introduced the Gen 1 product prototype – currently used for remote data collection
- Kicked off the design of the Gen 2 product prototype, a wearable CGM form factor

## CLINICAL DEVELOPMENT

- Demonstrated 11.27% MARD from data collected in normoglycemic and hyperglycemic ranges across 366 datasets, 3,300 reference points, and >1.7B data points
- Kicked off internal trial, N=30, with up to 100 participants focused on population with diabetes and increased data collection in the hyper and hypoglycemic ranges

# FY2023 In Review (Slide 2 of 2):

## SCIENTIFIC VALIDATION

- Peer-reviewed publication in Sensors Journal of proof-of-principle study in collaboration with Mayo Clinic – in vitro diagnostics; Poster presentations at APS and AACE
- *In vivo* results currently undergoing peer-review in a reputable journal
- Upcoming presentations at ATTD 2024 in Florence-Italy, including publication of the results of the current internal trial

## INTELLECTUAL PROPERTY

- Patents issued, pending, and in-process increased from 107 to 259 YoY (+142% vs. market +35%, ~4x market CAGR), reflecting our high rate of innovation
- Ranked by IPCG #1 in the world for non-invasive blood glucose monitoring IP

## FINANCE

- Completed public offering of 28,000,000 shares of KNW common stock at a public offering price of \$0.25 per share, achieving gross proceeds of \$7M
- Reduced burn rate from \$1.2M/month to \$700k/month

## STRATEGIC COLLABORATIONS

- JDA discussions are underway with potential biopharma, medical device manufacturers, and consumer electronics partners

## Gen 1 → “Computer mouse” form factor

Place your palm or arm on the portable device for on-demand blood glucose level data.

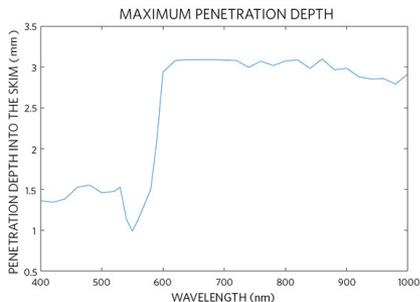
## Gen 2 → “Earbuds case” form factor

50% smaller wearable CGM under development for early 2024 release.



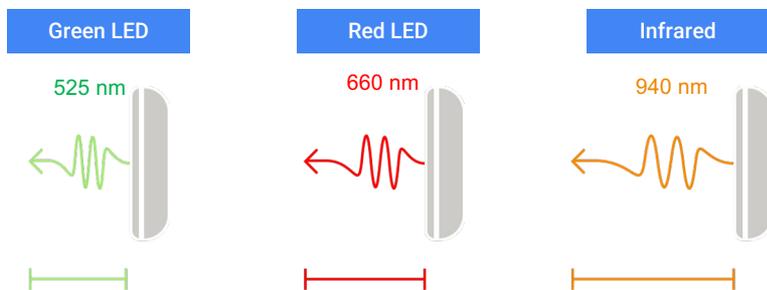
**Generation 1 Prototype Device:**  
A sophisticated research lab in your pocket.

# WHY IT WORKS: Overcoming the Limitations of Physics

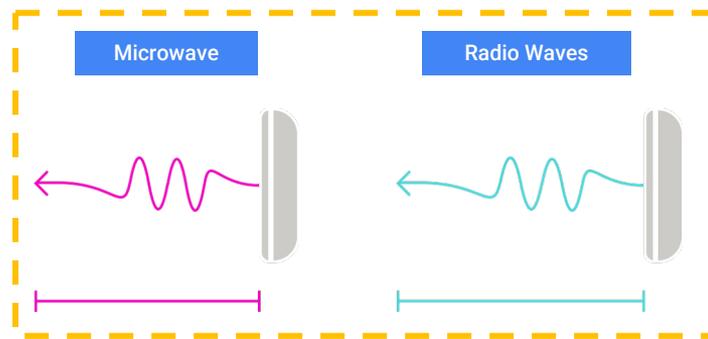


RF Dielectric Spectroscopy sweeps entire tissue stack to collect high resolution voltage data at high speed that fixed wavelength optical sensors are incapable of achieving.

Optical Sensors (400 nm – 1000 nm)



Radio Frequency (500 MHz – 4000 MHz)



--- All Health Wearable Devices ---

LOW

1 mm to 3 mm

SIGNAL TRANSMISSION DEPTH

12 mm to 13 mm

HIGH

# WHY IT WORKS: Delivering accuracy from *in vitro* to *in vivo* testing

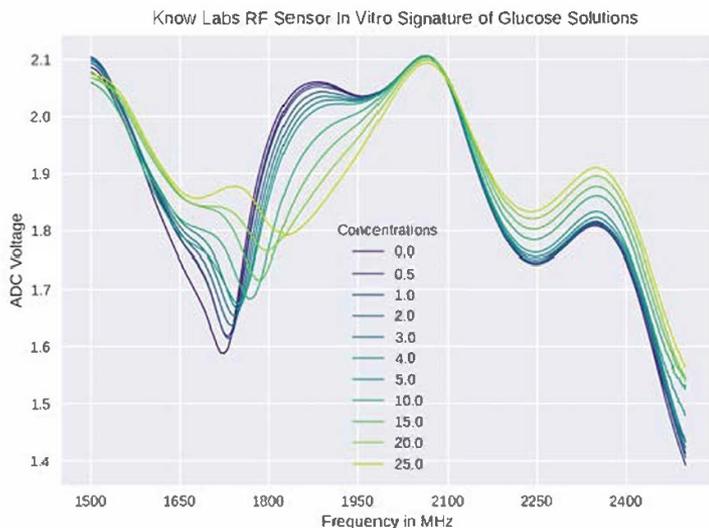
## IN VITRO

RF dielectric spectroscopy sensor can measure different concentrations of glucose in solution, where optical sensors cannot.

## IN VIVO

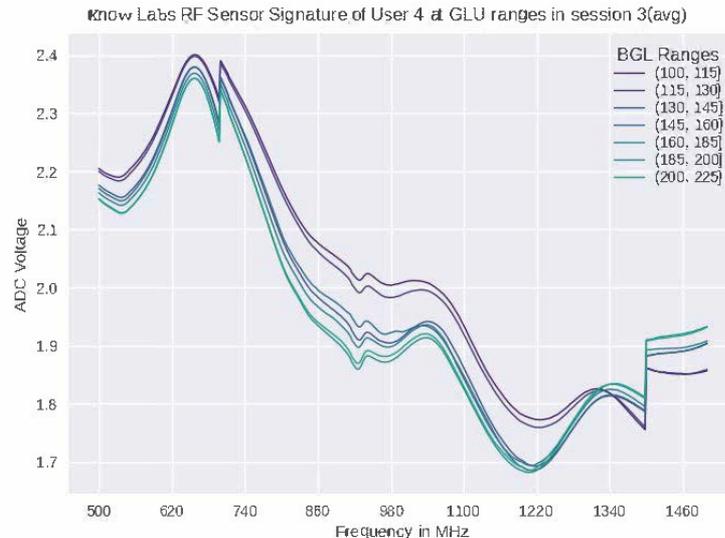
RF sensors based on dielectric permittivity can measure variance in blood glucose in BGL ranges.

## In Vitro Glucose Solutions Readings



**IN VITRO:** ADC Voltage (y-axis) measuring voltage variance based on glucose concentration and frequency sweeps

## In Vivo Glucose Readings Over 3 Hour Test



**IN VIVO:** ADC Voltage (y-axis) measuring voltage variance based on dielectric permittivities of blood glucose and frequency sweeps

# TIMELINE OF VALIDATION STUDIES FROM IN VITRO TO IN VIVO

	2021		2022		2023		TODAY
Manuscript	Proof of Principle with Mayo Clinic	Exploratory Clinical Study	Proof of Concept Clinical Study	Technical Feasibility Study	New Algorithm Refinement Study	Data Preprocessing Techniques Study	
Description	Demonstrated the accuracy of Bio-RFID sensor in quantifying different analytes <i>in vitro</i> (liquid solution).	First indication that Bio-RFID could be an accurate alternative to FDA-cleared glucose devices.	Proof of concept ability to quantify blood glucose non-invasively using RF.	Demonstrates Bio-RFID can deliver stable, repeatable results in measuring blood glucose levels.	Algorithm refinement in the non-invasive detection of blood glucose using Bio-RFID technology.	Improvement in machine learning model accuracy on an expanded mixed cohort dataset.	
Accuracy	Almost 100% <i>in vitro</i> accuracy	MARD <u>5.3%-6.7%</u>	MARD 19.3%	MARD 20.6%	MARD 12.9%	MARD <u>11.3%</u>	
# Participants	na	2	1	5	5	13	
# Datasets	na	3	22	106	106	366	
# Bio-RFID datapoints	na	<u>1.5M</u>	~183M	~430M	~430M	<u>~1.7B</u>	
# Reference Observations	na	75	~383	~1,555	~1,555	~3,311	

# 3-HOUR CLINICAL TESTING PROTOCOL

- Participant rests his/her arm on the device, making sure their skin is in contact with the device's array of antennas
- To take a measurement, the sensor scans through the frequency range, currently using 0.1 MHz intervals so that 10,001 data points are collected per sweep
- Reference data is collected every five minutes, while our sensor completes a sweep every 22 seconds (= one measurement)
- A glucose tolerance test is performed throughout the course of the test, which typically takes 3 hours, allowing our device to measure the participant's response to sugar



## Internal Trial - In Progress

### # of participants

Up to 100

### Target population

T2D and Pre-diabetes

### Reference points

IV and CGMs

### Format

Traditional GTT

# GEN 1 USE CASE – REMOTE DATA COLLECTION



Using Gen 1 Prototype on Forearm

Using Gen 1 Prototype on Hand



# EXPECTED PATH TO MARKET

- Completed FY 9/2018 - 2023
- Current FY 12/2023 - 2024
- Planned FY 9/2024 - 2026

	SENSOR INNOVATION	CONTROLLED LAB TESTING	REAL-WORLD USE TESTING	SCALE & COMMERCIAL SPECS	INTERNAL & FDA TRIALS	FDA CLEARANCE
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<b>GEN 0</b> Stationary Research System	Optical sensing path dropped	Exploratory Study (MARD 5.8% to 6.7%)						
	~200 RF antennas designed & tested	Proof of Principle Validation <i>in Vitro</i> with Mayo Clinic						
	Miniaturization to Bio-RFID Sensor	Technical Feasibility & Validation with Humans (MARD 11.3%)		Expand Dataset: Diverse Population, People with Diabetes & Blood Draw (Goal: MARD <10%)				
		N=1	N=5	N=13	N = 30 (up to 100)	Customizable Algorithm		
<b>GEN 1</b> Portable Research System	Design & Build Gen 1 Device (12 Units)	System & Sensor Characterization (Wired + Wireless)	N=5 (pilot study)	N>20 T1D IV Hypo & Hyper	N>20 IV Hypo & Hyper			
	JDA Opportunities (biopharma, medical device, and consumer electronics use cases)							
<b>GEN 2</b> Portable Medical Device		Design & Build Gen 2 Device (earbuds case size)	System & Sensor Characterization (Wireless)	Build 1,000 Gen2 Devices	N>500 Diverse Population Study	N=1,000 Design Freeze	N=TBD FDA Trials (multiple)	Gen 2 Device Launch
<b>GEN X</b>	<div style="display: flex; justify-content: center; align-items: center;"> <div style="font-size: 2em; margin-right: 10px;">←</div> <div style="text-align: center;"> <p><b>NEW GENERATIONS</b></p> <p>(New Format(s), Intended Use(s), etc.)</p> </div> <div style="font-size: 2em; margin-left: 10px;">→</div> </div>							

# FY2024 GOALS

## 1 Introduce Gen 2 CGM device

- Wearable CGM at least 50% smaller than Gen 1 (“earbuds case size”)
- Potential format for FDA submission

## 2 Further accelerate data collection and continue algorithm refinement

- Internal and external trials with research institutions
- Tens of billions of data points and reference points
  - Reference labels: IV, CGMs and finger sticks
  - Data range: hypo and hyperglycemic ranges
- Achieve MARD under 10% in large mixed cohorts
- Submit validation manuscripts to key global diabetes conference and peer-reviewed journals

## 3 Build upon current global IP leadership and interoperability in NI blood glucose monitoring

## 4 Refine regulatory strategy for Gen 2 form factor

## 5 Execute upon JDA opportunities

## 6 Prepare the organization for accelerated growth and go-to-market plan

# THANK YOU

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